AMENDMENTS
112 - 737

Draft report
Nicolás González Casares
(PE680.818v01-00)

A reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

Proposal for a regulation
Amendment 112
Joëlle Mélin

Proposal for a regulation
Recital 1

Text proposed by the Commission

(1) Pursuant to Articles 9 and 168 of the Treaty on the Functioning of the European Union (‘TFEU’) and Article 35 of the Charter of Fundamental Rights of the European Union the Union is to ensure a high level of human health protection in the definition and implementation of all Union policies and activities.

Amendment

(1) Pursuant to Articles 9 and 168 of the Treaty on the Functioning of the European Union (‘TFEU’) and Article 35 of the Charter of Fundamental Rights of the European Union the Union is to ensure a high level of human health protection in the definition and implementation of all Union policies and activities, within the strict limit defined by those two articles.

Or. fr

Amendment 113
Tilly Metz

Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission

(1a) The COVID-19 pandemic has highlighted risks to human health posed by over-exploitation of wildlife and other natural resources and accelerated loss of biodiversity. As health of humans, animals and the environment are inextricably linked and similar medicines and medical devices are used for humans and animals, it is crucial to take the ‘One Health’ approach to address current and emerging crises. This is paramount as the majority (72%) of emerging diseases of humans, including COVID-19, influenza and HIV/AIDS, are caused by zoonotic pathogens.

Amendment

(1a) The COVID-19 pandemic has highlighted risks to human health posed by over-exploitation of wildlife and other natural resources and accelerated loss of biodiversity. As health of humans, animals and the environment are inextricably linked and similar medicines and medical devices are used for humans and animals, it is crucial to take the ‘One Health’ approach to address current and emerging crises. This is paramount as the majority (72%) of emerging diseases of humans, including COVID-19, influenza and HIV/AIDS, are caused by zoonotic pathogens.
(2) The unprecedented experience of the COVID-19 pandemic has demonstrated that the Union should be more effective in managing the availability of medicinal products and medical devices and in developing medical countermeasures to address the threats posed to public health. The Union’s ability to do so has been severely impeded by the absence of a clearly defined legal framework for managing its response to the pandemic, and also by the limited degree of Union preparedness in case of a public health emergency impacting a majority of Member States.

(2) The unprecedented experience of the COVID-19 pandemic has shown the difficulties of Member States to cope with a cross-border or global health emergency, and has therefore demonstrated the need to strengthen the competences of the Union in order to be more effective, efficient and expeditious in managing the availability of medicinal products and medical devices, in asserting supply chains of medicinal products and medical devices, and in developing medical countermeasures to address the threats posed to public health. The unprecedented experience of the COVID-19 pandemic has also underlined the risks to human health posed by zoonotic spill-overs triggered by global biodiversity loss and wildlife over-exploitation. The Union’s ability to do so has been severely impeded by the absence of a clearly defined legal framework for managing its response to the pandemic, and also by the limited degree of Union preparedness in case of a public health emergency impacting a majority of Member States.
The unprecedented experience of the COVID-19 pandemic has demonstrated that the Union should be more effective in managing the availability of medicinal products and medical devices and in developing medical countermeasures to address the threats posed to public health. The Union’s ability to do so has been severely impeded by the absence of a clearly defined legal framework for managing its response to the pandemic, and also by the limited degree of Union preparedness in case of a public health emergency impacting a majority of Member States.

Proposal for a regulation
Recital 2

Text proposed by the Commission

The unprecedented experience of the COVID-19 pandemic has demonstrated that the Union should be more effective in managing the availability of medicinal products and medical devices and in developing medical countermeasures to address the threats posed to public health.

Amendment

The unprecedented experience of the COVID-19 pandemic has demonstrated that the Union should be more effective in managing the availability of medicinal products and medical devices and in developing medical countermeasures to address the threats posed to public health in a coordinated way between public authorities, industry and other entities of the pharmaceuticals' manufacturing, distribution and provision chains. A two-
also by the limited degree of Union preparedness in case of a public health emergency impacting a majority of Member States.

The unprecedented experience of the COVID-19 pandemic has demonstrated that the Union should be more effective in managing the availability of medicinal products and medical devices and in developing medical countermeasures to address the threats posed to public health. The Union’s ability to do so has been severely impeded by the absence of a clearly defined legal framework for managing its response to the pandemic, and also by the limited degree of Union preparedness in case of a public health emergency impacting a majority of Member States.

Amendment 117
Nathalie Colin-Oesterlé
Proposal for a regulation
Recital 2

Text proposed by the Commission

(2) The unprecedented experience of the COVID-19 pandemic has demonstrated that the Union should be more effective in managing the availability of medicinal products and medical devices and in developing medical countermeasures to address the threats posed to public health. The Union’s ability to do so has been severely impeded by the absence of a clearly defined legal framework for managing its response to the pandemic, and also by the limited degree of Union preparedness in case of a public health emergency impacting a majority of Member States.

Amendment

(2) The unprecedented experience of the COVID-19 pandemic has demonstrated that, by strengthening its capacity and improving cooperation and coordination between the EU Member States, the Union should be more effective in managing the availability of medicinal products and medical devices and in developing medical countermeasures to address the threats posed to public health. The Union’s ability to do so has been severely impeded by the absence of a clearly defined legal framework for managing its response to the pandemic, and also by the limited degree of Union preparedness in case of a public health emergency impacting a majority of Member States and by the lack of cooperation and coordination between the latter.
Tudor Ciuhodaru

Proposal for a regulation
Recital 2

Text proposed by the Commission

(2) The unprecedented experience of the COVID-19 pandemic has demonstrated that the Union should be more effective in managing the availability of medicinal products and medical devices and in developing medical countermeasures to address the threats posed to public health. The Union’s ability to do so has been severely impeded by the absence of a clearly defined legal framework for managing its response to the pandemic, and also by the limited degree of Union preparedness in case of a public health emergency impacting a majority of Member States.

Amendment

(2) The unprecedented experience of the COVID-19 pandemic has demonstrated that the Union should be more effective in managing the availability of medicinal products and medical devices and in developing medical countermeasures to address the threats posed to public health, but it has also demonstrated the need for closer cooperation and faster exchanges of information between Members States and the European institutions on the measures implemented. The Union’s ability to do so has been severely impeded by the absence of a clearly defined legal framework for managing its response to the pandemic, and also by the limited degree of Union preparedness in case of a public health emergency impacting a majority of Member States.

Or. ro

Amendment 119
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Nils Torvalds, Susana Solís Pérez, Andreas Glück, Jan Huitema, Ondřej Knotek, Martin Hojsík, María Soraya Rodríguez Ramos

Proposal for a regulation
Recital 2

Text proposed by the Commission

(2) The unprecedented experience of the COVID-19 pandemic has demonstrated that the Union should be more effective in managing the availability of medicinal products and medical devices and in developing medical countermeasures to address the threats posed to public health. The Union’s ability to do so has been

Amendment

(2) The unprecedented experience of the COVID-19 pandemic has demonstrated that the Union should be more effective in managing the availability of medicinal products and medical devices and in developing medical countermeasures to address the threats posed to public health from an early stage and in coordination
severely impeded by the absence of a clearly defined legal framework for managing its response to the pandemic, and also by the limited degree of Union preparedness in case of a public health emergency impacting a majority of Member States.

with the national authorities, the industry and other entities of the pharmaceutical supply chain. The Union’s ability to do so has been severely impeded by the absence of a clearly defined legal framework for managing its response to the pandemic, and also by the limited degree of Union preparedness in case of a public health emergency impacting a majority of Member States.

Or. en

Amendment 120
Joëlle Mélin
Proposal for a regulation
Recital 2

Text proposed by the Commission

(2) The unprecedented experience of the COVID-19 pandemic has demonstrated that the Union should be more effective in managing the availability of medicinal products and medical devices and in developing medical countermeasures to address the threats posed to public health. The Union’s ability to do so has been severely impeded by the absence of a clearly defined legal framework for managing its response to the pandemic, and also by the limited degree of Union preparedness in case of a public health emergency impacting a majority of Member States.

Amendment

(2) The unprecedented experience of the COVID-19 pandemic has demonstrated that, due to the significant risks posed by emerging zoonoses, the Union should be more effective in managing the availability of human or veterinary medicinal products and medical devices and in developing medical countermeasures to address the threats posed to public health. The Union’s ability to do so has been severely impeded by the absence of a clearly defined legal framework for managing its response to the pandemic, and also by the limited degree of Union preparedness in case of a public health emergency impacting a majority of Member States.

Or. fr

Amendment 121
Tilly Metz
Proposal for a regulation
Recital 2

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The unprecedented experience of the COVID-19 pandemic has demonstrated that the Union should be more effective in managing the availability of medicinal products and medical devices and in developing medical countermeasures to address the threats posed to public health. The Union’s ability to do so has been severely impeded by the absence of a clearly defined legal framework for managing its response to the pandemic, insufficient mandates of its health agencies and also by the limited degree of Union preparedness in case of a public health emergency impacting a majority of Member States.

Amendment 122
Dolors Montserrat
Proposal for a regulation
Recital 2 a (new)

(2a) As experienced during the COVID-19 crisis, regulatory capacity to adapt and activate exceptional measures to facilitate Marketing Authorisations for emergency medicines and medical devices is key for an effective and coordinated response to health emergencies at Union level. This capacity should be applied even beyond crisis situations, for example applying the Rolling Review procedures to critical medicinal products, covering procedures for changes in suppliers of APIs or for the designation of new manufacturing sites, leading to prevention and better mitigation of medicines shortage, in coherent and consistent coordination with Member States,
avoiding fragmentation of the internal market and inefficient outcomes. The National Agencies should align their regulatory capacity to the EMA enhanced one, in terms of reduced times, efficiency and flexibility to prevent shortages and effectively respond to patients’ clinical needs.

Amendment 123
Nathalie Colin-Oesterlé
Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission

Amendment

(2a) The COVID-19 crisis has shown that coordination and dialogue between European, national and regional authorities, industry, entities involved in the pharmaceutical supply chain, healthcare professionals and patients’ associations at European level are vital for countering health threats and should continue after the current health crisis ends so that the shortage of one-off and recurrent medicinal products can be tackled effectively. Ongoing dialogue between all such stakeholders should be assured.

Or. fr

Amendment 124
Aldo Patriciello
Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission

Amendment

(2a) The coronavirus pandemic has
demonstrated that a pan-European coordination and dialogue among authorities, industry and relevant supply chain actors, is needed to fight against health threats, and should be continued beyond health crisis to tackle medicines shortage. A two-way communication between regulatory authorities and industry actors should be guaranteed to better mitigate and prevent medicines shortage.

Amendment 125
Antoni Comin i Oliveres
Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission

(2a) It is therefore necessary that the Union be a full-fledged complementary component of European health systems, providing a guarantee or a last-resource stakeholder in case of serious cross-border health threats. For this reason, the know-how, expertise and capabilities of Union agencies should be strengthened accordingly.

Amendment

Or. en

Amendment 126
Aldo Patriciello
Proposal for a regulation
Recital 2 b (new)

Text proposed by the Commission

(2b) Capitalizing on all pragmatic efforts made during the covid19 crisis, it is important to continue to allow
regulatory flexibilities for Marketing Authorisations Holders even beyond crisis situations, for example covering procedures for changes in suppliers of APIs, the designation of new manufacturing sites, faster import authorisations, leading to better mitigation of medicines shortage. It is however crucial that those flexibilities are followed and applied in a coherent way by Member States avoiding fragmentation of the internal market and inefficient outcomes.

Amendment 127
Aldo Patriciello

Proposal for a regulation
Recital 2 c (new)

Text proposed by the Commission

Amendment

(2c) The root causes of medicines shortage should be assessed and tackled in the context of a strategy on medicines shortage. Root causes include economic causes, increasing regulatory burden, unforeseen surges in demand, supply chain interdependencies and manufacturing and quality challenges.

Amendment 128
Aldo Patriciello

Proposal for a regulation
Recital 2 d (new)

Text proposed by the Commission

Amendment

(2d) The combination of cost containment measures, lack of market
predictability, combined with an onerous and rigid regulatory framework are challenging sustainable and equitable access to medicines, especially for very old inexpensive essential drugs, as well as the competitiveness of the European pharmaceutical industry.

Amendment 129
Nathalie Colin-Oesterlé
Proposal for a regulation
Recital 3

**Text proposed by the Commission**

(3) The often complex supply chains of medicinal products and medical devices, national export restrictions and bans, border closures impeding the free movement of those goods, and uncertainty related to their supply and demand in the context of the COVID-19 pandemic have led to significant impediments to the smooth functioning of the single market and to addressing the serious threats to public health across the Union.

**Amendment**

(3) Disruptions to the often complex supply chains of medicinal products and medical devices, national export restrictions and bans, border closures impeding the free movement of those goods, uncertainty related to their supply and demand in the context of the COVID-19 pandemic, and the lack of production in Europe of certain essential medicinal products or chemical active ingredients have led to significant impediments to the smooth functioning of the single market and to addressing the serious threats to public health across the Union.

Amendment 130
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos
Proposal for a regulation
Recital 3

**Text proposed by the Commission**

(3) The often complex supply chains of medicinal products and medical devices, national export restrictions and bans, border closures impeding the free movement of those goods, and uncertainty related to their supply and demand in the context of the COVID-19 pandemic have led to significant impediments to the smooth functioning of the single market and to addressing the serious threats to public health across the Union.
medicinal products and medical devices, national export restrictions and bans, border closures impeding the free movement of those goods, and uncertainty related to their supply and demand in the context of the COVID-19 pandemic have led to significant impediments to the smooth functioning of the single market and to addressing the serious threats to public health across the Union. with dire consequences for its citizens.

Or. en

Amendment 131
Joëlle Mélin
Proposal for a regulation
Recital 3 a (new)

Text proposed by the Commission
(3a) The COVID-19 crisis has revealed the complexity of the supply of raw materials and highlighted a highly fragmented production chain and complex distribution networks, which are factors that the manufacturers and their management controllers are struggling to deal with and which require real collaboration between states, as well as a clear stance by the EMA.

Or. fr

Amendment 132
Joëlle Mélin
Proposal for a regulation
Recital 3 b (new)

Text proposed by the Commission
(3b) The essential free movement of goods should be possible with revised
Proposal for a regulation
Recital 4

Text proposed by the Commission

(4) Dealing with the issue of shortages of medicinal products has been a long-standing priority for the Member States and European Parliament as illustrated by several reports from the European Parliament\(^{11}\) as well as discussions under recent Presidencies of the Council of the European Union.

Amendment

(4) The issue of shortages of medicinal products has been a long-standing and insufficiently addressed priority for the Member States and European Parliament as illustrated by several reports from the European Parliament\(^{11}\) as well as discussions under recent Presidencies of the Council of the European Union.

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\(^{11}\) European Parliament resolution of 17 September 2020 on the shortage of medicines – how to address an emerging problem (2020/2071(INI))

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Proposal for a regulation
Recital 4

Text proposed by the Commission

(4) Dealing with the issue of shortages of medicinal products has been a long-standing priority for the Member States and European Parliament as illustrated by several reports from the European Parliament\(^{11}\) as well as discussions under recent Presidencies of the Council of the European Union.

Amendment

(4) Dealing with the issue of shortages of medicinal products has been a long-standing but unresolved problem for the Member States and European Parliament as illustrated by several reports from the European Parliament\(^{11}\) as well as discussions under recent Presidencies of the Council of the European Union.
Dealing with the issue of shortages of medicinal products has been a long-standing priority for the Member States and European Parliament as illustrated by several reports from the European Parliament as well as discussions under recent Presidencies of the Council of the European Union.

Amendment 136
Nathalie Colin-Oesterlé
Proposal for a regulation
Recital 4 a (new)

(4a) The long-standing issue of shortages of medicinal products within

Or. en

Or. fr
the Union has become significantly worse in recent years, and increased global demand exacerbated by the COVID-19 pandemic has led to further shortages, weakening the health systems of the Member States and posing significant risks to health and patient care, particularly in terms of disease progression or worsening of symptoms, longer delays or interruptions in care or treatment, longer periods of hospitalisation, increased exposure to fake medicinal products, medication errors or adverse reactions caused by substitutes for missing medicinal products, avoidable transmission of infectious diseases, significant psychological distress and increased costs for the healthcare systems.

Amendment 137
Joëlle Mélin
Proposal for a regulation
Recital 4 a (new)

Text proposed by the Commission

(4a) The COVID-19 pandemic has clearly illustrated that human health is linked to animal health and the environment, and that action to tackle health threats should take account of all three dimensions.

Amendment

Amendment 138
Tilly Metz
Proposal for a regulation
Recital 5
(5) The COVID-19 pandemic has exacerbated the problem of shortages for certain medicinal products considered as critical in addressing the pandemic, and has highlighted the structural limitations in the Union’s ability to rapidly and effectively react to such challenges during public health crises.

Effective communication among Member States about both anticipated and actual shortages and available stocks is essential. To ensure such information exchange, the Single Point of Contact Network (SPOC) should become an established monitoring system.

Or. en

Amendment 139
Nathalie Colin-Oesterlé

Proposal for a regulation
Recital 5

(5) The COVID-19 pandemic has exacerbated the existing problem of shortages for certain medicinal products considered as essential and critical in addressing the pandemic, and has highlighted the Union’s dependence on third countries such as India or China, particularly in terms of the production of chemical active ingredients, the lack of coordination and cooperation between Member States, the structural limitations in the Union’s ability to rapidly and effectively react to such challenges during public health crises, and the need to support and strengthen the Union’s industrial fabric through appropriate policies.

Or. fr
Amendment 140  
Dolors Montserrat

Proposal for a regulation  
Recital 5

Text proposed by the Commission

(5) The COVID-19 pandemic has exacerbated the problem of shortages for certain medicinal products considered as critical in addressing the pandemic, and has highlighted the structural limitations in the Union’s ability to rapidly and effectively react to such challenges during public health crises.

Amendment

(5) The COVID-19 pandemic has exacerbated the problem of shortages for certain medicinal products considered as critical in addressing the pandemic, and has highlighted the structural limitations in the Union’s ability to rapidly and effectively react to such challenges during public health crises and the need for a more active and extended involvement of the European institutions addressing the health of the European citizens.

Or. en

Amendment 141  
Aldo Patriciello

Proposal for a regulation  
Recital 5

Text proposed by the Commission

(5) The COVID-19 pandemic has exacerbated the problem of shortages for certain medicinal products considered as critical in addressing the pandemic, and has highlighted the structural limitations in the Union’s ability to rapidly and effectively react to such challenges during public health crises.

Amendment

(5) The COVID-19 pandemic has exacerbated the already existing problem of shortages for certain medicinal products considered as critical in addressing the pandemic, and has highlighted the structural limitations in the Union’s ability to rapidly and effectively react to such challenges during public health crises, also due to the lack of implementation of sustainable economic, regulatory and industrial policy reforms needed.

Or. en
Amendment 142
Antoni Comín i Oliveres

Proposal for a regulation
Recital 5

*Text proposed by the Commission*

(5) The COVID-19 pandemic has exacerbated the problem of shortages for certain medicinal products considered as critical in addressing the pandemic, and has highlighted the structural limitations in the Union’s ability to rapidly and effectively react to such challenges during public health crises.

*Amendment*

(5) The COVID-19 pandemic has exacerbated the problem of shortages for certain medicinal products, *devices and services* considered as critical in addressing the pandemic, and has highlighted the structural limitations in the Union’s ability to rapidly, *efficiently* and effectively react to such challenges during public health crises.

Or. en

Amendment 143
Nathalie Colin-Oesterlé

Proposal for a regulation
Recital 5 a (new)

*Text proposed by the Commission*

(5a) In order to tackle the Union’s dependence on third countries as well as production uncertainties and supply disruptions, emphasis must be placed on the importance of diversifying supplies and contracting practices for pharmaceutical products and on the need to offer prompt guidance to Member States, especially on the best way to apply the most economically advantageous tender criteria, without being confined to just the lowest price criterion. Investments in the manufacture of active ingredients and medicinal end products in the EU should also be retained as a criterion, as well as the number and location of production sites, the reliability of supply, the reinvestment of profits into R&D and the application of social, environmental,
ethic and quality standards.

Amendment 144
Antoni Comin i Oliveres
Proposal for a regulation
Recital 5 a (new)

Text proposed by the Commission

(5a) It is therefore necessary that the Agency assist the Commission in assessing the supply chain resilience of these products and devices in order to achieve a sufficient strategic autonomy of the Union in health products and devices. Ensuring supply chain resilience across the Union is not a primordial mission of the Agency, yet the European Medicines Agency (EMA) should provide data, knowledge, and skills, to the Commission and the ECDC in order to ensure supply chain resilience in Europe. Supply chain resilience is part of the four working groups of the COVID–19 taskforce of the EMA, alongside the therapeutic response, business continuity and impact, and human resources.

Amendment 145
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Nils Torvalds, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos
Proposal for a regulation
Recital 6

Text proposed by the Commission

(6) The rapid evolution of COVID-19 and the spread of the virus led to a sharp increase in demand for medical devices

(6) The rapid evolution of COVID-19 and the spread of the virus led to a sharp increase in demand for medical devices
such as ventilators, surgical masks, and COVID-19 test kits while disruption of production or limited capacity to rapidly increase production and the complexity and global nature of the supply chain for medical devices, led to a negative impact on supply. Those issues resulted in new entities being involved in the production of those products, which subsequently resulted in bottlenecks in conformity assessment, as well as the prevalence of non-compliant, unsafe, and in some cases counterfeit products. It is therefore appropriate to establish long-term structures within an appropriate Union body to ensure monitoring of shortages of medical devices resulting from a public health emergency.

(6) The rapid evolution of COVID-19 and the spread of the virus led to a sharp increase in demand for medical devices such as ventilators, surgical masks, and COVID-19 test kits while disruption of production or limited capacity to rapidly increase production and the complexity and global nature of the supply chain for medical devices, led to a negative impact on supply. Those issues resulted in new entities being involved in the production of medical devices, leading to a negative impact on supply and placing Member States in competition with each other to respond to the legitimate needs of their citizens, contributing to uncoordinated actions at national levels such as national hoarding and stockpiling. Those issues further resulted in new entities being involved in the rushed production of those products, which subsequently resulted in bottlenecks in conformity assessment, as well as the prevalence of non-compliant, unsafe, and in some cases counterfeit products. It is therefore appropriate to establish long-term structures within an appropriate Union body to ensure monitoring of shortages of medical devices resulting from a public health emergency, as well as increased and early dialogue with the industry to prevent and mitigate these shortages.

Or. en

Amendment 146
Tudor Ciuhodaru

Proposal for a regulation
Recital 6

Text proposed by the Commission

(6) The rapid evolution of COVID-19 and the spread of the virus led to a sharp increase in demand for medical devices such as ventilators, surgical masks, and COVID-19 test kits while disruption of production or limited capacity to rapidly increase production and the complexity and global nature of the supply chain for medical devices, led to a negative impact on supply. Those issues resulted in new entities being involved in the production of medical devices, leading to a negative impact on supply and placing Member States in competition with each other to respond to the legitimate needs of their citizens, contributing to uncoordinated actions at national levels such as national hoarding and stockpiling. Those issues further resulted in new entities being involved in the rushed production of those products, which subsequently resulted in bottlenecks in conformity assessment, as well as the prevalence of non-compliant, unsafe, and in some cases counterfeit products. It is therefore appropriate to establish long-term structures within an appropriate Union body to ensure monitoring of shortages of medical devices resulting from a public health emergency, as well as increased and early dialogue with the industry to prevent and mitigate these shortages.

Amendment

(6) The rapid evolution of COVID-19 and the spread of the virus led to a sharp increase in demand for medical devices such as ventilators, surgical masks, and COVID-19 test kits while disruption of production or limited capacity to rapidly increase production and the complexity and global nature of the supply chain for medical devices, led to a negative impact on supply. Those issues resulted in new entities being involved in the production of medical devices, leading to a negative impact on supply and placing Member States in competition with each other to respond to the legitimate needs of their citizens, contributing to uncoordinated actions at national levels such as national hoarding and stockpiling. Those issues further resulted in new entities being involved in the rushed production of those products, which subsequently resulted in bottlenecks in conformity assessment, as well as the prevalence of non-compliant, unsafe, and in some cases counterfeit products. It is therefore appropriate to establish long-term structures within an appropriate Union body to ensure monitoring of shortages of medical devices resulting from a public health emergency, as well as increased and early dialogue with the industry to prevent and mitigate these shortages.
those products, which subsequently resulted in bottlenecks in conformity assessment, as well as the prevalence of non-compliant, unsafe, and in some cases counterfeit products. It is therefore appropriate to establish long-term structures within an appropriate Union body to ensure monitoring of shortages of medical devices resulting from a public health emergency.

 Amendment 147
 Antoni Comín i Oliveres

 Proposal for a regulation
 Recital 6

 Text proposed by the Commission

 (6) The rapid evolution of COVID-19 and the spread of the virus led to a sharp increase in demand for medical devices such as ventilators, surgical masks, and COVID-19 test kits while disruption of production or limited capacity to rapidly increase production and the complexity and global nature of the supply chain for medical devices, led to a negative impact on supply. Those issues resulted in new entities being involved in the production of those products, which subsequently resulted in bottlenecks in conformity assessment, as well as the prevalence of non-compliant, unsafe, and in some cases counterfeit products. It is therefore appropriate to establish long-term structures within an appropriate Union body to ensure monitoring of shortages of medical devices resulting from a public health emergency.

 Amendment

 (6) The rapid evolution of COVID-19 and the spread of the virus led to a sharp increase in demand for medical devices such as ventilators, surgical masks, and COVID-19 test kits while disruption of production or limited capacity to rapidly increase production and the complexity and global nature of the supply chain for medical devices, led to a negative impact on supply. Those issues resulted in new entities being involved in the production of those products, which subsequently resulted in bottlenecks in conformity assessment, as well as the prevalence of non-compliant, unsafe, and in some cases counterfeit products. It is therefore appropriate to establish long-term structures within an appropriate Union body to ensure monitoring of shortages of medical devices resulting from a public health emergency. These structures should, among other obligations, assess supply chain resilience and reliance.
Amendment 148  
Nathalie Colin-Oesterlé  

Proposal for a regulation  
Recital 6  

Text proposed by the Commission  

(6) The rapid evolution of COVID-19 and the spread of the virus led to a sharp increase in demand for medical devices such as ventilators, surgical masks, and COVID-19 test kits while disruption of production or limited capacity to rapidly increase production and the complexity and global nature of the supply chain for medical devices, led to a negative impact on supply. Those issues resulted in new entities being involved in the production of those products, which subsequently resulted in bottlenecks in conformity assessment, as well as the prevalence of non-compliant, unsafe, and in some cases counterfeit products. It is therefore appropriate to establish long-term structures within an appropriate Union body to ensure monitoring of shortages of medical devices resulting from a public health emergency.

Amendment  

(6) The rapid evolution of COVID-19 and the spread of the virus led to a sharp increase in demand for medical devices such as ventilators, surgical masks, and COVID-19 test kits while disruption of production or limited capacity to rapidly increase production and the complexity and global nature of the supply chain for medical devices, led to a negative impact on supply and stock shortages. Those issues resulted in new entities being involved in the production of those products, which subsequently resulted in bottlenecks in conformity assessment, as well as the prevalence of non-compliant, unsafe, and in some cases counterfeit products. It is therefore appropriate to establish long-term structures within an appropriate Union body to ensure monitoring of shortages of medical devices resulting from a public health emergency and the necessary coordination within the Union.

Amendment 149  
Tilly Metz  

Proposal for a regulation  
Recital 6  

Text proposed by the Commission  

(6) The rapid evolution of COVID-19  

Amendment  

(6) The rapid evolution of COVID-19
and the spread of the virus led to a sharp increase in demand for medical devices such as ventilators, surgical masks, and COVID-19 test kits while disruption of production or limited capacity to rapidly increase production and the complexity and global nature of the supply chain for medical devices, led to a negative impact on supply. Those issues resulted in new entities being involved in the production of those products, which subsequently resulted in bottlenecks in conformity assessment, as well as the prevalence of non-compliant, unsafe, and in some cases counterfeit products. It is therefore appropriate to establish long-term structures within an appropriate Union body to ensure monitoring of shortages of medical devices resulting from a public health emergency.

Amendment 150
Dolors Montserrat
Proposal for a regulation
Recital 6 a (new)

Text proposed by the Commission

(6a) During the first stages of the COVID-19 pandemic, uncoordinated actions at national level, such as national hoarding and stockpiling, undermined industry ability to deliver equitable supply in all markets. This represents a lesson learned to avoid in any future crisis situations and highlights the urgent need for a more solid and effective coordination at Union level.

Amendment

Or. en
Margarita de la Pisa Carrión

Proposal for a regulation
Recital 6 a (new)

Text proposed by the Commission

(6a) The Covid-19 pandemic has shown the need for increased cooperation of the European Medicines Agency with Member States and the pharmaceutical industry in order to improve the capacity of the Union and Member States to combat future health emergencies or serious events.

Amendment

Or. en

Amendment 152
Nathalie Colin-Oesterlé

Proposal for a regulation
Recital 7

Text proposed by the Commission

(7) Uncertainty of supply and demand and the risk of shortages of essential medicinal products and medical devices during a public health emergency like the COVID-19 pandemic can trigger export restrictions amongst Member States and other national protective measures, which can seriously impact the functioning of the internal market. Furthermore, shortages of medicinal products can result in serious risks to the health of patients in the Union due to their lack of availability, which can cause, medication errors, increased duration of hospital stays, and adverse reactions caused by the administration of unsuitable products used as a substitute for unavailable ones. With respect to medical devices, shortages can lead to a lack of diagnostic resources with negative consequences for public health measures, a lack of treatment or deterioration of the

(7) Uncertainty of supply and demand and the risk of shortages of essential medicinal products and medical devices during a public health emergency like the COVID-19 pandemic can trigger export restrictions or bans amongst Member States and other national protective measures, such as inappropriate stockpiling, which can seriously impact the functioning of the internal market. Furthermore, shortages of medicinal products can result in serious risks to the health of patients in the Union due to their lack of availability, which can cause, medication errors, increased duration of hospital stays, and adverse reactions caused by the administration of unsuitable products used as a substitute for unavailable ones. With respect to medical devices, shortages can lead to a lack of diagnostic resources with negative
disease and may also prevent health professionals from adequately carrying out their tasks. Those shortages can also have a significant impact on controlling the spread of a given pathogen caused by, for example, an insufficient supply of COVID-19 test kits. It is therefore important to address the question of shortages and to reinforce and formalise monitoring of critical medicinal products and medical devices.

Amendment 153
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos, Jan Huitema

Proposal for a regulation
Recital 7

Text proposed by the Commission

(7) Uncertainty of supply and demand and the risk of shortages of essential medicinal products and medical devices during a public health emergency like the COVID-19 pandemic can trigger export restrictions amongst Member States and other national protective measures, which can seriously impact the functioning of the internal market. Furthermore, shortages of medicinal products can result in serious risks to the health of patients in the Union due to their lack of availability, which can cause, medication errors, increased duration of hospital stays, and adverse reactions caused by the administration of unsuitable products used as a substitute for unavailable ones. With respect to medical devices, shortages can lead to a lack of diagnostic resources with negative consequences for public health measures, a lack of treatment or deterioration of the disease and may also prevent health professionals from adequately carrying out their tasks. Those shortages can also have a significant impact on controlling the spread of a given pathogen caused by, for example, an insufficient supply of COVID-19 test kits or suitable PPE such as masks, gloves and protective clothing. It is therefore important to address the question of shortages, reinforce and formalise monitoring of critical medicinal products and medical devices, and improve coordination within the Union.

Amendment

(7) Uncertainty of supply and demand and the risk of shortages of essential medicinal products and medical devices during a public health emergency like the COVID-19 pandemic can trigger export restrictions amongst Member States and other national protective measures, which can seriously impact the functioning of the internal market. Furthermore, shortages of medicinal products can result in serious risks to the health of patients in the Union due to their lack of availability, which can cause, medication errors, increased duration of hospital stays, and adverse reactions caused by the administration of unsuitable products used as a substitute for unavailable ones. With respect to medical devices, shortages can lead to a lack of diagnostic resources with negative consequences for public health measures, a
lack of treatment or deterioration of the disease and may also prevent health professionals from adequately carrying out their tasks. Those shortages can also have a significant impact on controlling the spread of a given pathogen caused by, for example, an insufficient supply of COVID-19 test kits. It is therefore important to address the question of shortages and to reinforce and formalise monitoring of critical medicinal products and medical devices.

Amendment 154
Joëlle Mélin
Proposal for a regulation
Recital 7

Text proposed by the Commission

(7) Uncertainty of supply and demand and the risk of shortages of essential medicinal products and medical devices during a public health emergency like the COVID-19 pandemic can trigger export restrictions amongst Member States and other national protective measures, which can seriously impact the functioning of the internal market. Furthermore, shortages of medicinal products can result in serious risks to the health of patients in the Union due to their lack of availability, which can cause, medication errors, increased duration of hospital stays, and adverse reactions caused by the administration of unsuitable products used as a substitute for unavailable ones. With respect to medical devices, shortages can lead to a lack of diagnostic resources with negative consequences for public health measures, a lack of treatment or deterioration of the disease and may also prevent health professionals from adequately carrying out their tasks. Those shortages can also have a significant impact on controlling the spread of a given pathogen caused by, for example, an insufficient supply of COVID-19 test kits. It is therefore important to address the question of shortages and to reinforce and formalise monitoring of critical medicinal products and medical devices in the most efficient way and so as to avoid creating unnecessary burdens for stakeholders which may strain resources and cause additional delays.

Or. en

Amendment

(7) Uncertainty of supply and demand and the risk of shortages of essential medicinal products and medical devices during a public health emergency like the COVID-19 pandemic can trigger export restrictions amongst Member States and other national protective measures, which can seriously impact the functioning of the internal market. Furthermore, shortages of medicinal products can result in serious risks to the health of patients in the Union due to their lack of availability, which can cause, medication errors, increased duration of hospital stays, and adverse reactions caused by the administration of unsuitable products used as a substitute for unavailable ones. With respect to medical devices, shortages can lead to a lack of diagnostic resources with negative consequences for public health measures, a lack of treatment or deterioration of the disease and may also prevent health professionals from adequately carrying out their tasks. Those shortages can also have a significant impact on controlling the spread of a given pathogen caused by, for example, an insufficient supply of COVID-19 test kits. It is therefore important to address the question of shortages and to reinforce and formalise monitoring of critical medicinal products and medical devices in the most efficient way and so as to avoid creating unnecessary burdens for stakeholders which may strain resources and cause additional delays.
disease and may also prevent health professionals from adequately carrying out their tasks. Those shortages can also have a significant impact on controlling the spread of a given pathogen caused by, for example, an insufficient supply of COVID-19 test kits. It is therefore important to address the question of shortages and to reinforce and formalise monitoring of critical medicinal products and medical devices.

Or. fr

Amendment 155
Tilly Metz

Proposal for a regulation
Recital 7

Text proposed by the Commission

(7) Uncertainty of supply and demand and the risk of shortages of essential medicinal products and medical devices during a public health emergency like the COVID-19 pandemic can trigger export restrictions amongst Member States and other national protective measures, which can seriously impact the functioning of the internal market. Furthermore, shortages of medicinal products can result in serious risks to the health of patients in the Union due to their lack of availability, which can cause, medication errors, increased duration of hospital stays, and adverse reactions caused by the administration of unsuitable products used as a substitute for unavailable ones. With respect to medical devices, shortages can lead to a lack of diagnostic resources with negative consequences for public health measures, a lack of treatment or deterioration of the disease and may also prevent health professionals from adequately carrying out their tasks. Those shortages can also have a significant impact on controlling the spread of a given pathogen caused by, for example, an insufficient supply of COVID-19 test kits. It is therefore important to address the question of shortages and to reinforce and formalise monitoring of critical human and veterinary medicinal products and medical devices.
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Impact on controlling the spread of a given pathogen caused by, for example, an insufficient supply of COVID-19 test kits. It is therefore important to address the question of shortages and to reinforce and formalise monitoring of critical medicinal products and medical devices.

Amendment 156
Tudor Ciuhodaru
Proposal for a regulation
Recital 8

Text proposed by the Commission

(8) Safe and efficacious medicinal products that treat, prevent or diagnose diseases which cause public health emergencies, should be developed and made available within the Union as soon as possible during such emergencies. The COVID-19 pandemic has also highlighted sub-optimal coordination and decision-making as regards multinational clinical trials, and Union-level advice on the use of medicinal products in national compassionate use programmes or outside of their authorised indications in the Union, causing delays in the adoption of research outcomes and in the development and availability of new or repurposed medicines.

Amendment

(8) Safe and efficacious medicinal products that treat, prevent or diagnose diseases which cause public health emergencies, should be developed, if necessary through joint undertakings by public authorities, the private sector and academia, and made available within the Union as soon as possible during such emergencies. The COVID-19 pandemic has also highlighted sub-optimal coordination and decision-making as regards multinational clinical trials, and Union-level advice on the use of medicinal products in national compassionate use programmes or outside of their authorised indications in the Union, causing delays in the adoption of research outcomes and in the development and availability of new or repurposed medicines.

Amendment 157
Tilly Metz
Proposal for a regulation
Recital 8 a (new)
(8a) Experience with clinical trials during the Covid-19 pandemic revealed a tremendous amount of duplication of investigations on the same interventions, many small trials, under-representation of important population subgroups, based on gender, age, ethnicity or medical comorbidities, and a lack of collaboration, posing a risk of research waste. To improve the clinical research agenda, international regulators pointed out the need for robust evidence on quality, efficacy and safety of medicinal products. The main way to obtain reliable evidence is through co-ordinated, well-designed, well-powered large randomised controlled trials. Clinical trial results and data should be made public.
data should be made public.

Amendment 159
Tilly Metz
Proposal for a regulation
Recital 8 b (new)

Text proposed by the Commission

(8b) To accelerate, facilitate and coordinate the launch and development of clinical trials in Europe, the Agency should make full use of existing networks, including the Heads of Medicines Agencies (HMA), the Clinical Trials Facilitation and Coordination Group (CTFG), and the European Clinical Research Infrastructure Network (ECRIN).

Or. en

Amendment 160
Kateřina Konečná
Proposal for a regulation
Recital 8 b (new)

Text proposed by the Commission

(8b) To speed up, facilitate and coordinate the development and launch of clinical trials in Europe, the Agency should make full use of existing networks like the Heads of Medicines Agencies (HMA), the Clinical Trials Facilitation and Coordination Group (CTFG), and the European Clinical Research Infrastructure Network (ECRIN).

Or. en
Amendment 161
Antoni Comín i Oliveres

Proposal for a regulation
Recital 9

Text proposed by the Commission

(9) During the COVID-19 pandemic ad hoc solutions, including contingent arrangements between the Commission, the European Medicines Agency (‘the Agency’), marketing authorisation holders, manufacturers and Member States, had to be found to achieve the objective of making available safe and efficacious medicinal products to treat COVID-19 or prevent its spread, and to facilitate and speed up the development and marketing authorisation of treatments and vaccines.

Amendment

(9) During the COVID-19 pandemic ad hoc solutions, including contingent arrangements between the Commission, the European Medicines Agency (‘the Agency’), marketing authorisation holders, manufacturers and Member States, had to be found to achieve the objective of making available safe and efficacious medicinal products to treat COVID-19 or prevent its spread, and to facilitate and speed up the development and marketing authorisation of treatments and vaccines. These ad-hoc solutions should be taken into account as well as all the lessons learned during the pandemic in order to better use the Agency’s potential to face future outbreaks.

Or. en

Amendment 162
Nathalie Colin-Oesterlé

Proposal for a regulation
Recital 9

Text proposed by the Commission

(9) During the COVID-19 pandemic ad hoc solutions, including contingent arrangements between the Commission, the European Medicines Agency (‘the Agency’), marketing authorisation holders, manufacturers and Member States, had to be found to achieve the objective of making available safe and efficacious medicinal products to treat COVID-19 or

Amendment

(9) During the COVID-19 pandemic ad hoc solutions, including contingent arrangements between the Commission, the European Medicines Agency (‘the Agency’), marketing authorisation holders, manufacturers or other entities in the pharmaceutical supply chain and Member States, had to be found to achieve the objective of making available safe and
prevent its spread, and to facilitate and speed up the development and marketing authorisation of treatments and vaccines.

efficacious medicinal products to treat COVID-19 or prevent its spread, and to facilitate and speed up the development and marketing authorisation of treatments and vaccines.

Amendment 163
Aldo Patriciello

Proposal for a regulation
Recital 9

Text proposed by the Commission

(9) During the COVID-19 pandemic ad hoc solutions, including contingent arrangements between the Commission, the European Medicines Agency (‘the Agency’), marketing authorisation holders, manufacturers and Member States, had to be found to achieve the objective of making available safe and efficacious medicinal products to treat COVID-19 or prevent its spread, and to facilitate and speed up the development and marketing authorisation of treatments and vaccines.

Amendment

(9) During the COVID-19 pandemic ad hoc solutions, including contingent arrangements between the Commission, the European Medicines Agency (‘the Agency’), marketing authorisation holders, manufacturers, other entities of the pharmaceutical supply chain and Member States, had to be found to achieve the objective of making available safe and efficacious medicinal products to treat COVID-19 or prevent its spread, and to facilitate and speed up the development and marketing authorisation of treatments and vaccines.

Or. en

Amendment 164
Tudor Ciuhodaru

Proposal for a regulation
Recital 9

Text proposed by the Commission

(9) During the COVID-19 pandemic ad hoc solutions, including contingent arrangements between the Commission, the European Medicines Agency (‘the

Amendment

(9) During the COVID-19 pandemic ad hoc solutions, including contingent arrangements between the Commission, the European Medicines Agency (‘the
Agency’), marketing authorisation holders, manufacturers and Member States, had to be found to achieve the objective of making available safe and efficacious medicinal products to treat COVID-19 or prevent its spread, and to facilitate and speed up the development and marketing authorisation of treatments and vaccines.

Amendment 165
Nathalie Colin-Oesterlé

Proposal for a regulation
Recital 9 a (new)

Text proposed by the Commission

Amendment

(9a) In order to facilitate the supply of medicinal products during the COVID-19 pandemic, marketing authorisation holders were granted regulatory flexibility in relation to, for example, existing procedures for changing suppliers of active ingredients, designation of new production sites and faster processing of import permits, so that shortages of medicinal products could be addressed. Those solutions should remain in place to assist with future situations and those flexibilities should be applied consistently across the Member States to prevent fragmentation of the internal market and ineffective outcomes.

Amendment 166
Antoni Comín i Oliveres

Proposal for a regulation
Recital 10
In order to ensure a better functioning of the internal market of those products and contribute to a high level of human health protection, it is therefore appropriate to approximate the rules on monitoring of shortages of medicinal products and medical devices, and to facilitate the research and development of medicinal products, which may have the potential to treat, prevent, or diagnose diseases that cause public health crises. The Union's actions should be consistent with the WHO’s One Health approach, as well as with the Health in All Policies principle, recognising the interconnections between human and animal health and the environment and the cross-sectoral character of health policies.

Amendment 167
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ţeţeianu, Susana Solis Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos, Jan Huitema

Proposal for a regulation
Recital 10

In order to ensure a better functioning of the internal market of those products and contribute to a high level of human health protection, it is therefore appropriate to approximate the rules on monitoring of shortages of medicinal products and medical devices, and to facilitate the research and development of medicinal products, which may have the potential to treat, prevent, or diagnose diseases that cause public health crises, with a view to strategically complement the efforts of the Commission and other existing Agencies to that end, as well as
that of future key agencies such as the proposed European Health Emergency Preparedness and Response Authority (HERA).

Amendment 168
Aldo Patriciello
Proposal for a regulation
Recital 10

**Text proposed by the Commission**

(10) In order to ensure a better functioning of the internal market of those products and contribute to a high level of human health protection, it is therefore appropriate to approximate the rules on monitoring of shortages of medicinal products and medical devices, and to facilitate the research and development of medicinal products, which may have the potential to treat, prevent, or diagnose diseases that cause public health crises.

**Amendment**

(10) In order to ensure a better functioning of the internal market of those products and contribute to a high level of human health protection, it is therefore appropriate to approximate the rules on monitoring of shortages of medicinal products and medical devices, and to facilitate the research and development of medicinal products, which may have the potential to treat, prevent, or diagnose diseases that cause public health crises. **Requirements could be defined in close cooperation between authorities, industry and relevant entities of the pharmaceutical supply chain.**

Amendment 169
Nathalie Colin-Oesterlé
Proposal for a regulation
Recital 10

**Text proposed by the Commission**

(10) In order to ensure a better functioning of the internal market of those products and contribute to a high level of human health protection, it is therefore

**Amendment**

(10) In order to ensure a better functioning of the internal market of those products and contribute to a high level of human health protection, it is therefore
appropriate to approximate the rules on monitoring of shortages of medicinal products and medical devices, and to facilitate the research and development of medicinal products, which may have the potential to treat, prevent, or diagnose diseases that cause public health crises.

**Amendment 170**

**Joëlle Mélin**

**Proposal for a regulation**

**Recital 10**

*Text proposed by the Commission*

(10) In order to ensure a better functioning of the internal market of those products and contribute to a high level of human health protection, it is therefore appropriate to approximate the rules on monitoring of shortages of medicinal products and medical devices, and to facilitate the research and development of medicinal products, which may have the potential to treat, prevent, or diagnose diseases that cause public health crises.

**Amendment**

(10) In order to ensure a better functioning of the internal market of those products and contribute to a high level of human health protection, it is therefore appropriate to approximate the rules on monitoring of shortages of medicinal products and medical devices, and to facilitate the research and development of human and veterinary medicinal products, which may have the potential to treat, prevent, or diagnose diseases that cause public health crises.

**Or. fr**

**Amendment 171**

**Joëlle Mélin**

**Proposal for a regulation**

**Recital 10 a (new)**

*Text proposed by the Commission*

(10a) In order to ensure a better functioning of the internal market of...
those products and contribute to a high level of human health protection, it is therefore appropriate to facilitate the research and development of human and veterinary medicinal products, which may have the potential to treat, prevent, or diagnose diseases that cause serious public health events, including emerging zoonoses that particularly stem from human and animal environmental changes.

Or. fr

Amendment 172
Nathalie Colin-Oesterlé
Proposal for a regulation
Recital 10 a (new)

Text proposed by the Commission

(10a) In order to ensure effective health systems, stress tests should be introduced to assess the resilience of health systems in emergencies with a view to providing an effective means of countering shortages in the event of pandemics and identifying structural risk factors that create shortages.

Or. fr

Amendment 173
Joëlle Mélin
Proposal for a regulation
Recital 11

Text proposed by the Commission

(11) This Regulation aims to ensure the smooth functioning of the internal market as regards medicinal products and medical devices, with a high level of human health

Amendment

(11) This Regulation aims to ensure the smooth functioning of the internal market as regards human and veterinary medicinal products and medical devices,
protection being fundamental in those aims. Moreover, this Regulation aims to ensure the quality, safety and efficacy of medicinal products with the potential to address public health emergencies. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 TFEU, this Regulation establishes a framework for the monitoring and reporting on shortages of medicinal products and medical devices during public health crises. As regards Article 168(4)(c) TFEU, this Regulation provides for a strengthened Union framework ensuring the quality and safety of medicinal products and medical devices.

Amendment 174
Antoni Comín i Oliveres

Proposal for a regulation
Recital 11

**Text proposed by the Commission**

(11) This Regulation aims to ensure the smooth functioning of the internal market as regards medicinal products and medical devices, with a high level of human health protection being fundamental in those aims. Moreover, this Regulation aims to ensure the quality, safety and efficacy of medicinal products with the potential to address public health emergencies. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 TFEU, this Regulation establishes a framework for the monitoring and reporting on shortages of medicinal products and medical devices during public health crises.

**Amendment**

(11) This Regulation aims to ensure the smooth functioning of the internal market as regards medicinal products and medical devices, as well as a high level of human health protection being fundamental in those aims. Moreover, this Regulation aims to ensure the quality, safety and efficacy of medicinal products with the potential to address public health emergencies. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 TFEU, this Regulation establishes a framework for the monitoring and reporting on shortages of medicinal products and medical devices during public health crises.
Article 168(4)(c) TFEU, this Regulation provides for a strengthened Union framework ensuring the quality and safety of medicinal products and medical devices.

Amendment 175
Aldo Patriciello

Proposal for a regulation
Recital 11 a (new)

Text proposed by the Commission

(11a) This Regulation aims at establishing a pan-European coordination and information system to tackle all medicines shortage which is in place and functional also under normal circumstances to be able to better manage a crisis. In this respect, this regulation sets the basis for the creation of an harmonised pan-European interoperable and digitalized shortages reporting and notification system, interconnecting national reporting systems, with data collected in digital and harmonised fields, and based on a common definition, covering both Centralised and National Marketing Authorisations. The knowledge of digital reporting systems used already in some Member States should be used as best practices to develop a pan-European harmonized system.

Such harmonized and digital system should be supported by a two-way communication between industry and authorities as a prerequisite to pro-actively address medicines shortage and to use the two-months reporting lead time to try to avoid them. The combination of such information and communication systems would provide the transparency needed to take actions to prevent and mitigate cross border shortages, ultimately
ensuring that public health is not impacted and patients access their medicines with no disruption. It would also enable coordination and solidarity, increase efficiency, better visibility and predictability during crisis situations, speed-up the decision-making process, while avoiding duplications of efforts, red tapes and miss communication.

Amendment 176
Tilly Metz
Proposal for a regulation
Recital 11 a (new)

**Text proposed by the Commission**

(11a) This Regulation establishes a framework to address the problem of shortages during public health emergencies and major events. However, shortages of medicinal products and medical devices are a persistent problem that has been increasingly affecting health and lives of EU citizens for decades. Therefore, this Regulation should be a first step towards improving the EU response to this long-lasting issue. The Commission should subsequently propose the expansion of this framework to ensure that the issue of shortages is broadly and permanently tackled in the upcoming revision of Regulation (EC) 726/2004 and Directive 2001/83/EC.

Amendment 177
Dolors Montserrat
Proposal for a regulation
Recital 11 a (new)
(11a) This Regulation aims at establishing the foundations of a European Union of Health coordination and early-warning digitalized interoperable system, to monitor and report medicines shortage, based on shared definitions and procedures, in order to be prepared and better react during a crisis. The existing best practices of digital reporting systems at national level should be shared and taken into account after a common evaluation.

Amendment 178
Antoni Comín i Oliveres

Proposal for a regulation
Recital 12

Text proposed by the Commission

(12) In order to improve crisis preparedness and management for medicinal products and medical devices and increase resilience and solidarity across the Union, the procedures and the respective roles and obligations of different concerned entities involved should be clarified. The framework should build on the ad hoc solutions identified so far in the response to the COVID-19 pandemic.

Amendment

(12) In order to improve crisis preparedness and management for medicinal products and medical devices and increase resilience and solidarity across the Union, the procedures and the respective roles and obligations of different concerned entities involved should be clarified. The framework should build on the ad hoc solutions identified so far in the response to the COVID-19 pandemic that have proven effective and operative and that can provide foundational protocols on which to build upon.

Amendment 179
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ştefănuţă, Nils Torvalds, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos
Proposal for a regulation
Recital 12

Text proposed by the Commission

(12) In order to improve crisis preparedness and management for medicinal products and medical devices and increase resilience and solidarity across the Union, the procedures and the respective roles and obligations of different concerned entities involved should be clarified. The framework should build on the ad hoc solutions identified so far in the response to the COVID-19 pandemic.

Amendment

(12) In order to improve crisis preparedness and management for medicinal products and medical devices and increase resilience and solidarity across the Union, the procedures and the respective roles and obligations of different concerned entities involved should be clarified. The framework should build on the ad hoc solutions identified so far in the response to the COVID-19 pandemic, while remaining flexible enough to tackle any future health crisis in the most efficient way to the benefit of public health and patients.

Or. en

Amendment 180
Joëlle Mélin

Proposal for a regulation
Recital 12

Text proposed by the Commission

(12) In order to improve crisis preparedness and management for medicinal products and medical devices and increase resilience and solidarity across the Union, the procedures and the respective roles and obligations of different concerned entities involved should be clarified. The framework should build on the ad hoc solutions identified so far in the response to the COVID-19 pandemic.

Amendment

(12) In order to improve crisis preparedness and management for human and veterinary medicinal products and medical devices and increase resilience and solidarity across the Union, the procedures and the respective roles and obligations of different concerned entities involved should be clarified. The framework should build on the ad hoc solutions identified so far in the response to the COVID-19 pandemic.

Or. fr
Amendment 181
Aldo Patriciello

Proposal for a regulation
Recital 13

Text proposed by the Commission

(13) A harmonised system of monitoring of shortages of medicinal products and medical devices should be established, which will facilitate appropriate access to critical medicinal products and medical devices during public health emergencies and major events, which may have a serious impact on public health. That system should be complemented with improved structures to ensure appropriate management of public health crises and coordinate and provide advice on the research and development of medicinal products which may have the potential to address public health emergencies. In order to facilitate the monitoring and reporting on potential or actual shortages of medicinal products and medical devices, the Agency should be able to ask and obtain information and data from the concerned marketing authorisation holders, manufacturers and Member States through designated points of contact.

Amendment

(13) A harmonised system, based on common data fields, of monitoring of shortages of medicinal products, personal protective equipment and medical devices should be established, which will facilitate appropriate access for relevant national and Union authorities on markets situations for critical medicinal products and medical devices during public health emergencies and major events, which may have a serious impact on public health. That system should be complemented with improved telematics structures to ensure appropriate management of public health crises and coordinate and provide advice on the research and development of medicinal products which may have the potential to address public health emergencies. In order to facilitate the monitoring and reporting on potential or actual shortages of medicinal products and medical devices, as well as to avoid duplications of the information submitted, the system should be interoperable with the national shortages reporting system, the Agency should be able to ask and obtain additional any information and data – not already in the system - from the concerned marketing authorisation holders, manufacturers and Member States who should all have the obligation to provide complete information and data through designated points of contact (iSPOC and SPOC).

Or. en

Amendment 182
Antoni Comín i Oliveres

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EN
Proposal for a regulation

Recital 13

Text proposed by the Commission

(13) A harmonised system of monitoring of shortages of medicinal products and medical devices should be established, which will facilitate appropriate access to critical medicinal products and medical devices during public health emergencies and major events, which may have a serious impact on public health. That system should be complemented with improved structures to ensure appropriate management of public health crises and coordinate and provide advice on the research and development of medicinal products which may have the potential to address public health emergencies. In order to facilitate the monitoring and reporting on potential or actual shortages of medicinal products and medical devices, the Agency should be able to ask and obtain information and data from the concerned marketing authorisation holders, manufacturers and Member States through designated points of contact.

Amendment

(13) A harmonised system of monitoring of shortages of medicinal products and medical devices should be established, which will facilitate appropriate access to critical medicinal products and medical devices during public health emergencies and access to critical medicinal products, devices and applications in major events, which may have a serious impact on public health. That system should be complemented with improved structures to ensure appropriate management of public health crises and coordinate and provide advice on the research, innovation and development of medicinal products which may have the potential to address public health emergencies. In order to facilitate the monitoring and reporting on potential or actual shortages of medicinal products and medical devices, the Agency should be able to ask demand and obtain information and data from the concerned marketing authorisation holders, manufacturers and Member States through designated points of contact. Should any of the aforementioned stakeholders not give information to the Agency in the time lapse established by the Agency, the Commission should assist the Agency in obtaining such information, with the prospect of an eventual sanction, which should also be duly made available to the public.

Or. en

Amendment 183
Tilly Metz

Proposal for a regulation
Recital 13
Text proposed by the Commission

(13) A harmonised system of monitoring of shortages of medicinal products and medical devices should be established, which will facilitate appropriate access to critical medicinal products and medical devices during public health emergencies and major events, which may have a serious impact on public health. That system should be complemented with improved structures to ensure appropriate management of public health crises and coordinate and provide advice on the research and development of medicinal products which may have the potential to address public health emergencies. In order to facilitate the monitoring and reporting on potential or actual shortages of medicinal products and medical devices, the Agency should be able to ask and obtain information and data from the concerned marketing authorisation holders, manufacturers and Member States through designated points of contact.

Amendment

(13) A harmonised system of monitoring of shortages of medicinal products and medical devices should be established, which will facilitate appropriate access to critical medicinal products and medical devices during public health emergencies and major events, which may have a serious impact on public health. That system should be complemented with improved structures to ensure appropriate management of public health crises and coordinate and provide advice on the research and development of medicinal products which may have the potential to mitigate public health emergencies. In order to facilitate the monitoring and reporting on potential or actual shortages of medicinal products and medical devices, the Agency should be able to ask and obtain information and data from the concerned marketing authorisation holders, manufacturers, wholesalers and Member States through designated points of contact.

The Agency should also establish a system for the exchange of information on the availability of medicines and medical devices with healthcare professionals, in particular medical doctors and community and hospital pharmacists, consumers and patients facilitated through national medicines agencies.

Or. en

Amendment 184
Dolors Montserrat

Proposal for a regulation
Recital 13

Text proposed by the Commission

(13) A harmonised system of monitoring of shortages of medicinal

Amendment

(13) A harmonised European Union of Health digitalized and interoperable
products and medical devices should be established, which will facilitate appropriate access to critical medicinal products and medical devices during public health emergencies and major events, which may have a serious impact on public health. That system should be complemented with improved structures to ensure appropriate management of public health crises and coordinate and provide advice on the research and development of medicinal products which may have the potential to address public health emergencies. In order to facilitate the monitoring and reporting on potential or actual shortages of medicinal products and medical devices, the Agency should be able to ask and obtain information and data from the concerned marketing authorisation holders, manufacturers and Member States through designated points of contact.

Amendment 185
Joëlle Mélin
Proposal for a regulation
Recital 13

Text proposed by the Commission

(13) A harmonised system of monitoring of shortages of medicinal products and medical devices should be established, which will facilitate appropriate access to critical medicinal products and medical devices during public health emergencies and major events, which may have a

Amendment

(13) A harmonised system of monitoring of shortages of medicinal products and medical devices should be established, which will facilitate appropriate access to critical medicinal products and medical devices during public health emergencies and major events, which may have a
serious impact on public health. That system should be complemented with improved structures to ensure appropriate management of public health crises and coordinate and provide advice on the research and development of medicinal products which may have the potential to address public health emergencies. In order to facilitate the monitoring and reporting on potential or actual shortages of medicinal products and medical devices, the Agency should be able to ask and obtain information and data from the concerned marketing authorisation holders, manufacturers and Member States through designated points of contact.

Amendment 186
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ştefănuţă, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos

Proposal for a regulation
Recital 13 a (new)

Text proposed by the Commission

(13a) However, in order to facilitate the prevention, monitoring and reporting of shortages of medicinal products, it would be necessary for the Union and Member States to set up an electronic platform capable of determining the volume of stocks and detecting, predicting and preventing shortages of medicinal products. To facilitate the development of such a system, lessons could be learnt from projects such as CISMED, funded by the Union through Horizon Europe. The platform should provide the national competent authorities with real-time access to unmet demands from wholesale distributors, community pharmacies and hospital pharmacies, providing accurate data in order to understand the
functioning of the supply chain and anticipate potential shortages of medicinal products. The platform should also act as the sole portal for marketing authorisation holders and wholesale distributors to provide the information required during major events and public health emergencies once fully implemented, with a view to increase efficiency, predictability during crises, and speed-up the decision making process while avoiding duplication of efforts and unjustified burden on all stakeholders. In order to facilitate the coordination role of the Agency, Member States' supply monitoring platforms should be interoperable and replicate their information in a Union database managed by the Agency. To accelerate the implementation of the system at Union and national level, its development and implementation should be supported by Union funding from, inter alia, the EU4Health Programme or the Recovery and Resilience Facility established by Regulation (EU) 2021/241 of the European Parliament and of the Council.


Justification

While supporting the Rapporteur's proposal for a streamlined and single platform to monitor, detect, predict and prevent shortages of medicinal products so as to be immediately operational in preparation for or during a health crisis, the tracking and tracing system appears too costly, burdensome for pharmacies, hospitals and self-dispensing doctors. We therefore propose to amend his proposal to rely on volumes of stocks throughout the supply chain rather than a tracking-and-tracing system of each individual product.
Amendment 187
Nathalie Colin-Oesterlé
Proposal for a regulation
Recital 13 a (new)

Text proposed by the Commission

(13a) In order to ensure that Member State strategies, particularly in terms of stock management, are correctly implemented and coordinated, the Agency should become the regulatory authority responsible for preventing shortages of medicinal products within the Union, not only during crises but also in normal times, and its mandate and resources should also be strengthened.

Or. fr

Amendment 188
Antoni Comín i Oliveres
Proposal for a regulation
Recital 13 a (new)

Text proposed by the Commission

(13a) The Agency, together with the Commission, should also do its utmost to counterbalance smear campaigns and disinformation on medicines, medical products, devices or applications, in order to ensure proper information to the public.

Or. en

Amendment 189
Nathalie Colin-Oesterlé
Proposal for a regulation
Recital 15
(15) With respect to medicinal products, an executive steering group should be established within the Agency to ensure a robust response to major events and to coordinate urgent actions within the Union in relation to the management of issues relating to the supply of medicinal products. The Steering Group should establish lists of critical medicinal products to ensure monitoring of those products and it should be able to provide advice on the necessary action to take to safeguard the quality, safety, and efficacy of medicinal products and ensure a high level of human health protection.

(15) With respect to medicinal products, an executive steering group should be established within the Agency to ensure a robust response to major events and to coordinate urgent actions within the Union in relation to the management of issues relating to the supply of medicinal products. The Steering Group should establish a European list of essential and critical medicinal products, in cooperation with all stakeholders, to ensure monitoring of those products and it should be able to provide advice on the necessary action to take to safeguard the quality, safety, and efficacy of medicinal products and ensure a high level of human health protection as well as adequate supplies. Priorities should be established for the different types of medicinal product by drawing a distinction in particular between ‘medicinal products of major therapeutic interest’ (MITMs), i.e. medicines for which an interruption of treatment is likely to jeopardise the vital prognosis of patients in the short or medium term or significantly diminishes the patient’s chances with regard to the progressive potential of the disease, or for which there are no suitable therapeutic alternatives available in sufficient quantity, and ‘medicinal products of health and strategic importance’ (MISSs), for which the interruption of treatment causes an immediate threat to the patient’s life.

Amendment 190
Dolors Montserrat

Proposal for a regulation
Recital 15

Text proposed by the Commission

Amendment
(15) With respect to medicinal products, an executive steering group should be established within the Agency to ensure a robust response to major events and to coordinate urgent actions within the Union in relation to the management of issues relating to the supply of medicinal products. The Steering Group should establish lists of critical medicinal products to ensure monitoring of those products and it should be able to provide advice on the necessary action to take to safeguard the quality, safety, and efficacy of medicinal products and ensure a high level of human health protection.

Amendment 191
Aldo Patriciello

Proposal for a regulation
Recital 15

Text proposed by the Commission
(15) With respect to medicinal products, an executive steering group should be established within the Agency to ensure a robust response to major events and to coordinate urgent actions within the Union in relation to the management of issues relating to the supply of medicinal products. The Steering Group should establish lists of critical medicinal products to ensure monitoring of those products and it should be able to provide advice on the necessary action to take to safeguard the

Amendment
(15) With respect to medicinal products, an executive steering group should be established within the Agency to ensure a robust response to major events and to coordinate urgent actions within the Union in relation to the management of issues relating to the supply of medicinal products. The Steering Group should establish a single pan-European lists of critical medicinal products, in close cooperation with industry, to ensure monitoring of those products and it should
be able to provide advice on the necessary action to take to safeguard the quality, safety, and efficacy of medicinal products and ensure a high level of human health protection during public health emergencies and major events. Such a list should take into account and integrate the outcomes of the ongoing discussions in the context of the EC structured dialogue on manufacturing and supply chain among institutions, national authorities and stakeholders, in order to avoid duplications of work and contradicting results.

Or. en

**Amendment 192**
Antoni Comín i Oliveres

**Proposal for a regulation**
**Recital 15**

*Text proposed by the Commission*

(15) With respect to medicinal products, an executive steering group should be established within the Agency to ensure a robust response to major events and to coordinate urgent actions within the Union in relation to the management of issues relating to the supply of medicinal products. The Steering Group should establish lists of critical medicinal products to ensure monitoring of those products and it should be able to provide advice on the necessary action to take to safeguard the quality, safety, and efficacy of medicinal products and ensure a high level of human health protection.

*Amendment*

(15) With respect to medicinal products, an executive steering group should be established within the Agency to ensure a robust response to major events and to coordinate urgent actions within the Union in relation to the management of issues relating to the supply of medicinal products. The Steering Group should establish lists of critical medicinal products to ensure monitoring of those products and it should be able to provide advice on the necessary action to take to safeguard the quality, safety, and efficacy of medicinal products and ensure a high level of human health protection. *The World Health Organization Model List of Essential Medicines for adults and for children is the best base for the identification of critical medicinal products at Union level.*

Or. en
Amendment 193
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Nils Torvalds, María Soraya Rodríguez Ramos, Martin Hojsík, Andreas Glück, Susana Solís Pérez

Proposal for a regulation
Recital 15

Text proposed by the Commission

(15) With respect to medicinal products, an executive steering group should be established within the Agency to ensure a robust response to major events and to coordinate urgent actions within the Union in relation to the management of issues relating to the supply of medicinal products. The Steering Group should establish critical lists of medicinal products to ensure monitoring of those products and it should be able to provide advice on the necessary action to take to safeguard the quality, safety, and efficacy of medicinal products and ensure a high level of human health protection.

Amendment

(15) With respect to medicinal products, an executive steering group should be established within the Agency to ensure a robust response to major events and to coordinate urgent actions within the Union in relation to the management of issues relating to the supply of medicinal products. The Steering Group should establish single European lists of critical medicinal products in consultation with the industry and healthcare professionals, to ensure monitoring of those products and it should be able to provide advice on the necessary action to take to safeguard the quality, safety, and efficacy of medicinal products and ensure a high level of human health protection.

Or. en

Amendment 194
Joëlle Mélin

Proposal for a regulation
Recital 15

Text proposed by the Commission

(15) With respect to medicinal products, an executive steering group should be established within the Agency to ensure a robust response to major events and to coordinate urgent actions within the Union in relation to the management of issues relating to the supply of medicinal products. The Steering Group should...

Amendment

(15) With respect to medicinal products, an executive steering group should be established within the Agency to ensure a robust response to major events and to coordinate urgent actions within the Union in relation to the management of issues relating to the supply of medicinal products. The Steering Group should...
establish lists of critical medicinal products to ensure monitoring of those products and it should be able to provide advice on the necessary action to take to safeguard the quality, safety, and efficacy of medicinal products and ensure a high level of human health protection.

establish lists of critical human and veterinary medicinal products to ensure monitoring of those products and it should be able to provide advice on the necessary action to take to safeguard the quality, safety, and efficacy of those medicinal products and ensure a high level of human health protection.

Amendment 195
Joëlle Mélin
Proposal for a regulation
Recital 16

Text proposed by the Commission

(16) The Executive Steering Group on Shortages and Safety of Medicinal Products should benefit from the Agency’s extensive scientific expertise as regards the evaluation and supervision of medicinal products and should further develop the Agency’s leading role in coordinating and supporting the response to shortages during the COVID-19 pandemic.

Amendment

(16) The Executive Steering Group on Shortages and Safety of Human and Veterinary Medicinal Products should benefit from the Agency’s extensive scientific expertise as regards the evaluation and supervision of medicinal products and should further develop the Agency’s leading role in coordinating and supporting the response to shortages during the COVID-19 pandemic.

Or. fr

Amendment 196
Antoni Comín i Oliveres
Proposal for a regulation
Recital 16 a (new)

Text proposed by the Commission

(16a) In order to facilitate the prevention, monitoring and reporting of shortages of medicinal products, devices and applications, the Agency and the Commission should establish an
electronic platform to track and follow medicinal products, devices and applications throughout the supply chain. This platform should also be a one-stop shop for marketing authorisation holders and wholesale distributors to provide required information during major health events. This platform should use the distributed ledger technology (DLT) and include data from national and regional competent authorities. The platform should, among other duties, determine the volume of stock, the capabilities of all stakeholders linked in the supply chain or chains, the actual, current and foreseeable level of demand. This platform should also obtain, record and share information.

Amendment 197
Antoni Comin i Oliveres
Proposal for a regulation
Recital 16 b (new)

Text proposed by the Commission

Amendment

(16b) Finally, this platform should also be linked to the Health data space and managed by the Agency and the Commission.

Or. en

Amendment 198
Antoni Comin i Oliveres
Proposal for a regulation
Recital 17

Text proposed by the Commission

Amendment

(17) In order to ensure that safe, high

In order to ensure that safe, high
quality, and efficacious medicinal products, which have the potential to address public health emergencies, can be developed and made available within the Union as soon as possible during public health emergencies, an emergency task force should be established within the Agency to provide advice on such medicinal products. The Emergency Task Force should provide advice free of charge on scientific questions related to the development of treatments and vaccines and on clinical trial protocols, to those organisations involved in their development, such as marketing authorisation holders, clinical trial sponsors, public health bodies, and academia, irrespective of their exact role in the development of such medicinal products.

The lessons learned during the COVID pandemic should be taken into account in order to better use the Agency’s potential to face future health crises.

Or. en

Amendment 199
Tudor Ciuhodaru

Proposal for a regulation
Recital 17

Text proposed by the Commission

(17) In order to ensure that safe, high quality, and efficacious medicinal products, which have the potential to address public health emergencies, can be developed and made available within the Union as soon as possible during public health emergencies, an emergency task force should be established within the Agency to provide advice on such medicinal products. The Emergency Task Force should provide advice free of charge on scientific questions related to the development of such medicinal products.

Amendment

(17) In order to ensure that safe, high quality, and efficacious medicinal products, which have the potential to address public health emergencies, can be developed and made available within the Union as soon as possible during public health emergencies, an emergency task force should be established within the Agency to provide advice on such medicinal products. The Emergency Task Force should provide advice free of charge on scientific questions related to the development of such medicinal products.
development of treatments and vaccines and on clinical trial protocols, to those organisations involved in their development, such as marketing authorisation holders, clinical trial sponsors, public health bodies, and academia, irrespective of their exact role in the development of such medicinal products.

Amendment 200
Joëlle Mélin
Proposal for a regulation
Recital 17

*Text proposed by the Commission*

(17) In order to ensure that safe, high quality, and efficacious medicinal products, which have the potential to address public health emergencies, can be developed and made available within the Union as soon as possible during public health emergencies, an emergency task force should be established within the Agency to provide advice on such medicinal products. The Emergency Task Force should provide advice free of charge on scientific questions related to the development of treatments and vaccines and on clinical trial protocols, to those organisations involved in their development, such as marketing authorisation holders, clinical trial sponsors, public health bodies, and academia, irrespective of their exact role in the development of such medicinal products.

*Amendment*

(17) In order to ensure that safe, high quality, and efficacious human and veterinary medicinal products, which have the potential to address public health emergencies, can be developed and made available within the Union as soon as possible during public health emergencies, an emergency task force should be established within the Agency to provide advice on such medicinal products. The Emergency Task Force should provide advice free of charge on scientific questions related to the development of treatments and vaccines and on clinical trial protocols, to those organisations involved in their development, such as marketing authorisation holders, clinical trial sponsors, public health bodies, and academia, irrespective of their exact role in the development of such medicinal products.
Amendment 201
Antoni Comín i Oliveres

Proposal for a regulation
Recital 18

Text proposed by the Commission

(18) The work of the Emergency Task Force should be separate from the work of the scientific committees of the Agency and should be carried out without prejudice to the scientific assessments of those committees. The Emergency Task Force should provide recommendations with regard to the use of medicinal products in the fight against the disease that is responsible for the public health crisis. The Committee for Medicinal Products for Human Use should be able to use those recommendations when preparing scientific opinions on compassionate or other early use of a medicinal product prior to marketing authorisation.

Amendment

(18) The work of the Emergency Task Force should be separate from the work of the scientific committees of the Agency and should be carried out without prejudice to the scientific assessments of those committees, although communication between these two bodies should be guaranteed. The Emergency Task Force should provide recommendations with regard to the use of medicinal products in the fight against the disease that is responsible for the public health crisis. The Committee for Medicinal Products for Human Use should be able to use those recommendations when preparing scientific opinions on compassionate or other early use of a medicinal product prior to marketing authorisation.

Or. en

Amendment 202
Tilly Metz

Proposal for a regulation
Recital 18

Text proposed by the Commission

(18) The work of the Emergency Task Force should be separate from the work of the scientific committees of the Agency and should be carried out without prejudice to the scientific assessments of those committees. The Emergency Task Force should provide recommendations with regard to the use of medicinal products in the fight against the disease that is responsible for the public health crisis. The

Amendment

(18) The work of the Emergency Task Force should be separate from the work of the scientific committees of the Agency and should be carried out without prejudice to the scientific assessments of those committees. The Emergency Task Force should provide recommendations with regard to the use of medicinal products in the fight to overcome the public health crisis. The Committee for Medicinal Products for Human Use should be able to use those recommendations when preparing scientific opinions on compassionate or other early use of a medicinal product prior to marketing authorisation.
Committee for Medicinal Products for Human Use should be able to use those recommendations when preparing scientific opinions on compassionate or other early use of a medicinal product prior to marketing authorisation.

Products for Human Use should be able to use those recommendations when preparing scientific opinions on compassionate or other early use of a medicinal product prior to marketing authorisation.

Or. en

**Justification**

Not every health crisis is resulted from a disease. For example, extreme heat waves can also lead to health crises.

**Amendment 203**
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos

Proposal for a regulation
Recital 19

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tbody>
<tr>
<td>(19) The establishment of the Emergency Task Force should build on the support provided by the Agency during the COVID-19 pandemic, notably as regards scientific advice on clinical trials design and product development as well as the ‘rolling’ review i.e. on an on-going basis, of emerging evidence to allow a more efficient assessment of medicinal products including vaccines during public health emergencies.</td>
<td>(19) The establishment of the Emergency Task Force should build on the support provided by the Agency during the COVID-19 pandemic, notably as regards scientific advice on clinical trials design and product development as well as the ‘rolling’ review i.e. on an on-going basis, of emerging evidence to allow a more efficient assessment of medicinal products including vaccines during public health emergencies while guaranteeing a high level of human health protection.</td>
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Or. en

**Amendment 204**
Simona Baldassarre, Silvia Sardone, Marco Dreosto, Joëlle Mélin, Gianantonio Da Re, Lucia Vuolo

Proposal for a regulation
Recital 19 a (new)
Text proposed by the Commission

(19a) In order to ensure the full application of Article 35 of Regulation (EU) no. 536/2014 of the European Parliament and of the Council 1a, with regard to emergency clinical trials on subjects unable to provide informed consent, a special independent monitoring committee for emergency clinical trials is setup, in order to avoid the duplication of similar studies that could harm the human dignity and to ensure closer pharmacovigilance due to the particularity of the trial in question.


Or. en

Amendment 205
Tilly Metz

Proposal for a regulation
Recital 20

Text proposed by the Commission

(20) Individual research entities may agree together, or with another party, to act as a sponsor in order to prepare one harmonised Union-wide clinical trial protocol, yet experience during the COVID-19 pandemic has shown that initiatives to set up large multinational trials struggle to materialise due to the lack of a single entity that can undertake all the

Amendment

(20) Individual research entities may agree together, or with another party, to act as a sponsor in order to prepare one harmonised Union-wide clinical trial protocol, yet experience during the COVID-19 pandemic has shown that initiatives to set up large multinational trials struggle to materialise due to the lack of a single entity that can undertake all the
responsibilities and activities of a sponsor within the Union, while interacting with multiple Member States. It is therefore appropriate for the Agency to identify and facilitate such initiatives by giving advice on the possibilities to act as a sponsor or, where applicable, to define respective responsibilities as co-sponsors in accordance with Article 72 of Regulation (EU) 536/2014. Such an approach would strengthen the research environment in the Union, and promote harmonisation and avoid subsequent delays in integrating the results of research to a marketing authorisation. A Union sponsor could benefit from Union research funding available at the time of the public health emergency as well as existing clinical trial networks to facilitate the development, application, submission, and running of the trial. This may be particularly valuable for trials established by Union or international public health or research organisations.

Amendment 206
Antoni Comín i Oliveres
Proposal for a regulation
Recital 20 a (new)

Text proposed by the Commission

(20a) The Emergency Task Force should build on the trial networks to ensure that adequate data on new medicinal products, devices and applications, and it could build also upon the HERA Incubator, presented by
Amendment 207
Antoni Comín i Oliveres

Proposal for a regulation
Recital 21

*Text proposed by the Commission*

(21) With respect to medical devices, an executive steering group on medical devices should be established to coordinate urgent actions within the Union in relation to the management of supply and demand issues of medical devices, and to establish a list of critical devices in the case of a public health emergency.

*Amendment*

(21) With respect to medical devices, an executive steering group on medical devices should be established to coordinate urgent actions within the Union in relation to the management of supply and demand issues of medical devices, and to establish a list of critical devices in the case of a public health emergency. *The executive steering group on medical devices should be managed by the Commission and the Agency.*

Amendment 208
Tudor Ciuhodaru

Proposal for a regulation
Recital 21

*Text proposed by the Commission*

(21) With respect to medical devices, an executive steering group on medical devices should be established to coordinate urgent actions within the Union in relation to the management of supply and demand issues of medical devices, and to establish a list of critical devices in the case of a public health emergency.

*Amendment*

(21) With respect to medical devices, an executive steering group on medical devices should be established to coordinate urgent actions within the Union in relation to the management of supply and demand issues of medical devices, and to establish a list of critical devices *and minimum stock levels required* in the case of a public health emergency.
health emergency.

Amendment 209
Tilly Metz

Proposal for a regulation
Recital 24

Text proposed by the Commission

(24) Given the Agency’s long-standing and proven record of expertise in the field of medicinal products and considering the Agency’s experience from working with a multitude of groups of experts, it is appropriate to establish the appropriate structures within the Agency to monitor potential shortages of medical devices in the context of a public health emergency and to provide the Agency with a mandate to host the expert panels on medical devices. This would allow for long-term sustainability for the functioning of the panels and provide clear synergies with related crisis preparedness work for medicinal products. Those structures would in no way change the regulatory system or the decision-making procedures in the area of medical devices already in place in the Union, which should remain clearly distinct from the one for medicinal products.

Amendment

(24) Given the Agency’s long-standing and proven record of expertise in the field of medicinal products and considering the Agency’s experience from working with a multitude of groups of experts, it is appropriate to establish the appropriate structures within the Agency to monitor potential shortages of medical devices in the context of a public health emergency and to provide the Agency with a mandate to host the expert panels on medical devices. In this regard, all national and, eventually, Union entities engaged in stockpiling of medical devices, should report their stocks to the Agency. This would allow for long-term sustainability for the functioning of the panels and provide clear synergies with related crisis preparedness work for medicinal products. Those structures would in no way change the regulatory system or the decision-making procedures in the area of medical devices already in place in the Union, which should remain clearly distinct from the one for medicinal products.

Amendment 210
Aldo Patriciello

Proposal for a regulation
Recital 25
(25) In order to facilitate the work and the exchange of information under this Regulation, provision should be made for the establishment and management of IT infrastructures and synergies with other existing IT systems or systems under development, including the EUDAMED IT platform for medical devices. That work should also be facilitated by, where appropriate, emerging digital technologies such as computational models and simulations for clinical trials, as well as data from the EU Space Programme such as the Galileo geolocation services, and Copernicus earth observation data.

Amendment

(25) In order to facilitate the work and the exchange of information under this Regulation, provision should be made for the establishment and management of IT infrastructures and synergies with other existing IT systems or systems under development, including the use of the European Medicines Verification System (set up in the context of the Falsified Medicines FMD) data for mapping consumption for human medicines and preventing medicines shortages, and of the Substance, product, organisation and referential (SPOR) master management for human medicines and the EUDAMED IT platform for medical devices.

Or. en
Copernicus earth observation data. for human medicines and the EUDAMED IT platform for medical devices. That work should also be facilitated by, where appropriate, emerging digital technologies such as computational models and simulations for clinical trials, as well as data from the EU Space Programme such as the Galileo geolocation services, and Copernicus earth observation data.

Amendment 212
Tudor Ciuhodaru

Proposal for a regulation
Recital 25

(25) In order to facilitate the work and the exchange of information under this Regulation, provision should be made for the establishment and management of IT infrastructures and synergies with other existing IT systems or systems under development, including the EUDAMED IT platform for medical devices. That work should also be facilitated by, where appropriate, emerging digital technologies such as computational models and simulations for clinical trials, as well as data from the EU Space Programme such as the Galileo geolocation services, and Copernicus earth observation data.

Amendment

(25) In order to facilitate the work and the exchange of information under this Regulation, provision should be made for the establishment and management of IT infrastructures and synergies with other existing IT systems or systems under development, including the EUDAMED IT platform for medical devices, alongside enhanced protection of data infrastructure and dissemination from possible cyberattacks. That work should also be facilitated by, where appropriate, emerging digital technologies such as computational models and simulations for clinical trials, as well as data from the EU Space Programme such as the Galileo geolocation services, and Copernicus earth observation data.

Amendment 213
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos
Proposal for a regulation
Recital 25

Text proposed by the Commission

(25) In order to facilitate the work and the exchange of information under this Regulation, provision should be made for the establishment and management of IT infrastructures and synergies with other existing IT systems or systems under development, including the EUDAMED IT platform for medical devices. That work should also be facilitated by, where appropriate, emerging digital technologies such as computational models and simulations for clinical trials, as well as data from the EU Space Programme such as the Galileo geolocation services, and Copernicus earth observation data.

Amendment

(25) In order to facilitate the work and the exchange of information under this Regulation, provision should be made for the establishment and management of IT infrastructures and synergies with other existing IT systems or systems under development, including **SPOR data management for human medicines** and the EUDAMED IT platform for medical devices. That work should also be facilitated by, where appropriate, emerging digital technologies such as computational models and simulations for clinical trials, as well as data from the EU Space Programme such as the Galileo geolocation services, and Copernicus earth observation data.

Or. en

Amendment 214
Dolors Montserrat

Proposal for a regulation
Recital 26

Text proposed by the Commission

(26) Rapid access and exchange of health data, including real world data i.e. health data generated outside of clinical studies, is essential to ensure effective management of public health emergencies and other major events. This Regulation should allow the Agency to use and facilitate such exchange and be part of the establishment and operation of the European Health Data Space infrastructure.

Amendment

(26) Rapid access and exchange of health data, including real world data i.e. health data generated outside of clinical studies, is essential to ensure effective management of public health emergencies and other major events. This Regulation should allow the Agency to use and facilitate such exchange and be part of the establishment and operation of the European Health Data Space **interoperable infrastructure**, **taking advantage of all the potential of the supercomputing, the Artificial Intelligence and the Big Data science**
to develop predicting models and take better and more timely-effective decisions, without compromising the privacy rights.

Amendment 215
Tudor Ciuhodaru
Proposal for a regulation
Recital 26

Text proposed by the Commission

(26) Rapid access and exchange of health data, including real world data i.e. health data generated outside of clinical studies, is essential to ensure effective management of public health emergencies and other major events. This Regulation should allow the Agency to use and facilitate such exchange and be part of the establishment and operation of the European Health Data Space infrastructure.

Amendment

(26) Rapid access and exchange of health data, including real world data i.e. health data generated outside of clinical studies, is essential to ensure effective management of public health emergencies and other major events. This Regulation should allow the Agency to use and facilitate such exchange and be part of the establishment and operation of the European Health Data Space infrastructure, but with clear rules on controlling access to the data (users with access, data retention period) and ensuring adequate protection of the data.

Amendment 216
Tilly Metz
Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission

(26a) Due to the sensitive nature of health data, the Agency should safeguard and guarantee its processing operations respect the data protection principles of lawfulness, fairness, transparency, purpose limitation, data minimisation,
accuracy, storage limitation, integrity and confidentiality. The Agency should strictly respect the principles of data protection as defined in Article 27 of Regulation (EU)2018/1725 EUDPR, while also determining appropriate technical and organisational security measures in accordance with Article 33 EUDPR.

Amendment 217
Petar Vitanov
Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission

Amendment

(26a) Where it is necessary for the purposes of this Regulation to process personal data, this should be done in accordance with Union law on the protection of personal data. Any processing of personal data based on this Regulation should take place in accordance with Regulations (EU)2016/679 and (EU) 2018/1725.

Or. en

Amendment 218
Aldo Patriciello
Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission

Amendment

(26a) In order to facilitate the reliable exchange of medicinal product information in a robust and consistent manner, identification of human medicinal products will be based on ISO IDMP standards.
Amendment 219
Tilly Metz

Proposal for a regulation
Recital 26 b (new)

Text proposed by the Commission

(26b) Where processing of personal data is not necessary to perform the activities of the Agency, measures should be put in place to ensure use of anonymous data in line with the principle of data minimisation. Where anonymisation would not allow to achieve the specific purpose of the processing, the data should be pseudonymised. Where it is necessary for the purposes of this Regulation to process personal data, this should be carried out in accordance with Union law on the protection of personal data. Any processing of personal data based on this Regulation shall take place in accordance with Regulation 2018/1725 (EUDPR).

Amendment

(26c) It is imperative to have in place robust transparency measures and standards regarding the Agency’s regulatory activities on medicinal products and medical devices falling under the scope of this Regulation. These measures should include timely publication of all relevant information on
approved products and clinical data, including full clinical trial protocols. The Agency should apply high degree of transparency on the membership, recommendations, opinions and decisions of the newly established Steering Groups and the Emergency Task Force. Members of the Steering Groups and the Emergency Task Force should have no financial or other interests in the pharmaceutical or medical device industry which could affect their impartiality.

Or. en

Amendment 221
Tilly Metz

Proposal for a regulation
Recital 26 d (new)

Text proposed by the Commission

(26d) Credibility of the Agency and public trust in its decisions relies on a high degree of transparency. Therefore, proactive engagement of adequate communication tools with the general public should be foreseen. In addition, strengthened and accelerated transparency standards and measures regarding the Agency’s working bodies and clinical data assessed for the evaluation and surveillance of medicinal products and medical devices are paramount to gain and upheld public trust. This Regulation establishes a framework for these strengthened transparency standards and measures, based on the EMA’s efforts, standards and measures put in place during the Covid-19 pandemic.

Or. en
Amendment 222
Aldo Patriciello

Proposal for a regulation
Recital 27

Text proposed by the Commission

(27) During a public health emergency or in relation to a major event, the Agency should ensure cooperation with the European Centre for Disease Prevention and Control and other Union Agencies as appropriate. Such cooperation should include data sharing, including data on epidemiological forecasting, regular communication at an executive level, and invitations to representatives of the European Centre for Disease Prevention and Control and other Union Agencies to attend meetings of the Emergency Task Force, the Medicines Steering Group, and the Medical Devices Steering Group, as appropriate. Regular two-way communication and exchange of information between regulators, industry and pertinent stakeholders of the pharmaceutical supply chain shall also be guaranteed to kick off prompt debates about estimated potential drug shortages in the market by way of sharing expected supply constraints which authorities become aware of via the notification process, allowing better coordination, interactions and proper response when required.

Or. en

Amendment 223
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ştefănuţă, Nils Torvalds, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos, Jan Huitema
Proposal for a regulation
Recital 27

Text proposed by the Commission

(27) During a public health emergency or in relation to a major event, the Agency should ensure cooperation with the European Centre for Disease Prevention and Control and other Union Agencies as appropriate. Such cooperation should include data sharing, including data on epidemiological forecasting, regular communication at an executive level, and invitations to representatives of the European Centre for Disease Prevention and Control and other Union Agencies to attend meetings of the Emergency Task Force, the Medicines Steering Group, and the Medical Devices Steering Group, as appropriate.

Amendment

(27) During a public health emergency or in relation to a major event, the Agency should ensure cooperation with the European Centre for Disease Prevention and Control and other Union Agencies as appropriate. Such cooperation should include data sharing, including data on epidemiological forecasting, regular communication at an executive level, and invitations to representatives of the European Centre for Disease Prevention and Control and other Union Agencies to attend meetings of the Emergency Task Force, the Medicines Steering Group, and the Medical Devices Steering Group, as appropriate. This cooperation should also include strategic discussions with relevant entities of the Union in a position to boost the research and development of appropriate solutions and technologies to mitigate the effects of the public health emergency or major event, or prevent future similar public health emergencies or major events, such as the proposed European Health Emergency Preparedness and Response Authority (HERA).

Or. en
and Control and other Union Agencies as appropriate. Such cooperation should include data sharing, including data on epidemiological forecasting, regular communication at an executive level, and invitations to representatives of the European Centre for Disease Prevention and Control and other Union Agencies to attend meetings of the Emergency Task Force, the Medicines Steering Group, and the Medical Devices Steering Group, as appropriate.

(27a) Public trust relies on full transparency. Pro-active engagement with adequate communication tools with the general public should be foreseen. Strengthened and accelerated transparency standards and measures regarding the Agency working bodies and clinical data assessed for the evaluation and surveillance of medicinal products and medical devices are paramount to gain and upheld public trust. The EMA has put in place strengthened and accelerated transparency standards and measures during the Covid-19 pandemic. This Regulation establishes a framework for these strengthened transparency standards and measures.

Amendment 226
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ştefănuță, Susana Solís Pérez,
Proposal for a regulation
Recital 27 a (new)

Text proposed by the Commission

(27a) During a public health emergency or in relation to a major event, the Agency should enable regular exchanges of information with the industry, relevant entities of the pharmaceutical supply chain, representatives of healthcare professionals, patients and consumers, to guarantee early discussions on potential drug shortages in the market and supply constraints, so as to allow better coordination and synergies to mitigate and respond to the public health emergency or major event.

Amendment 227
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ştefănuţă, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos, Jan Huitema, Ondřej Knotek

Proposal for a regulation
Recital 29

Text proposed by the Commission

(29) In order to ensure that sufficient resources are available for the work provided for under this Regulation, expenditure of the Agency should be covered by the contribution from the Union to the Agency’s revenue.

Amendment

(29) In order to ensure that sufficient resources, including appropriate staffing and adequate expertise, are available for the work provided for under this Regulation, expenditure of the Agency should be covered by the contribution from the Union to the Agency’s revenue.

Amendment 228
Joanna Kopcińska
Proposal for a regulation
Recital 29 a (new)

Text proposed by the Commission

(29a) The Commission retains the right to adjust the Agency's proposed resources and staffing allocation following the upcoming publication of the legislative proposal to establish a European Biomedical Research and Development Agency (BARDA) / European Health Emergency Preparedness and Response Authority (HERA).

Or. en

Amendment 229
Pietro Fiocchi

Proposal for a regulation
Recital 31 a (new)

Text proposed by the Commission

(31a) National Competent Authorities (NCAs) should establish a reliable and harmonised pan-European interoperable and digital reporting system for shortages and preventing duplication of shortages reporting. The standardized reporting requirements for information on clearly defined shortages should be agreed, giving priority to critical products with high potential impact. For this the NCAs should establish a uniform harmonized pan-European interoperable and digital NCAs reporting system consisting of harmonised and common data fields and interoperable with other systems like Substance, product, organisation and referential (SPOR) master management, EMA systems and Industry Single Point of Contact (iSPOC) and operating in a digital environment and having an effective alert system to
discriminate between national and/or pan-European shortages.

Amendment 230
Danilo Oscar Lancini

Proposal for a regulation
Recital 31 a (new)

Text proposed by the Commission

(31a) National Competent Authorities (NCAs) should establish a reliable and harmonised pan-European interoperable and digital reporting system for shortages and preventing duplication of shortages reporting. The standardized reporting requirements for information on clearly defined shortages should be agreed, giving priority to critical products with high potential impact. For this the NCAs should establish a uniform harmonised pan-European interoperable and digital NCAs reporting system consisting of harmonised and common data fields and interoperable with other systems like Substance, product, organisation and referential (SPOR) master management, EMA systems and Industry Single Point of Contact (iSPOC) and operating in a digital environment and having and effective alert system to discriminate between national and/or pan-European shortages.
In the specific case of the COVID-19 epidemic, the shortage of adjuvant treatments for the disease had a variety of causes, ranging from production difficulties in third countries to logistical or production difficulties, whilst the shortage of vaccines was due to a rarer cause, namely an unexpectedly high and rising demand.

It is important to acknowledge the role of the pharmaceutical industry during the COVID-19 crisis and the fact that the industry demonstrated its resilience, through continuous manufacturing, avoiding any major disruption of supply to patients throughout the COVID-19 crisis.

In order to facilitate the reliable exchange of information on medicinal products in a robust and consistent manner, identification of human
medicinal products should be based on the standards of the International Organization for Standardization (ISO) for the identification of medicinal products (IDMP).

Amendment 234
Danilo Oscar Lancini
Proposal for a regulation
Recital 31 b (new)

Text proposed by the Commission

Amendment

(31b) Shortages consist of different and complex root causes which still need to be further mapped, understood and analysed together with all different stakeholders to be capable of addressing all the different root causes.

Amendment 235
Margarita de la Pisa Carrión
Proposal for a regulation
Recital 31 b (new)

Text proposed by the Commission

Amendment

(31b) The establishment of an interoperable electronic platform between Member States and the Union is necessary for the prevention, monitoring and reporting of shortages of medicines and medical devices.

Amendment 236
Joëlle Mélin

Proposal for a regulation
Recital 31 b (new)

*Text proposed by the Commission*  
*(31b)* It is important to take into account, in the assessment of potential health emergencies, the contribution of zoonoses and the role of veterinary services where they are involved.

Or. fr

Amendment 237  
Margarita de la Pisa Carrión

Proposal for a regulation
Recital 31 c (new)

*Text proposed by the Commission*  
*(31c)* Shortages consist of different and complex root causes which still need to be further mapped, understood and analysed together with all different stakeholders to be capable of addressing all the different root causes. A better understanding of the root causes and drivers of shortages should include identification of bottlenecks in the supply chain via the European Medicines Verification System (set up in the context of the Falsified Medicines Directive) could readily be used for this purpose.

Or. en

Amendment 238  
Pietro Fiocchi

Proposal for a regulation
Recital 31 c (new)
(31c) It is important to acknowledge the role of the pharmaceutical industry during the Covid-19 crisis and the fact that industry demonstrated resilience, through continued manufacturing, avoiding any major supply disruption for patients during the whole Covid-19 crisis.

Or. en

Amendment 239
Pietro Fiocchi
Proposal for a regulation
Recital 31 d (new)

(31d) Shortages consist of different and complex root causes which still need to be further mapped, understood and analysed together with all different stakeholders to be capable of addressing all the different root causes. A better understanding of the root causes and drivers of shortages should include identification of bottlenecks in the supply chain via the European Medicines Verification System (setup in the context of the Falsified Medicines Directive) could readily be used for this purpose.

Or. en

Amendment 240
Pietro Fiocchi
Proposal for a regulation
Recital 31 e (new)

(31e) During Covid-19 the regulatory
flexibility allowed by the Commission has proven to be a tool for industry to prevent shortages. Such regulatory flexibilities, such as electronic product information (e-leaflet), should also be feasible outside of a crisis to help manufacturers to prevent shortages.

Or. en

Amendment 241
Joëlle Mélin

Proposal for a regulation
Article 1 – paragraph 1 – point a

Text proposed by the Commission

(a) prepare for and manage the impact of major events on medicinal products for human use and of public health emergencies on medicinal products for human use and on medical devices;

Amendment

(a) prepare for and manage the impact of major events on medicinal products for human and veterinary use and of public health emergencies on medicinal products for human and veterinary use and on medical devices;

Or. fr

Amendment 242
Dolors Montserrat

Proposal for a regulation
Article 1 – paragraph 1 – point a

Text proposed by the Commission

(a) prepare for and manage the impact of major events on medicinal products for human use and of public health emergencies on medicinal products for human use and on medical devices;

Amendment

(a) prevent, prepare for, manage and coordinate at European level the impact of major events on medicinal products for human use and of public health emergencies on medicinal products for human use and on medical devices;

Or. en
Amendment 243
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 1 – paragraph 1 – point a

Text proposed by the Commission

(a) prepare for and manage the impact of major events on medicinal products for human use and of public health emergencies on medicinal products for human use and on medical devices;

Amendment

(a) prepare for, coordinate and manage at European level the impact of major events on medicinal products for human use and of public health emergencies on medicinal products for human use and on medical devices;

Or. fr

Amendment 244
Traian Băsescu

Proposal for a regulation
Article 1 – paragraph 1 – point a

Text proposed by the Commission

(a) prepare for and manage the impact of major events on medicinal products for human use and of public health emergencies on medicinal products for human use and on medical devices;

Amendment

(a) prepare for and manage the impact of major events in order to limit urgently that impact on medicinal products for human use and of public health emergencies on medicinal products for human use and on medical devices;

Or. ro

Amendment 245
Aldo Patriciello

Proposal for a regulation
Article 1 – paragraph 1 – point a

Text proposed by the Commission

(a) prepare for and manage the impact of major events on medicinal products for human use and of public health

Amendment

(a) prepare and manage (at a pan-European level) the impact of major events on medicinal products for human use and of public health emergencies on medicinal products for human use and on medical devices;
emergencies on medicinal products for human use and on medical devices; use and of public health emergencies on medicinal products for human use and on medical devices;

Amendment 246
Sara Cerdas

Proposal for a regulation
Article 1 – paragraph 1 – point a

*Text proposed by the Commission*  
(a) prepare for and manage the impact of major events on medicinal products for human use and of public health emergencies on medicinal products for human use and on medical devices;

*Amendment*

(a) prevent, prepare for and manage the impact of major events on medicinal products for human use and of public health emergencies on medicinal products for human use and on medical devices;

Amendment 247
Aldo Patriciello

Proposal for a regulation
Article 1 – paragraph 1 – point a – point i (new)

*Text proposed by the Commission*  
i) Set up the relevant harmonised pan-European interoperable and digitalized infrastructure and information systems in place and functional also under normal circumstances to monitor and report on shortages, as a basis to better manage crisis situations;

*Amendment*

Or. en

Amendment 248
Dolors Montserrat
Proposal for a regulation
Article 1 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(aa) Set up the European Union of Health digitalized and interoperable early-warning system of shortages of medicinal products and medical devices, interconnecting national reporting systems, with common definitions and data collection procedures, as a basis to better prevent, manage and coordinate health emergencies at Union level;

Or. en

Amendment 249
Traian Băsescu

Proposal for a regulation
Article 1 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) monitor and report on shortages of medicinal products for human use and medical devices;

(b) monitor and report on shortages of medicinal products for human use and medical devices, and adopt all adequate and necessary measures to ensure that shortages of essential medicinal products can be avoided and patients have access to safe medicinal products and treatments at accessible prices;

Or. ro

Amendment 250
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 1 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) prevent, monitor and report on shortages of medicinal products for human use and medical devices;
medicinal products for human use and medical devices; shortages of medicinal products for human use and medical devices;

Or. fr

Amendment 251
Margarita de la Pisa Carrión

Proposal for a regulation
Article 1 – paragraph 1 – point b

Text proposed by the Commission

(b) monitor and report on shortages of medicinal products for human use and medical devices;

Amendment

(b) monitor and report to prevent on shortages of medicinal products for human use and medical devices;

Or. en

Amendment 252
Kateřina Konečná

Proposal for a regulation
Article 1 – paragraph 1 – point b

Text proposed by the Commission

(b) monitor and report on shortages of medicinal products for human use and medical devices;

Justification

A proactive policy of anticipation and prevention of manufacturing disruptions should be streamlined rather than a reactive policy based on monitoring and reporting of shortages exposing European citizens to possible negative consequences.

(b) prevent, monitor and report on shortages of medicinal products for human use and medical devices;

Or. en

Amendment 253
Tilly Metz

Proposal for a regulation
Article 1 – paragraph 1 – point b

Text proposed by the Commission

(b) monitor and report on shortages of medicinal products for human use and medical devices;

Amendment

(b) **prevent**, monitor and report on shortages of medicinal products for human use and medical devices;

Justification

A proactive policy of anticipation and prevention of manufacturing disruptions should be streamlined rather than a reactive policy based on monitoring and reporting of shortages exposing European citizens to possible negative consequences.

Amendment 254
Antoni Comín i Oliveres

Proposal for a regulation
Article 1 – paragraph 1 – point b a (new)

Text proposed by the Commission

(ba) set up an interoperable and digital database at Union level to track, monitor, report and share information on shortages of medicinal products, devices and applications;

Amendment

Or. en

Amendment 255
Joëlle Mélin

Proposal for a regulation
Article 1 – paragraph 1 – point c

Text proposed by the Commission

(c) provide advice on medicinal products for human use with the potential to address public health emergencies;

Amendment

(c) provide advice on medicinal products for human and *veterinary* use with the potential to address public health emergencies;
Amendment 256
Margarita de la Pisa Carrión

Proposal for a regulation
Article 2 – paragraph 1 – point a

Text proposed by the Commission

(a) ‘public health emergency’ means a public health emergency at Union level recognised by the European Commission in accordance with Article 23(1) of Regulation (EU) 2020/[…];

Amendment

(a) ‘public health emergency’ means a public health emergency at Unión level recognised by the European Commission in accordance with Article 23(1) of Regulation (EU) 2020/[…] and the Agency will define upfront the actual criteria to capture the drivers of such an emergency in Article 3.


Or. fr

Amendment 257
Pietro Fiocchi

Proposal for a regulation
Article 2 – paragraph 1 – point a

Text proposed by the Commission

(a) ‘public health emergency’ means a public health emergency at Union level recognised by the European Commission in accordance with Article 23(1) of Regulation (EU) 2020/[…];

Amendment

(a) ‘public health emergency’ means a public health emergency at Union level recognised by the European Commission in accordance with Article 23(1) of Regulation (EU) 2020/[…] and the Agency will define upfront the actual criteria to capture the drivers of such an emergency in Article 3.


Or. en
Amendment 258
Joëlle Mélin

Proposal for a regulation
Article 2 – paragraph 1 – point a

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
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<td>(a) ‘public health emergency’ means a public health emergency at Union level recognised by the European Commission in accordance with Article 23(1) of Regulation (EU) 2020/[…][17];</td>
<td>(a) ‘public health emergency’ means a temporary public health emergency at Union level recognised by the European Commission in accordance with Article 23(1) of Regulation (EU) 2020/[…][17];</td>
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Or. fr

Amendment 259
Traian Băsescu

Proposal for a regulation
Article 2 – paragraph 1 – point a

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</table>


Or. fr

Amendment 260
Cristian-Silviu Bușoi, Radan Kanev

Proposal for a regulation
Article 2 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) 'supply' means total volume of stock of an individual medicinal product or medical device that is made available on the national market by a marketing authorisation holder or a manufacturer either distributors, or any other actor in the distribution chain respectively;

Or. en

Amendment 261
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos, Ondřej Knotek

Proposal for a regulation
Article 2 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) 'supply' means total volume of stock of an individual medicinal product or medical device that is placed on the national market by a marketing authorisation holder, a manufacturer, a distributor, or any other actor in the distribution chain respectively;
Amendment 262
Pietro Fiocchi

Proposal for a regulation
Article 2 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) ‘supply’ means total volume of stock of an individual medicinal product or medical device that is made available on the national market by a marketing authorisation holder, a manufacturer, a distributor, or any other actor in the distribution chain respectively;

Amendment 263
Joëlle Mélin

Proposal for a regulation
Article 2 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment


Amendment 264
Cristian-Silviu Buşoi, Radan Kanev

Proposal for a regulation
Article 2 – paragraph 1 – point c b (new)

Text proposed by the Commission

Amendment
(cb) ‘demand’ means total volume of an individual medicinal product or medical device that is requested in the national market in response to a clinical need, including the necessary buffer stock at wholesale level;

Or. en

Amendment 265
Pietro Fiocchi

Proposal for a regulation
Article 2 – paragraph 1 – point c b (new)

Text proposed by the Commission

Amendment

(cb) ‘demand’ means total volume of an individual medicinal product or medical device that is requested in the national market in response to treatments need;

Or. en

Amendment 266
Joëlle Mélin

Proposal for a regulation
Article 2 – paragraph 1 – point d

Text proposed by the Commission

Amendment

(d) ‘shortage’ means that supply of a medicinal product for human use or a medical device does not meet demand for that medicinal product or medical device;

(d) ‘shortage’ means that supply of a medicinal product for human or veterinary use or a medical device does not meet demand, i.e. patient needs plus appropriate buffer stocks, for that medicinal product or medical device, no matter the cause;

Or. fr

Amendment 267
Danilo Oscar Lancini
Proposal for a regulation
Article 2 – paragraph 1 – point d

Text proposed by the Commission

(d) ‘shortage’ means that supply of a medicinal product for human use or a medical device does not meet demand for that medicinal product or medical device;

Amendment

(d) ‘shortage’ means that supply of a medicinal product for human use or a medical device does not meet demand for that medicinal product or medical device for patient and healthcare actors’ needs;

Or. en

Amendment 268
Pietro Fiocchi
Proposal for a regulation
Article 2 – paragraph 1 – point d

Text proposed by the Commission

(d) ‘shortage’ means that supply of a medicinal product for human use or a medical device does not meet demand for that medicinal product or medical device;

Amendment

(d) ‘shortage’ means that supply of a medicinal product for human use or a medical device does not meet demand for that medicinal product or medical device for patient and healthcare actors’ needs;

Or. en

Amendment 269
Cyrus Engerer
Proposal for a regulation
Article 2 – paragraph 1 – point d

Text proposed by the Commission

(d) ‘shortage’ means that supply of a medicinal product for human use or a medical device does not meet demand for that medicinal product or medical device;

Amendment

(d) ‘shortage’ means that supply of a medicinal product for human use or a medical device does not meet demand, that is patient demand together with appropriate buffer stocks, for that medicinal product or medical device;
Amendment 270
Pernille Weiss

Proposal for a regulation
Article 2 – paragraph 1 – point d

Text proposed by the Commission

(d) ‘shortage’ means that supply of a medicinal product for human use or a medical device does not meet demand for that medicinal product or medical device;

Amendment

(d) ‘shortage’ means that supply of a medicinal product for human use or a medical device does not meet patients’ demand for that medicinal product or medical device at national level for a period of more than two weeks;

Or. en

Amendment 271
Margarita de la Pisa Carrión

Proposal for a regulation
Article 2 – paragraph 1 – point d

Text proposed by the Commission

(d) ‘shortage’ means that supply of a medicinal product for human use or a medical device does not meet demand for that medicinal product or medical device;

Amendment

(d) ‘shortage’ means that supply of a medicinal product for human or veterinary use or a medical device does not meet patient need for that medicinal product or medical device at national level no matter the cause;

Or. en

Amendment 272
Aldo Patriciello

Proposal for a regulation
Article 2 – paragraph 1 – point d

Text proposed by the Commission

AM\1229960EN.docx 95/324 PE691.443v01-00
(d) ‘shortage’ means that supply of a medicinal product for human use or a medical device does not meet demand for that medicinal product or medical device;

(d) ‘shortage’ means that supply of a medicinal product for human use or a medical device does not meet patient and healthcare actors’ needs;

Or. en

Amendment 273
Petar Vitanov

Proposal for a regulation
Article 2 – paragraph 1 – point d

Text proposed by the Commission
(d) ‘shortage’ means that supply of a medicinal product for human use or a medical device does not meet demand for that medicinal product or medical device;

Amendment
(d) ‘shortage’ means that supply of a medicinal product for human use or a medical device does not meet patient demand plus the appropriate buffer stocks for that medicinal product or medical device;

Or. en

Amendment 274
Tilly Metz

Proposal for a regulation
Article 2 – paragraph 1 – point d

Text proposed by the Commission
(d) ‘shortage’ means that supply of a medicinal product for human use or a medical device does not meet demand for that medicinal product or medical device;

Amendment
(d) ‘shortage’ means that supply of a medicinal product for human use or a medical device does not meet the anticipated demand for that medicinal product or medical device, no matter the cause;

Or. en

Justification

Shortages must be anticipated and coughed at an early stage to prevent negative impact on the health of patients. Shortages of medicinal products and medical devices have several
causes and all of them need to be covered by the definition of ‘shortage’, including the withdrawal of products from the market for commercial reasons.

**Amendment 275**
Nathalie Colin-Oesterlé

**Proposal for a regulation**
**Article 2 – paragraph 1 – point d**

<table>
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<td>(d) ‘shortage’ means that supply of a medicinal product for human use or a medical device does not meet <em>demand for that medicinal product or medical device</em>;</td>
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Or. fr

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**Amendment 276**
Carlo Calenda

**Proposal for a regulation**
**Article 2 – paragraph 1 – point d**

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Or. it

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**Amendment 277**
Sara Cerdas

**Proposal for a regulation**
**Article 2 – paragraph 1 – point d**

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AM\:1229960EN.docx 97/324 PE691.443v01-00
medical device does not meet demand for that medicinal product or medical device; medical device does not meet demand for that medicinal product or medical device, regardless the cause;

Or. en

Amendment 278
Dolors Montserrat

Proposal for a regulation
Article 2 – paragraph 1 – point d

Text proposed by the Commission
(d) ‘shortage’ means that supply of a medicinal product for human use or a medical device does not meet demand for that medicinal product or medical device;

Amendment
(d) ‘shortage’ means that supply of a medicinal product for human use or a medical device does not meet demand for that medicinal product or medical device, no matter the cause;

Or. en

Amendment 279
Kateřina Konečná

Proposal for a regulation
Article 2 – paragraph 1 – point d

Text proposed by the Commission
(d) ‘shortage’ means that supply of a medicinal product for human use or a medical device does not meet demand for that medicinal product or medical device;

Amendment
(d) shortage’ means that supply of a medicinal product for human use or a medical device does not meet demand for that medicinal product or medical device, no matter the cause;

Or. en

Justification

Shortages of medicinal products and medical devices have several causes and all of them need to be covered by the definition of ‘shortage’, including the parallel trade or the withdrawal of products from the market for commercial reasons. The shortages caused by commercial withdrawals are very frequent and can have a disproportionate impact on patients’ care and public health. Shortages can be extremely long and difficult to solve.
Amendment 280
Danilo Oscar Lancini

Proposal for a regulation
Article 2 – paragraph 1 – point d a (new)

Text proposed by the Commission

(da) 'supply' means total volume of stock of an individual medicinal product or medical device that is made available on the national market by a marketing authorisation holder, a manufacturer, a distributors, or any other actor in the distribution chain respectively;

Amendment

Or. en

Amendment 281
Danilo Oscar Lancini

Proposal for a regulation
Article 2 – paragraph 1 – point d b (new)

Text proposed by the Commission

(db) 'demand' means total volume of an individual medicinal product or medical device that is requested in the national market in response to treatments need;

Amendment

Or. en

Amendment 282
Danilo Oscar Lancini

Proposal for a regulation
Article 2 – paragraph 1 – point e

Text proposed by the Commission

(e) ‘developer’ means any legal or natural person seeking to generate scientific data with regard to the quality,

Amendment

(c) ‘developer’ means any legal or natural person holding intellectual property rights for a medicinal product
safety and efficacy of a medicinal product as part of that product’s development;  

and who, as part of that product’s development, is seeking to generate scientific data with regard to the product’s quality, safety and efficacy of a medicinal product as part of that product’s development;

Or. en

Amendment 283
Pernille Weiss

Proposal for a regulation
Article 2 – paragraph 1 – point e

Text proposed by the Commission

(e) ‘developer’ means any legal or natural person seeking to generate scientific data with regard to the quality, safety and efficacy of a medicinal product as part of that product’s development;

Amendment

(e) ‘developer’ means any legal or natural person holding intellectual property rights for a medicinal product who is seeking to generate scientific data with regard to the quality, safety and efficacy of that medicinal product as part of the product’s development;

Or. en

Amendment 284
Margarita de la Pisa Carrión

Proposal for a regulation
Article 2 – paragraph 1 – point e

Text proposed by the Commission

(e) ‘developer’ means any legal or natural person seeking to generate scientific data with regard to the quality, safety and efficacy of a medicinal product as part of that product’s development;

Amendment

(e) ‘developer’ means any legal or natural person holding intellectual property rights for a medicinal product and who, as part of that product’s development, is seeking to generate scientific data with regard to the product’s quality, safety and efficacy;

Or. en
Amendment 285
Danilo Oscar Lancini

Proposal for a regulation
Article 2 – paragraph 1 – point f

Text proposed by the Commission

(f) ‘major event’ means an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State. Such an event concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin or incident that can affect the supply or quality, safety, and efficacy of medicinal products. Such an event may lead to shortages of medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection.

Amendment

(f) ‘major event’ means an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State. Such an event concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin or incident that can affect the supply or quality, safety, and efficacy of medicinal products. Such an event may lead to shortages of critical medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection.

Or. en

Amendment 286
Joëlle Mélin

Proposal for a regulation
Article 2 – paragraph 1 – point f

Text proposed by the Commission

(f) ‘major event’ means an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State. Such an event concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin or incident that can affect the supply or quality, safety, and efficacy of medicinal products. Such an event may...
lead to shortages of medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection.

(f) ‘major event’ means an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State. Such an event concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin or incident that can affect the supply or quality, safety, and efficacy of medicinal products. Such an event may lead to shortages of medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection.

(f) ‘major event’ means an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State. Such an event concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin or incident that can affect the supply or demand, quality, safety, and efficacy of medicinal products. Such an event may lead to shortages of critical medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection.
which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State. Such an event concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin or incident that can affect the supply or quality, safety, and efficacy of medicinal products. Such an event may lead to shortages of medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection.

Amendment 289
Traian Băsescu
Proposal for a regulation
Article 2 – paragraph 1 – point f

Text proposed by the Commission

(f) ‘major event’ means an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State. Such an event concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin or incident that can affect the supply or quality, safety, and efficacy of medicinal products. Such an event may lead to shortages of medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection.

Amendment

(f) ‘major event’ means an event which is likely to pose a serious risk to public health in relation to medicinal products in one or more Member State. Such an event concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin or incident that can affect the supply or quality, safety, and efficacy of medicinal products. Such an event may lead to shortages of medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection.

Or. it

Amendment 290
Dolors Montserrat

Proposal for a regulation
Article 2 – paragraph 1 – point f a (new)

Text proposed by the Commission

Amendment

(fa) ‘demand’ relates to the request for a medicinal product or a medical device by a healthcare professional or patient in response to a clinical need. For demand to be satisfactorily met, the medicinal product will need to be acquired in time and sufficient quantity to allow continuity of best care of patients, while following real, adequate prescription needs.

Or. en

Amendment 291
Joëlle Mélin

Proposal for a regulation
Article 2 – paragraph 1 – point f a (new)

Text proposed by the Commission

Amendment

(fa) ‘critical medicinal product’ means any medicinal product for human and veterinary use within the meaning of Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council, or a constituent thereof, that is considered necessary for the management of a public health emergency and until such time as the emergency is resolved.

Or. fr

Amendment 292
Joanna Kopcińska

Proposal for a regulation
Article 2 – paragraph 1 – point f a (new)
(fa) ‘major non-communicable disease’ means a chronic disease which tends to be of long duration and is the result of a combination of genetic, physiological, environmental and behavioural factors, such as a cardiovascular disease, cancer, respiratory disease, diabetes or mental illness, and which affects a significant number of people in the Union.

Amendment 293
Sara Cerdas
Proposal for a regulation
Article 2 – paragraph 1 – point f a (new)

(fa) ‘demand’ relates to the request for a medicinal product or a medical device by a healthcare professional or patient in response to a clinical need. For demand to be satisfactorily met, the medicinal product will need to be acquired in time and sufficient quantity to allow continuity of best care of patients.

Amendment 294
Kateřina Konečná
Proposal for a regulation
Article 2 – paragraph 1 – point f a (new)

(fa) ‘demand’ relates to the request for a medicinal product or a medical device by a healthcare professional or patient in
response to a clinical need. For demand to be satisfactorily met, the medicinal product will need to be acquired in time and sufficient quantity to allow continuity of best care of patients.

Or. en

Amendment 295
Tilly Metz

Proposal for a regulation
Article 2 – paragraph 1 – point f a (new)

Text proposed by the Commission

(fa) ‘demand’ relates to the request for a medicinal product or a medical device by a healthcare professional or patient in response to a clinical need. For demand to be satisfactorily met, the medical product will need to be acquired in time and sufficient quantity to allow continuity of best care of patients.

Or. en

Justification

‘Demand’ needs to be defined in the regulation as it determines the scope of shortages, which are at the core of the text. We recommend using as a basis the inclusive definition proposed in the EMA/HMA Guidance on the detection and notification of shortages of medicinal products for marketing authorisation holders. It acknowledges that healthcare professionals are the main prescribers of medicines and medical devices, while the ultimate objective is to guarantee the continuity of best care of patients.

Amendment 296
Aldo Patriciello

Proposal for a regulation
Article 2 – paragraph 1 – point f a (new)

Text proposed by the Commission

(fa) 'demand' means total volume of an
individual medicinal product or medical device that is requested in the national market in response to a clinical need

Amendment 297
Antoni Comín i Oliveres
Proposal for a regulation
Article 2 – paragraph 1 – point f a (new)

Text proposed by the Commission

Amendment

(fa) ‘Health in all policies’ means health in all policies as defined in Regulation (EU) .../... EU 4 Health [OJ: ...]

Or. en

Amendment 298
Tilly Metz
Proposal for a regulation
Article 2 – paragraph 1 – point f b (new)

Text proposed by the Commission

Amendment

(fb) ‘Supply’ refers to the total volume of stock of an individual medicinal product or a medical device that is placed on the market by the Marketing Authorisation Holder or the producer, including situations in which a product is withdrawn from the market for commercial reasons.

Or. en

Justification

‘Supply’ needs to be defined in the regulation as it determines the scope of shortages, which are at the core of the text. We recommend using as a basis the definition proposed in the EMA/HMA Guidance on the detection and notification of shortages of medicinal products for
MHAs8, making clear that it should also cover situations in which the MAH withdraws a product from the market for commercial reasons.

**Amendment 299**  
Kateřina Konečná

Proposal for a regulation  
Article 2 – paragraph 1 – point f b (new)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(fb) ‘supply’ refers to the total volume of stock of an individual medicinal product or a medical device that is placed on the market by the Marketing Authorisation Holder or the producer, including situations in which a product is withdrawn from the market for commercial reasons.</td>
<td></td>
</tr>
</tbody>
</table>

**Or. en**

**Amendment 300**  
Antoni Comín i Oliveres

Proposal for a regulation  
Article 2 – paragraph 1 – point f b (new)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(fb) ‘One Health approach’ means One health approach as defined in Regulation(EU) .../... EU 4 Health [OJ: ...]</td>
<td></td>
</tr>
</tbody>
</table>

**Or. en**

**Amendment 301**  
Antoni Comín i Oliveres

Proposal for a regulation  
Article 2 – paragraph 1 – point f c (new)
Text proposed by the Commission

(FC) ‘zoonosis’ means an infectious disease that has jumped from a non-human animal to humans through zoonotic spill-over;

Or. en

Amendment 302
Antoni Comín i Oliveres

Proposal for a regulation
Article 2 – paragraph 1 – point f d (new)

Text proposed by the Commission

(FD) ‘zoonotic spill-over’ is the spread of a non-human disease to humans resulting in zoonosis;

Or. en

Amendment 303
Antoni Comín i Oliveres

Proposal for a regulation
Article 2 – paragraph 1 – point f e (new)

Text proposed by the Commission

(Fe) 'veterinary medicinal product' means a medicinal product as defined in point (1) of Article 4 of Regulation (EU) 2019/6 of the European Parliament and the Council;

Or. en

Amendment 304
Antoni Comín i Oliveres

Proposal for a regulation
Article 2 – paragraph 1 – point f (new)

Text proposed by the Commission

(ff) 'supply' means total volume of stock of a medicinal product, a medical device, or a medical application, that is placed on the market by a marketing authorisation holder or a manufacturer;

Amendment

Or. en

Amendment 305
Antoni Comín i Oliveres

Proposal for a regulation
Article 2 – paragraph 1 – point f g (new)

Text proposed by the Commission

(fg) ‘supply chain’ is a steps-based network of activities, information and resources between a manufacturer company and its suppliers willing to produce and distribute a specific product to the final buyer;

Amendment

Or. en

Amendment 306
Aldo Patriciello

Proposal for a regulation
Article 2 – paragraph 1 a (new)

Text proposed by the Commission

'supply' means total volume of stock of an individual medicinal product or medical device that is made available on the national market by a marketing authorisation holder or a manufacturer either distributors, or any other actor in the distribution chain respectively;

'demand' means total volume of an
individual medicinal product or medical device that is requested in the national market in response to a clinical need;

Or. en

Amendment 307
Dolors Montserrat

Proposal for a regulation
Article 2 a (new)

Text proposed by the Commission

Amendment

Article 2 a

The setting of a European Union of Health digitalized and interoperable early-warning system

1. In order to better manage health crisis, a European Union of Health digitalized and interoperable early-warning system to monitor and report all medicines shortage is hereby established, through an infrastructure which is in place and functional also under normal circumstances.

2. Through such a harmonized, digitalized and interoperable system, the reporting shall be based on collecting data at the national level, with data collected on common definitions and procedures, covering both Centralised and National Marketing Authorisations. The Agency shall receive, when relevant, aggregated data from national databases to monitor any potential cross-border shortages.

Or. en

Amendment 308
Joëlle Mélin

Proposal for a regulation
Article 3 – paragraph 1
1. The Executive Steering Group on Shortages and Safety of Medicinal Products (‘the Medicines Steering Group’) is hereby established as part of the Agency. It shall meet either in person or remotely, in preparation for or during a public health emergency or following a request for assistance referred to in Article 4(3). The Agency shall provide its secretariat.

**Amendment**

1. The Executive Steering Group on Shortages and Safety of Human and Veterinary Medicinal Products (‘the Medicines Steering Group’) is hereby established as part of the Agency. It shall meet either in person or remotely, in preparation for or during a public health emergency or following a request for assistance referred to in Article 4(3). The Agency shall provide its secretariat.

**Or. fr**

**Amendment 309**

**Tudor Ciuhodaru**

**Proposal for a regulation**

**Article 3 – paragraph 1**

**Text proposed by the Commission**

1. The Executive Steering Group on Shortages and Safety of Medicinal Products (‘the Medicines Steering Group’) is hereby established as part of the Agency. It shall meet either in person or remotely, in preparation for or during a public health emergency or following a request for assistance referred to in Article 4(3). The Agency shall provide its secretariat.

**Amendment**

1. The Executive Steering Group on Shortages and Safety of Medicinal Products (‘the Medicines Steering Group’) is hereby established as part of the Agency. It shall meet as often as needed, either in person or remotely, in preparation for or during a public health emergency or following a request for assistance referred to in Article 4(3). The Agency shall provide its secretariat.

**Or. ro**

**Amendment 310**

**Margarita de la Pisa Carrión**

**Proposal for a regulation**

**Article 3 – paragraph 1 a (new)**

**Text proposed by the Commission**

1. The Executive Steering Group on Shortages and Safety of Medicinal Products (‘the Medicines Steering Group’) is hereby established as part of the Agency. It shall meet either in person or remotely, in preparation for or during a public health emergency or following a request for assistance referred to in Article 4(3). The Agency shall provide its secretariat.

**Amendment**

1. The Executive Steering Group on Shortages and Safety of Medicinal Products (‘the Medicines Steering Group’) is hereby established as part of the Agency. It shall meet as often as needed, either in person or remotely, in preparation for or during a public health emergency or following a request for assistance referred to in Article 4(3). The Agency shall provide its secretariat.
1 a. The Medicines Steering Group will be established for a fixed term and will cease its activities when the health emergency or the imminent major event has been declared to end;

Amendment 311
Antoni Comín i Oliveres

Proposal for a regulation
Article 3 – paragraph 2

Text proposed by the Commission

2. The Medicines Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields.

Amendment

2. The Medicines Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one senior representative per Member State. Each Member State shall appoint their representative. Those Member States with devolved competences in health may appoint a representative from a regional competent authority who will represent the whole Member State. Members may be accompanied by experts in specific scientific or technical fields. The Steering Group shall also include a representative of the Patients’ and Consumers’ Working Party as well as a representative of the Healthcare Professionals’ Working Party as observers.

Or. en

Amendment 312
Tilly Metz

Proposal for a regulation
Article 3 – paragraph 2

Text proposed by the Commission

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2. The Medicines Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields.

Justification

Patients, consumers and HCPs need to be part of the Steering Group as shortages primarily impact patients’ health and care. Their experience as end-users or healthcare professionals/providers is needed to identify medicines considered as critical for public health and/or patients’ best care in crisis situations, and to provide adequate recommendations and guidelines to prevent or mitigate shortages. It would also help improve the transparency and communication on the Steering Group activities, as the two representatives would report to the EMA PCWP and HCPWP.

Amendment 313
Dolors Montserrat

Proposal for a regulation
Article 3 – paragraph 2

Text proposed by the Commission

2. The Medicines Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields.

Amendment

2. The Medicines Steering Group shall be composed of a representative of the Agency, a representative of the Commission, a representative of the Patients' organizations, a representative of the Healthcare Professionals' organizations and one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields. The list of members of the Steering Group shall be made public on the EMA web-portal.
members of the Steering Group shall be transparent and made public on the EMA web-portal.

Or. en

Amendment 314
Kateřina Konečná

Proposal for a regulation
Article 3 – paragraph 2

Text proposed by the Commission

2. The Medicines Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields.

Amendment

2. The Medicines Steering Group shall be composed of a representative of the Agency, a representative of the Commission, and one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields. The Steering Group shall also include a representative of the Patients’ and Consumers’ Working Party and a representative of the Healthcare Professionals’ Working Party.

Or. en

Justification

The Regulation must allow patients to contribute their expertise to decision-making processes regarding the development of new medicines and the availability of critical products. This will help ensure that new pharmaceutical products meet the needs and expectations of end users. Likewise, it will contribute to improving the management of shortages by including the views of those most affected by supply disruptions.

Amendment 315
Dan-Ştefan Motreanu

Proposal for a regulation
Article 3 – paragraph 2

Text proposed by the Commission

Amendment

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PE691.443v01-00
2. The Medicines Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields.

**Amendment 316**

**Tudor Ciuhodaru**

Proposal for a regulation

**Article 3 – paragraph 2**

*Text proposed by the Commission*

2. The Medicines Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields.

*Amendment*

2. The Medicines Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one senior representative per Member State, as well as one alternate for unforeseen circumstances. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields.

**Or. ro**

**Amendment 317**

**Joanna Kopcińska**

Proposal for a regulation

**Article 3 – paragraph 2**

*Text proposed by the Commission*

2. The Medicines Steering Group

*Amendment*

2. The Medicines Steering Group

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shall be composed of a representative of the Agency, a representative of the Commission and one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields. shall be composed of a representative of the Agency, a representative of the Commission and one "authorised" senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields.

Amendment 318
Tilly Metz
Proposal for a regulation
Article 3 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. Members of the Medicines Steering Group must have no financial or other interests that could affect their impartiality. They shall act in the public interest and in an independent manner and make an annual declaration of their financial interests. All indirect interests which could relate to the industry shall be entered in a register held by the Agency and be accessible to the public, upon request.

Amendment 319
Nathalie Colin-Oesterlé
Proposal for a regulation
Article 3 – paragraph 3

Text proposed by the Commission

Amendment

3. The Medicines Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medicinal product
interest groups and marketing authorisation holders to attend its meetings.

interest groups, marketing authorisation holders or any other entity in the relevant pharmaceutical supply chain, healthcare professionals and patients' associations, to attend its meetings to ensure transparent and effective dialogue between all stakeholders in the supply chain and the relevant authorities.

Or. fr

Amendment 320
Margarita de la Pisa Carrión

Proposal for a regulation
Article 3 – paragraph 3

Text proposed by the Commission

3. The Medicines Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medicinal product interest groups and marketing authorisation holders to attend its meetings.

Amendment

3. The Medicines Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medicinal product interest groups and marketing authorisation holders to attend its meetings. The Chair shall ensure that a broad spectrum of opinions is taken into account. The chair shall ensure that the stakeholders in the medicines supply chain can give an informed opinion about the situation in the various Member States concerned;

Or. en

Amendment 321
Sara Cerdas

Proposal for a regulation
Article 3 – paragraph 3

Text proposed by the Commission

3. The Medicines Steering Group shall be chaired by the Agency. The Chair may invite third parties, including

Amendment

3. The Medicines Steering Group shall be chaired by the Agency. All members of the Medicines Steering Group
representatives of medicinal product interest groups and marketing authorisation holders to attend its meetings.

may propose to the Chair to invite third parties, including representatives of medicinal product interest groups, representatives of healthcare professionals, patients and consumers, and marketing authorisation holders to attend its meetings when their contribution may inform the discussions of the Steering Group.

Or. en

Amendment 322
Tilly Metz

Proposal for a regulation
Article 3 – paragraph 3

Text proposed by the Commission

3. The Medicines Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medicinal product interest groups and marketing authorisation holders to attend its meetings.

Amendment

3. The Medicines Steering Group shall be chaired by the Agency. All members of the Medicines Steering Group may propose to the Chair to invite third parties, including representatives of medicinal product interest groups, in particular healthcare professionals, patients, consumers and marketing authorisation holders to attend its meetings when their contribution may inform the discussions of the Steering Group.

Or. en

Justification

All members of the Steering Group should be allowed to propose inviting third parties which have information, experience or expertise that could help the discussions and decisions of the SG. Healthcare professionals, patients and consumers have a first-hand experience and invaluable insight into medicine shortages, which may however differ according to their position, country, profession, disease area. The invitation of single organisations based on their specific expertise is thus complementary to the participation of representatives of PCWP and HCPWP as members of the SG.

Amendment 323
Cristian-Silviu Bușoi, Radan Kanev

Proposal for a regulation
Article 3 – paragraph 3

**Text proposed by the Commission**

3. The Medicines Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medicinal product interest groups and marketing authorisation holders to attend its meetings.

**Amendment**

3. The Medicines Steering Group shall be chaired by the Agency. On a regular basis, the Chair shall invite third parties, including representatives of medicinal product interest groups and marketing authorisation holders to attend its meetings. In the event of an actual or imminent major event, the Chair shall invite relevant entities from the pharmaceutical supply chain to attend its meetings.

Or. en

**Amendment 324**
Dolors Montserrat

Proposal for a regulation
Article 3 – paragraph 3

**Text proposed by the Commission**

3. The Medicines Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medicinal product interest groups and marketing authorisation holders to attend its meetings.

**Amendment**

3. The Medicines Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medicinal product interest groups, marketing authorisation holders, representatives of healthcare professionals, and of patients to attend its meetings, when their contribution may inform the discussions of the Steering Group.

Or. en

**Amendment 325**
Adam Jarubas

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Proposal for a regulation

Article 3 – paragraph 3

**Text proposed by the Commission**

3. The Medicines Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medicinal product interest groups and marketing authorisation holders to attend its meetings.

**Amendment**

3. The Medicines Steering Group shall be chaired by the Agency. The Chair shall invite third parties, including representatives of medicinal product interest groups, marketing authorisation holders and other representatives of the pharmaceutical supply chain to attend its meetings and actively participate in the dialog with the authorities.

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**Amendment 326**
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos, Ondřej Knotek

**Proposal for a regulation**

**Article 3 – paragraph 3**

**Text proposed by the Commission**

3. The Medicines Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medicinal product interest groups and marketing authorisation holders to attend its meetings.

**Amendment**

3. The Medicines Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medicinal product interest groups and marketing authorisation holders, representatives of healthcare professionals, patients and consumers to attend its meetings.

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**Amendment 327**
Kateřina Konečná

**Proposal for a regulation**

**Article 3 – paragraph 3**

**Text proposed by the Commission**

3. The Medicines Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medicinal product interest groups and marketing authorisation holders to attend its meetings.

**Amendment**

3. The Medicines Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medicinal product interest groups and marketing authorisation holders, representatives of healthcare professionals, patients and consumers to attend its meetings.
3. The Medicines Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medicinal product interest groups and marketing authorisation holders to attend its meetings.

Amendment 328
Dan-Ștefan Motreanu

Proposal for a regulation
Article 3 – paragraph 3

Text proposed by the Commission

3. The Medicines Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medicinal product interest groups and marketing authorisation holders to attend its meetings.

Amendment

3. The Medicines Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medicinal product interest groups and marketing authorisation holders, representatives of patients, consumers and healthcare professionals to attend its meetings.

Or. en

Amendment 329
Danilo Oscar Lancini

Proposal for a regulation
Article 3 – paragraph 3

Text proposed by the Commission

3. The Medicines Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medicinal product interest groups and marketing authorisation holders to attend its meetings.

Amendment

3. The Medicines Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medicinal product interest groups and marketing authorisation holders, and other stakeholders in the medicines supply chain, to attend its meetings.

Or. en
meetings.

Amendment 330
Margarita de la Pisa Carrión

Proposal for a regulation
Article 3 – paragraph 3

Text proposed by the Commission

3. The Medicines Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medicinal product interest groups and marketing authorisation holders to attend its meetings.

Amendment

3. The Medicines Steering Group shall be chaired by the Agency. The Chair shall invite third parties, including representatives of medicinal product interest groups and marketing authorisation holders to attend its meetings.

Amendment 331
Joëlle Mélin

Proposal for a regulation
Article 3 – paragraph 3 a (new)

Text proposed by the Commission

3a. The Medicines Steering Group shall regularly invite representatives of interest groups in the field of medicinal products and marketing authorisation holders, as well as other stakeholders in the pharmaceutical industry to exchange regularly on the situation of medicine production in Europe and worldwide. On the basis of these exchanges, the Medicines Steering Group shall draw up strategic recommendations which it shall address to the Member States during the public health emergency period.

Amendment

3a. The Medicines Steering Group shall regularly invite representatives of interest groups in the field of medicinal products and marketing authorisation holders, as well as other stakeholders in the pharmaceutical industry to exchange regularly on the situation of medicine production in Europe and worldwide. On the basis of these exchanges, the Medicines Steering Group shall draw up strategic recommendations which it shall address to the Member States during the public health emergency period.
Amendment 332
Kateřina Konečná

Proposal for a regulation
Article 3 – paragraph 4

Text proposed by the Commission

4. The Medicines Steering Group shall establish its rules of procedure including procedures relating to the working party referred to the paragraph 5 and on the adoption of lists, sets of information, and recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.

Amendment

4. The Medicines Steering Group shall establish its rules of procedure including procedures relating to the working party referred to the paragraph 5 and on the adoption of lists, sets of information, and recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency. The agenda and minutes of the Steering Group as well as the rules of procedure and recommendations shall be made available to the public via the EMA web-portal.

Or. en

Amendment 333
Tilly Metz

Proposal for a regulation
Article 3 – paragraph 4

Text proposed by the Commission

4. The Medicines Steering Group shall establish its rules of procedure including procedures relating to the working party referred to the paragraph 5 and on the adoption of lists, sets of information, and recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.

Amendment

4. The Medicines Steering Group shall establish its rules of procedure including procedures relating to the working party referred to the paragraph 5 and on the adoption of lists, sets of information, and recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency. Agendas and minutes of the Steering Group as well as the rules of procedure and
Recommendations shall be made available to the public via the EMA web-portal.

Amendment 334
Joanna Kopcińska, Margarita de la Pisa Carrión

Proposal for a regulation
Article 3 – paragraph 4

Text proposed by the Commission

4. The Medicines Steering Group shall establish its rules of procedure including procedures relating to the working party referred to the paragraph 5 and on the adoption of lists, sets of information, and recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.

Amendment

4. The Medicines Steering Group shall establish its rules of procedure including procedures relating to the working party referred to the paragraph 5 and on the adoption of lists, sets of information, and recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency. The agenda, minutes and recommendations of the Medicines Steering Group shall be made available to the public through the Agency's online portal.

Amendment 335
Margarita de la Pisa Carrión

Proposal for a regulation
Article 3 – paragraph 4

Text proposed by the Commission

4. The Medicines Steering Group shall establish its rules of procedure including procedures relating to the working party referred to the paragraph 5 and on the adoption of lists, sets of information, and recommendations. The rules of procedure shall enter into force

Amendment

4. The Medicines Steering Group shall establish its rules of procedure including the clarified mention of its competences, procedures relating to the working party referred to the paragraph 5 and on the adoption of lists, sets of information, and recommendations. The
after receiving a favourable opinion from the Commission and the Management Board of the Agency. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.

Amendment 336
Antoni Comín i Oliveres

Proposal for a regulation
Article 3 – paragraph 5

Text proposed by the Commission

5. The Medicines Steering Group shall be supported in its work by a working party comprised of single points of contact related to shortages from national competent authorities for medicinal products established in accordance with Article 9(1).

Amendment

5. The Medicines Steering Group shall be supported in its work by a working party comprised of single points of contact related to shortages from national, and where applicable regional, competent authorities for medicinal products established in accordance with Article 9(1).

Amendment 337
Danilo Oscar Lancini

Proposal for a regulation
Article 3 – paragraph 5 a (new)

Text proposed by the Commission

5 a. The Medicines Steering Group shall be supported in its work by a working party comprised of industry single points of contact related to shortages (iSPOC) and a two way communication line need to be established between the Medicines Steering Group and the iSPOC.

Amendment

5 a. The Medicines Steering Group shall be supported in its work by a working party comprised of industry single points of contact related to shortages (iSPOC) and a two way communication line need to be established between the Medicines Steering Group and the iSPOC.
Amendment 338  
Pietro Fiocchi  
Proposal for a regulation  
Article 3 – paragraph 5 a (new)  

Text proposed by the Commission  

5 a. The Medicines Steering Group shall be supported in its work by a working party comprised of industry single points of contact related to shortages (iSPOC) and a two way communication line need to be established between the Medicines Steering Group and the iSPOC.

Or. en

Amendment 339  
Cristian-Silviu Buşoi, Radan Kanev  
Proposal for a regulation  
Article 3 – paragraph 6  

Text proposed by the Commission  

6. The Medicines Steering Group shall be responsible for fulfilling the tasks referred to in Article 4(4) and Articles 5 to 8.

Amendment 340  
Joëlle Mélin  
Proposal for a regulation  
Article 3 – paragraph 6 a (new)  

Text proposed by the Commission  

6a. All members of the Medicines Steering Group shall comply with the usual rules in force in the Union on

Amendment 341
Danilo Oscar Lancini

Proposal for a regulation
Article 3 – paragraph 6 a (new)

Text proposed by the Commission  
Amendment

6 a. The Medicines Steering Group together with the industry (via the industry single points of contacts - iSPOCs) shall determine the list of critical products and any future actions taken for the molecules included on the critical product list.

Amendment 342
Dan-Ştefan Motreanu

Proposal for a regulation
Article 3 – paragraph 6 a (new)

Text proposed by the Commission  
Amendment

6 a. The members of the Medicines Steering Group must have no financial or other interests that could affect their impartiality. The list of members shall be published on the EMA’s website.

Amendment 343
Kateřina Konečná
Proposal for a regulation
Article 3 – paragraph 6 a (new)

Text proposed by the Commission

6 a. The members of the Medicines Steering Group must have no financial or other interests that could affect their impartiality. The list of members shall be published on the EMA’s website.

Justification

Unlike in the section that describes the functioning of the Emergency Task Force, there is no reference in the proposed Regulation about the need to ensure the impartiality of the members of the Steering Groups. This should be addressed.

Amendment 344
Margarita de la Pisa Carrión, Joanna Kopcińska

Proposal for a regulation
Article 3 – paragraph 6 a (new)

Text proposed by the Commission

6 a. The Medicines Steering Group shall exercise its competencies in full compliance with the principles of proportionality and subsidiarity;

Amendment 345
Joëlle Mélin

Proposal for a regulation
Article 4 - title

Text proposed by the Commission

Monitoring of events and preparedness for major events and public health

Amendment

Monitoring of events and preparedness for temporary major events and public health
Amendment 346
Tilly Metz
Proposal for a regulation
Article 4 – paragraph 1

Text proposed by the Commission
1. The Agency shall continuously monitor any event that is likely to lead to a major event or a public health emergency.

Amendment
1. The Agency shall continuously monitor any event that has the potential to lead to a major event or a public health emergency. In this regard, the Agency shall cooperate closely with the European Centre for Disease Prevention and Control (ECDC) and other Union agencies, where relevant.

Or. en

Amendment 347
Margarita de la Pisa Carrión
Proposal for a regulation
Article 4 – paragraph 1

Text proposed by the Commission
1. The Agency shall continuously monitor any event that is likely to lead to a major event or a public health emergency.

Amendment
1. The Agency shall continuously monitor any event that is likely to lead to a major event or a public health emergency and it shall be capable of establishing the necessary preventive mechanisms that are necessary.

Or. en

Amendment 348
Nathalie Colin-Oesterlé
Proposal for a regulation
Article 4 – paragraph 1

Text proposed by the Commission

1. The Agency shall continuously monitor any event that is likely to lead to a major event or a public health emergency.

Amendment

1. The Agency shall continuously monitor any event that is likely to lead to a major event or a public health emergency in coordination with the relevant national or regional authorities.

Or. fr

Amendment 349
Antoni Comín i Oliveres

Proposal for a regulation
Article 4 – paragraph 1

Text proposed by the Commission

1. The Agency shall continuously monitor any event that is likely to lead to a major event or a public health emergency.

Amendment

1. The Agency shall continuously monitor any event that is likely to lead to a major event or a public health emergency in coordination with the national and regional competent authorities.

Or. en

Amendment 350
Stanislav Polčák

Proposal for a regulation
Article 4 – paragraph 1

Text proposed by the Commission

1. The Agency shall continuously monitor any event that is likely to lead to a major event or a public health emergency.

Amendment

1. The Agency shall continuously monitor any event in the Union or in third countries that is likely to lead to a major event or a public health emergency.

Or. cs
Amendment 351
Joëlle Mélin

Proposal for a regulation
Article 4 – paragraph 1

Text proposed by the Commission
1. The Agency shall continuously monitor any event that is likely to lead to a major event or a public health emergency.

Amendment
1. The Agency, in coordination with the ECDC, shall continuously monitor any event that is likely to lead to a major event or a public health emergency.

Or. fr

Amendment 352
Aldo Patriciello

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission
2. To facilitate the monitoring task referred to in paragraph 1, the national competent authorities, through the single points of contact referred to in Article 3(5), shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report to the Agency on any event, including a shortage of a medicinal product in a given Member State, that is likely to lead to a major event or a public health emergency. Where a national competent authority informs the Agency of a shortage of a medicinal product in a given Member State, it shall provide the Agency with any information received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC. Based on a report of an event from a national competent authority and in order to understand the impact of the event in other Member States, the Agency may request information from the national competent authorities, through the working party referred to in Article 3(5).

Amendment
2. To facilitate the monitoring task referred to in paragraph 1, the national competent authorities, through the single points of contact referred to in Article 3(5), shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), upload in the harmonised pan-European interoperable and digitalized shortages reporting and notification system, any event, including a shortage of a medicinal product in a given Member State, that is likely to lead to a major event or a public health emergency. Where a national competent authority uploads the information of a shortage of a medicinal product in a given Member State on the pan-European harmonized system, it shall provide the Agency with any information received from the marketing authorization holder pursuant to Article 23a of Directive 2001/83/EC. The information uploaded in the pan-European system are directly accessible for the Agency and national competent authorities and while avoiding
duplications of reporting, it shall support a two-way communication between authorities and industry to provide the transparency needed to take actions to prevent and mitigate cross border shortages. Based on a report of an event from a national competent authority and in order to understand the impact of the event in other Member States, the Agency may request information from the national competent authorities, through the working party referred to in Article 3(5).

Or. en

Amendment 353
Joëlle Mélin

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission

2. To facilitate the monitoring task referred to in paragraph 1, the national competent authorities, through the single points of contact referred to in Article 3(5), shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report to the Agency on any event, including a shortage of a medicinal product in a given Member State, that is likely to lead to a major event or a public health emergency. Where a national competent authority informs the Agency of a shortage of a medicinal product in a given Member State, it shall provide the Agency with any information received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC. Based on a report of an event from a national competent authority and in order to understand the impact of the event in other Member States, the Agency may request information from the national competent authorities, through the working

Amendment

2. To facilitate the monitoring task referred to in paragraph 1, the national competent authorities, through the single points of contact referred to in Article 3(5), shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report to the Agency on any event, including a shortage of a **human or veterinary** medicinal product in a given Member State, that is likely to lead to a major event or a public health emergency in other Member States. Where a national competent authority informs the Agency of a shortage of a medicinal product in a given Member State, it shall provide the Agency with any information received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC, **as well as any relevant additional information provided by stakeholders and actors in the pharmaceutical industry, with due regard for confidentiality and privacy, as provided for in Regulation (EU) 2016/769**
party referred to in Article 3(5). of the European Parliament and of the Council (General Data Protection Regulation – GDPR). Based on a report of an event from a national competent authority and in order to understand and, in particular, anticipate the impact of the event in other Member States, the Agency may request information from the national competent authorities, through the working party referred to in Article 3(5). 

Amendment 354
Antoni Comín i Oliveres

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission

2. To facilitate the monitoring task referred to in paragraph 1, the national competent authorities, through the single points of contact referred to in Article 3(5), shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report to the Agency on any event, including a shortage of a medicinal product in a given Member State, that is likely to lead to a major event or a public health emergency. Where a national competent authority informs the Agency of a shortage of a medicinal product in a given Member State, it shall provide the Agency with any information received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC. Based on a report of an event from a national competent authority and in order to understand the impact of the event in other Member States, the Agency may request information from the national competent authorities, through the working party referred to in Article 3(5). 

Amendment

2. To facilitate the monitoring task referred to in paragraph 1, the national, and where applicable regional, competent authorities, through the single points of contact referred to in Article 3(5) or the digital interoperable database referred to in Article 1(b) and Article 12(g), shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report to the Agency on any event, including a shortage of a medicinal product in a given Member State, that is likely to lead to a major event or a public health emergency. Where a national, and where applicable regional, competent authority informs the Agency of a shortage of a medicinal product in a given Member State, it shall provide the Agency with any information received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC. Based on a report of an event from a national or regional competent authority and in order to understand the impact of the event in other Member States, the Agency may request information from the national and where
applicable regional, competent authorities, through the working party referred to in Article 3(5).

Amendment 355
Cristian-Silviu Bușoi, Radan Kanev

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission

2. To facilitate the monitoring task referred to in paragraph 1, the national competent authorities, through the single points of contact referred to in Article 3(5), shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report to the Agency on any event, including a shortage of a medicinal product in a given Member State, that is likely to lead to a major event or a public health emergency. Where a national competent authority informs the Agency of a shortage of a medicinal product in a given Member State, it shall provide the Agency with any information received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC. Based on a report of an event from a national competent authority and in order to understand the impact of the event in other Member States, the Agency may request information from the national competent authorities, through the working party referred to in Article 3(5).

Amendment

2. To facilitate the monitoring task referred to in paragraph 1, the national competent authorities, through the single points of contact referred to in Article 3(5), shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report to the Agency, in due time, in an interoperable and digitalized platform for reporting and notifying shortages, on any event, including a shortage of a medicinal product in a given Member State, that is likely to lead to a major event or a public health emergency. Where a national competent authority informs the Agency of a shortage of a medicinal product in a given Member State, it shall provide the Agency with any information received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC. Based on a report of an event from a national competent authority and in order to understand the impact of the event in other Member States, the Agency may request information from the national competent authorities, through the working party referred to in Article 3(5).

Amendment 356
2. To facilitate the monitoring task referred to in paragraph 1, the national competent authorities, through the single points of contact referred to in Article 3(5), shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report to the Agency on any event, including a shortage of a medicinal product in a given Member State, that is likely to lead to a major event or a public health emergency. Where a national competent authority informs the Agency of a shortage of a medicinal product in a given Member State, it shall provide the Agency with any information received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC. Based on a report of an event from a national competent authority and in order to understand the impact of the event in other Member States, the Agency may request information from the national competent authorities, through the working party referred to in Article 3(5).

Amendment 357
Danilo Oscar Lancini

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission

2. To facilitate the monitoring task referred to in paragraph 1, the national competent authorities, through the single points of contact referred to in Article 3(5), shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report to the Agency on any event, including a shortage of a medicinal product in a given Member State, that is likely to lead to a major event or a public health emergency. Where a national competent authority informs the Agency of a shortage of a medicinal product in a given Member State, it shall provide the Agency with any information received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC. Based on a report of an event from a national competent authority and in order to understand the impact of the event in other Member States, the Agency may request information from the national competent authorities, through the working party referred to in Article 3(5).

Amendment

2. To facilitate the monitoring task referred to in paragraph 1, the national competent authorities, through the single points of contact referred to in Article 3(5), shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report to the Agency on any potential shortage of a medicinal product in a given Member State, that is likely to jeopardise a timely and appropriate response to a major event or a public health emergency. Where a national competent authority informs the Agency of a shortage of a medicinal product in a given Member State, it shall provide the Agency with any information received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC. Based on a report of an event from a national competent authority and in order to understand the impact of the event in other Member States, the Agency may request information from the national competent authorities, through the working party referred to in Article 3(5).
shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report to the Agency on any event, including a shortage of a medicinal product in a given Member State, that is likely to lead to a major event or a public health emergency. Where a national competent authority informs the Agency of a shortage of a medicinal product in a given Member State, it shall provide the Agency with any information received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC. Based on a report of an event from a national competent authority and in order to understand the impact of the event in other Member States, the Agency may request information from the national competent authorities, through the working party referred to in Article 3(5).

shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report to the Agency on any potential event, including a shortage of a critical medicinal product in a given Member State, that is likely to lead to following a major event or a public health emergency. Where a national competent authority informs the Agency of a shortage of a medicinal product in a given Member State, it shall provide the Agency with any information received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC. Based on a report of an event from a national competent authority and in order to understand the impact of the event in other Member States, the Agency may request information from the national competent authorities, through the working party referred to in Article 3(5).

Or. en

Amendment 358
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission

2. To facilitate the monitoring task referred to in paragraph 1, the national competent authorities, through the single points of contact referred to in Article 3(5), shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report to the Agency on any event, including a shortage of a medicinal product in a given Member State, that is likely to lead to a major event or a public health emergency. Where a national competent authority informs the Agency of a shortage of a medicinal product in a given Member State, it shall provide the Agency with any

Amendment

2. To facilitate the monitoring task referred to in paragraph 1, the national competent authorities, through the single points of contact referred to in Article 3(5), shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report without delay to the Agency on any event, including a shortage of a medicinal product in a given Member State, that is likely to lead to a major event or a public health emergency. Where a national competent authority informs the Agency of a shortage of a medicinal product in a given Member State, it shall
information received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC. Based on a report of an event from a national competent authority and in order to understand the impact of the event in other Member States, the Agency may request information from the national competent authorities, through the working party referred to in Article 3(5).

provide the Agency with any information received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC. Based on a report of an event from a national competent authority and in order to understand the impact of the event in other Member States, the Agency may request information from the national competent authorities, through the working party referred to in Article 3(5).

Amendment 359
Tilly Metz

Proposal for a regulation
Article 4 – paragraph 2

2. To facilitate the monitoring task referred to in paragraph 1, the national competent authorities, through the single points of contact referred to in Article 3(5), shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report to the Agency on any event, including a shortage of a medicinal product in a given Member State, that is likely to lead to a major event or a public health emergency. Where a national competent authority informs the Agency of a shortage of a medicinal product in a given Member State, it shall provide the Agency with any information received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC. Based on a report of an event from a national competent authority and in order to understand the impact of the event in other Member States, the Agency may request information from the national competent authorities, through the working party referred to in Article 3(5).

Or. en
Amendment 360
Stanislav Polčák

Proposal for a regulation
Article 4 – paragraph 3

Text proposed by the Commission

3. Where the Agency considers that an actual or imminent major event needs to be addressed, it shall inform the Commission and the Member States thereof. The Commission, on its own initiative or following a request from one or more Member States, or the Executive Director of the Agency may request the assistance of the Medicines Steering Group to address the major event.

Amendment

3. Where the Agency considers that an actual or imminent major event needs to be addressed, it shall inform the Commission and the Member States thereof. The Commission, on its own initiative or following a request from one or more Member States, or the Executive Director of the Agency may request the assistance of the Medicines Steering Group to address the major event. Where requested to do so by at least two Member States or the Executive Director of the Agency, the Commission shall request the assistance of the Steering Group.

Or. cs

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Amendment 361
Kateřina Konečná

Proposal for a regulation
Article 4 – paragraph 3

Text proposed by the Commission

3. Where the Agency considers that an actual or imminent major event needs to be addressed, it shall inform the Commission and the Member States thereof. The Commission, on its own initiative or following a request from one or more Member States, or the Executive Director of the Agency may request the assistance of the Medicines Steering Group to address the major event.

Amendment

3. Where the Agency considers that an actual or imminent major event needs to be addressed, it shall inform the Commission and the Member States thereof. The Commission shall then request the assistance of the Medicines Steering Group to address the major event.

Or. en
Justification

The proposed Regulation gives the option to the Commission to request the assistance of a Medicines Steering Group composed by Member State representatives, as soon as a major event that can put at risk the safety or availability of pharmaceutical products is identified. Considering the vital role that such a body can play in the management of major events, most notably by fostering coordination and joint action among Member States, it is crucial that the Steering Group is convened as soon as a major event is identified.

Amendment 362
Tilly Metz

Proposal for a regulation
Article 4 – paragraph 3

Text proposed by the Commission

3. Where the Agency considers that an actual or imminent major event needs to be addressed, it shall inform the Commission and the Member States thereof. The Commission, on its own initiative or following a request from one or more Member States, or the Executive Director of the Agency may request the assistance of the Medicines Steering Group to address the major event.

Amendment

3. Where the Agency considers that an actual or imminent major event needs to be addressed, it shall inform the Commission and the Member States thereof. The Commission shall then request the assistance of the Medicines Steering Group to address the major event.

Or. en

Justification

The proposed Regulation gives the option to the Commission to request the assistance of a Medicines Steering Group composed by Member State representatives, as soon as a major event that can put at risk the safety or availability of pharmaceutical products is identified. Considering the vital role that such a body can play in the management of major events, most notably by fostering coordination and joint action among Member States, it is crucial that the Steering Group is convened as soon as a major event is identified.

Amendment 363
Dan-Ștefan Motreanu

Proposal for a regulation
Article 4 – paragraph 3
3. Where the Agency considers that an actual or imminent major event needs to be addressed, it shall inform the Commission and the Member States thereof. The Commission, **on its own initiative or following a request from one or more Member States, or the Executive Director of the Agency may** request the assistance of the Medicines Steering Group to address the major event.
health emergency may affect the safety, quality, and efficacy of medicinal products, Article 5 shall apply;

Amendment 366
Antoni Comín i Oliveres

Proposal for a regulation
Article 5 – title

Text proposed by the Commission
Evaluation of information and the provision of advice on action in relation to the safety, quality, and efficacy of medicinal products related to public health emergencies and major events

Amendment
Evaluation of information and the provision of advice on action in relation to the production, manufacturing, safety, quality, distribution and efficacy of medicinal products, devices and applications related to public health emergencies and major events

Or. en

Amendment 367
Stanislav Polčák

Proposal for a regulation
Article 5 – title

Text proposed by the Commission
Evaluation of information and the provision of advice on action in relation to the safety, quality, and efficacy of medicinal products related to public health emergencies and major events

Amendment
(Does not affect English version.)

Or. cs

Amendment 368
Antoni Comín i Oliveres
Proposal for a regulation
Article 5 – paragraph 1

Text proposed by the Commission

Following the recognition of a public health emergency or a request for assistance referred to in Article 4(3), the Medicines Steering Group shall evaluate the information related to the major event or the public health emergency and consider the need for urgent and coordinated action with regard to the safety, quality, and efficacy of the medicinal products concerned.

Amendment

Following the recognition of a public health emergency or a request for assistance referred to in Article 4(3), the Medicines Steering Group shall evaluate the information related to the major event or the public health emergency and consider the need for urgent and coordinated action with regard to the production, manufacturing, safety, quality, distribution and efficacy of devices and applications concerned.

Or. en

Amendment 369
Margarita de la Pisa Carrión
Proposal for a regulation
Article 5 – paragraph 1

Text proposed by the Commission

Following the recognition of a public health emergency or a request for assistance referred to in Article 4(3), the Medicines Steering Group shall evaluate the information related to the major event or the public health emergency and consider the need for urgent and coordinated action with regard to the safety, quality, and efficacy of the medicinal products concerned.

Amendment

Following the express recognition of a public health emergency or a request for assistance referred to in Article 4(3), the Medicines Steering Group shall evaluate the information related to the major event or the public health emergency and consider the need for urgent and coordinated action with regard to the safety, quality, and efficacy of the medicinal products concerned.

Or. en

Amendment 370
Nathalie Colin-Oesterlé
Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission

The Medicines Steering Group shall provide advice to the Commission and Member States on any appropriate action it believes should be taken at Union level on the medicinal products concerned in accordance with the provisions of Directive 2001/83/EC or Regulation (EC) No 726/2004\textsuperscript{18}.

\textsuperscript{18} Regulation (EC) No 726/2004

Amendment

The Medicines Steering Group shall provide advice \textit{and recommendations} to the Commission and Member States on any appropriate action it believes should be taken at Union level on the medicinal products concerned in accordance with the provisions of Directive 2001/83/EC or Regulation (EC) No 726/2004\textsuperscript{18}.

\textsuperscript{18} Regulation (EC) No 726/2004

Or. fr

Amendment 371
Joëlle Mélin

Proposal for a regulation
Article 6 – paragraph 1

Text proposed by the Commission

1. Following a request for assistance referred to in Article 4(3) and after consultation of its working party, the Medicines Steering Group shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the major event (‘the major event critical medicines list’). The list shall be updated whenever necessary until the major event has been sufficiently addressed.

Amendment

1. Following a request for assistance referred to in Article 4(3) and after consultation of its working party, the Medicines Steering Group, \textit{after consulting the marketing authorisation holders and representatives of stakeholders in the sector}, shall adopt a list of \textit{human and veterinary} medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the major event (‘the major event critical medicines list’). The list shall be updated whenever necessary until the major event has been sufficiently addressed, \textit{and shall cease to apply at the end of the major event}.

Or. fr
Amendment 372
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ştefănuţă, Nils Torvalds, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos

Proposal for a regulation
Article 6 – paragraph 1

Text proposed by the Commission

1. Following a request for assistance referred to in Article 4(3) and after consultation of its working party, the Medicines Steering Group shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the major event (‘the major event critical medicines list ’). The list shall be updated whenever necessary until the major event has been sufficiently addressed.

Amendment

1. Following a request for assistance referred to in Article 4(3) and after consultation of its working party, the Medicines Steering Group shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the major event (‘the major event critical medicines list ’). The list shall be updated whenever necessary until the major event has been sufficiently addressed and it is confirmed that the assistance of the Medicines Steering group is no longer needed as per Article 4(4).

Or. en

Amendment 373
Adam Jarubas

Proposal for a regulation
Article 6 – paragraph 1

Text proposed by the Commission

1. Following a request for assistance referred to in Article 4(3) and after consultation of its working party, the Medicines Steering Group shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the major event (‘the major event critical medicines list ’). The list shall be updated whenever

Amendment

1. Following a request for assistance referred to in Article 4(3) and after consultation of its working party, medicinal product interest groups and supply chain stakeholders, in time adequate to the major event, Medicines Steering Group shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it

necessary until the major event has been sufficiently addressed.

Amendment 374
Margarita de la Pisa Carrión

Proposal for a regulation
Article 6 – paragraph 1

Text proposed by the Commission

1. Following a request for assistance referred to in Article 4(3) and after consultation of its working party, the Medicines Steering Group shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the major event (‘the major event critical medicines list’). The list shall be updated whenever necessary until the major event has been sufficiently addressed.

Amendment

1. Following a request for assistance referred to in Article 4(3) and after consultation of its working party, the Medicines Steering Group, in consultation with marketing authorisation holders, shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the major event (‘the major event critical medicines list’). The list shall be updated whenever necessary until the major event has been sufficiently addressed.

Amendment 375
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 6 – paragraph 1

Text proposed by the Commission

1. Following a request for assistance referred to in Article 4(3) and after consultation of its working party, the Medicines Steering Group shall adopt a list

Amendment

1. Following a request for assistance referred to in Article 4(3) and after consultation of its working party, the Medicines Steering Group, in coordination
of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the major event (‘the major event critical medicines list ’). The list shall be updated whenever necessary until the major event has been sufficiently addressed.

with stakeholders in the sector, shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the major event (‘the major event critical medicines list ’). The list shall be updated whenever necessary until the major event has been sufficiently addressed.

Amendment 376
Danilo Oscar Lancini

Proposal for a regulation
Article 6 – paragraph 1

Text proposed by the Commission

1. Following a request for assistance referred to in Article 4(3) and after consultation of its working party, the Medicines Steering Group shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the major event (‘the major event critical medicines list ’). The list shall be updated whenever necessary until the major event has been sufficiently addressed.

Amendment

1. Following a request for assistance referred to in Article 4(3) and after consultation of its working party, the Medicines Steering Group, in consultation with marketing authorisation holders, shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the major event (‘the major event critical medicines list ’). The list shall be updated whenever necessary until the major event has been sufficiently addressed.

Amendment 377
Antoni Comín i Oliveres

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission

Amendment

AM\1229960EN.docx 147/324 PE691.443v01-00
2. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medicines Steering Group shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the public health emergency (‘the public health emergency critical medicines list’). The list shall be updated whenever necessary until the termination of the recognition of the public health emergency.

2. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medicines Steering Group shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the public health emergency (‘the public health emergency critical medicines list’). The World Health Organization Model List of Essential Medicines for adults and for children shall be used as the base for its identification of critical medicinal products at Union level. The Agency shall make the public health emergency critical medicines list within 12 months after the entry into force of this Regulation. The list shall be updated whenever necessary until the termination of the recognition of the public health emergency as well as with the Commission and the European Centre for Disease Prevention and Control.

Or. en

Amendment 378
Joëlle Mélin

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission

2. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medicines Steering Group shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the public health emergency (‘the public health emergency critical medicines list’). The list shall be updated whenever necessary until the termination of the recognition of the

Amendment

2. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medicines Steering Group shall adopt a list of human and veterinary medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the public health emergency (‘the public health emergency critical medicines list’). The list shall be updated whenever necessary until the termination of the
public health emergency. recognition of the public health emergency, and shall cease to apply at the end of the public health emergency.

Amendment 379
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Nils Torvalds, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos, Ondřej Knotek

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission

2. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medicines Steering Group shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the public health emergency ('the public health emergency critical medicines list'). The list shall be updated whenever necessary until the termination of the recognition of the public health emergency.

Or. fr

Amendment

2. Immediately following the recognition of a public health emergency and after consultation of its working party, the industry and representatives of health professionals, the Medicines Steering Group shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the public health emergency ('the public health emergency critical medicines list'). The list shall be updated whenever necessary until the termination of the recognition of the public health emergency.

Or. en

Amendment 380
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission

2. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medicines Steering Group shall adopt a

Amendment

2. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medicines Steering Group, in
list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the public health emergency (‘the public health emergency critical medicines list’). The list shall be updated whenever necessary until the termination of the recognition of the public health emergency.

**Amendment 381**

Antoni Comín i Oliveres

**Proposal for a regulation**

**Article 6 – paragraph 2 a (new)**

*Text proposed by the Commission*

2 a. In case of an eventual zoonotic spill-over, the Medicines Steering Group shall work with the other relevant bodies of the Agency in order to counter it as soon as possible.

*Or. en*

**Amendment 382**

Cristian-Silviu Buşoi, Radan Kanev

**Proposal for a regulation**

**Article 6 – paragraph 3**

*Text proposed by the Commission*

3. The Medicines Steering Group shall adopt a set of information and actions necessary to monitor the supply and demand of medicinal products included on the lists referred to in paragraphs 1 and 2 (‘the critical medicines lists’) and inform its working party thereof.

*The Medicines Steering Group shall report the Agency*
and the Commission in due time on the monitoring and shall notify immediately on any major event or shortage in the supply.

Amendment 383
Tilly Metz

Proposal for a regulation
Article 6 – paragraph 3

Text proposed by the Commission

3. The Medicines Steering Group shall adopt a set of information necessary to monitor the supply and demand of medicinal products included on the lists referred to in paragraphs 1 and 2 (‘the critical medicines lists’) and inform its working party thereof.

Amendment

3. The Medicines Steering Group shall adopt a set of information necessary to monitor the supply and demand of medicinal products included on the lists referred to in paragraphs 1 and 2 (‘the critical medicines lists’) and inform its working party thereof. Union or national entities that are engaged in stockpiling of medicinal products shall be informed accordingly.

Justification

As the Commission plans to issue a legislative proposal for a new EU agency HERA which should engage, inter alia, in stockpiling, it is appropriate to address future developments in this regulation.

Amendment 384
Joëlle Mélin

Proposal for a regulation
Article 6 – paragraph 3

Text proposed by the Commission

3. The Medicines Steering Group shall adopt a set of information necessary to monitor the supply and demand of

Amendment

3. The Medicines Steering Group shall adopt a set of information necessary to monitor the supply and demand of
medicinal products included on the lists referred to in paragraphs 1 and 2 (‘the critical medicines lists’) and inform its working party thereof.

**human and veterinary** medicinal products included on the lists referred to in paragraphs 1 and 2 (‘the critical medicines lists’) and inform its working party thereof.

### Amendment 385

**Joëlle Mélin**

**Proposal for a regulation**

**Article 6 – paragraph 4**

**Text proposed by the Commission**


**Amendment**

4. The Agency shall immediately publish the critical medicines lists and any updates to those lists on its web-portal referred to in Article 26 of Regulation (EC) No 726/2004. *This list shall be published in a clear and accessible way so that Member States, actors in the pharmaceutical supply chain and all stakeholders can easily access this information and, where appropriate, can easily report possible changes or publication problems.*

### Amendment 386

**Danilo Oscar Lancini**

**Proposal for a regulation**

**Article 6 – paragraph 4**

**Text proposed by the Commission**


**Amendment**

4. *Access to* the critical medicines lists and any updates to those lists shall be granted to Member State representatives and the European Commission on a confidential basis, via the Agency’s web-portal referred to in Article 26 of Regulation (EC) No 726/2004.
Amendment 387
Pernille Weiss

Proposal for a regulation
Article 6 – paragraph 4

Text proposed by the Commission


Amendment

4. Member State representatives and the European Commission shall on a confidential basis be granted access to the critical medicines lists and any updates to those lists via the web-portal referred to in Article 26 of Regulation (EC) No 726/2004.

Or. en

Amendment 388
Carlo Calenda

Proposal for a regulation
Article 6 – paragraph 4

Text proposed by the Commission


Amendment

4. The Agency shall make available the critical medicines lists and any updates to those lists to the representatives of the Member States and the Commission.

Or. it

Amendment 389
Antoni Comín i Oliveres

Proposal for a regulation
Article 6 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

AM\1229960EN.docx 153/324 PE691.443v01-00
4 a. The Agency, under its own assessment, shall establish an open, digital and interoperable database with information on expected and actual shortages of critical medical products, devices and applications. The database shall contain information on but not limited to:

a. Trade name and international non-proprietary name;

b. Indication;

c. Reason for the shortage;

d. Start and end dates;

e. Member States and/or regions affected, especially cross-border regions;

f. Possible consequences to non-communicable diseases or conditions, such as mental health and possible medical solutions and other measures;

g. Information for healthcare professionals and patients, including information on alternative treatments.

This database shall be accessible to the public. The Agency shall include the national, and where applicable regional, registries on medicine shortages on its web-portal.

Amendment 390
Tilly Metz
Proposal for a regulation
Article 6 – paragraph 4 a (new)

Text proposed by the Commission

4 a. The Agency shall establish a publicly accessible database with information on expected and actual shortages of critical medicines. Reference to national shortage registries shall also
be linked on the web portal. The database shall contain information on, but not limited to:

(a) Trade name and international non-proprietary name;
(b) Indication;
(c) Reason for the shortage;
(d) Start and end dates;
(e) Member States affected;
(f) Information for healthcare professionals and patients, including information on alternative treatments.

Amendment 391
Kateřina Konečná

Proposal for a regulation
Article 6 – paragraph 4 a (new)

Text proposed by the Commission

4 a. The Agency shall establish a database with information on expected and actual shortages of critical medicines. The database shall contain information on but not limited to:

(a) Trade name and international non-proprietary name;
(b) Indication;
(c) Reason for the shortage;
(d) Start and end dates;
(e) Member States affected;
(f) Information for healthcare professionals and patients, including information on alternative treatments.

Or. en
Justification

The Regulation should require that the EMA sets up a public database to inform patients, consumers and healthcare professionals about the expected or actual shortage of medicines that are critical to address a major event or public health emergency. This is essential to consider potential alternatives and minimise as much as possible the impact on care. The database should also contain information on those critical medical devices that are on shortage.

Amendment 392
Dan-Ştefan Motreanu

Proposal for a regulation
Article 6 – paragraph 4 a (new)

Text proposed by the Commission
Amendment

4 a. The Agency shall establish a database with information on expected and actual shortages of critical medicines. The database shall contain information on but not limited to:
(a) Trade name and international non-proprietary name;
(b) Indication;
(c) Reason for the shortage;
(d) Start and end dates;
(e) Member States affected;
(f) Information for healthcare professionals and patients, including information on alternative treatments.

Or. en

Amendment 393
Joëlle Mélin

Proposal for a regulation
Article 6 – paragraph 4 a (new)

Text proposed by the Commission
Amendment

4a. The Agency, in cooperation with
the Commission and the national competent authorities of the Member States, shall work with representatives of the European medicinal product industry to ensure that medicinal products included on the critical medicines list made available in one Member State are equally available in all Member States, in one form or another, and in particular in smaller Member States.

Amendment 394
Pietro Fiocchi

Proposal for a regulation
Article 6 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. The Medicines Steering Group together with the industry (via the industry single points of contacts - iSPOCs) will determine the list of critical products and any future actions taken for the molecules included on the critical product list.

Amendment 395
Dan-Ştefan Motreanu

Proposal for a regulation
Article 6 – paragraph 4 b (new)

Text proposed by the Commission

Amendment

4 b. The database shall be accessible to the public.
Amendment 396
Kateřina Konečná

Proposal for a regulation
Article 6 – paragraph 4 b (new)

Text proposed by the Commission

Amendment

4 b. The database shall be accessible to the public.

Or. en

Amendment 397
Dan-Ştefan Motreanu

Proposal for a regulation
Article 6 – paragraph 4 c (new)

Text proposed by the Commission

Amendment

4 c. The Agency shall list on its web-portal the national registries on medicine shortages.

Or. en

Amendment 398
Kateřina Konečná

Proposal for a regulation
Article 6 – paragraph 4 c (new)

Text proposed by the Commission

Amendment

4 c. The Agency shall list on its web-portal the national registries on medicine shortages.

Or. en

Amendment 399
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Susana Solís Pérez,
Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos, Jan Huitema

Proposal for a regulation

Article 7 – paragraph 1

On the basis of the critical medicines lists and the information and data provided in accordance with Articles 10 and 11, the Medicines Steering Group shall monitor supply and demand of medicinal products included on those lists with a view to identifying any potential or actual shortages of those medicinal products. As part of that monitoring, the Medicines Steering Group shall liaise, where relevant, with the Health Security Committee established in Article 4 of Regulation (EU) 2020/[…] and, in the case of a public health emergency, the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation.

19 [insert reference to adopted text referred to in footnote 4]

Amendment 400
Joëlle Mélin

Text proposed by the Commission

On the basis of the single European critical medicines lists and the information and data provided in accordance with Articles 10 and 11, , and the database established in accordance with Article 12a once fully operational, the Medicines Steering Group shall monitor supply and demand of medicinal products included on those lists with a view to identifying any potential or actual shortages of those medicinal products. As part of that monitoring, the Medicines Steering Group shall liaise, where relevant, with the Health Security Committee established in Article 4 of Regulation (EU) 2020/[…] and, in the case of a public health emergency, the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation, as well as with the European Centre for Disease Prevention and Control. The Medicines Steering Group shall also guarantee an open communication and close cooperation with the industry, relevant entities of the pharmaceutical supply chain, and representatives of healthcare professionals, patients and consumers with a view to enable early notification or identification of potential or actual shortages of critical medicines.

19 [insert reference to adopted text referred to in footnote 4]

Or. en
Proposal for a regulation

Article 7 – paragraph 1

**Text proposed by the Commission**

On the basis of the critical medicines lists and the information and data provided in accordance with Articles 10 and 11, the Medicines Steering Group shall monitor supply and demand of medicinal products included on those lists with a view to identifying any potential or actual shortages of those medicinal products. As part of that monitoring, the Medicines Steering Group shall liaise, where relevant, with the Health Security Committee established in Article 4 of Regulation (EU) 2020/[…]\(^{19}\) and, in the case of a public health emergency, the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation.

**Amendment**

On the basis of the critical medicines lists and the information and data provided in accordance with Articles 10 and 11 of this Regulation, the Medicines Steering Group shall **meet regularly throughout the major event or public health emergency with the working group of designated national contact points for medicines shortages within the national competent authorities for medicines and with representatives of the medicines production and distribution sectors in order to** monitor supply and demand of medicinal products included on those lists with a view to identifying any potential or actual shortages of those medicinal products **and to adapt the list as well as possible throughout the major event or emergency.** As part of that monitoring, the Medicines Steering Group shall liaise, where relevant, with the Health Security Committee established in Article 4 of Regulation (EU) 2020/[…]\(^{19}\) and, in the case of a public health emergency, the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation.

\(^{19}\) [insert reference to adopted text referred to in footnote 4]

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**Amendment 401**

**Danilo Oscar Lancini**

Proposal for a regulation

Article 7 – paragraph 1

**Text proposed by the Commission**

On the basis of the critical medicines lists

**Amendment**

On the basis of the critical medicines lists,
and the information and data provided in accordance with Articles 10 and 11, the Medicines Steering Group shall monitor supply and demand of medicinal products included on those lists with a view to identifying any potential or actual shortages of those medicinal products. As part of that monitoring, the Medicines Steering Group shall liaise, where relevant, with the Health Security Committee established in Article 4 of Regulation (EU) 2020/[…]\(^9\) and, in the case of a public health emergency, the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation.

\(^9\) [insert reference to adopted text referred to in footnote 4]

**Amendment 402**  
**Antoni Comín i Oliveres**

**Proposal for a regulation**  
**Article 7 – paragraph 1**

**Text proposed by the Commission**

On the basis of the critical medicines lists and the information and data provided in accordance with Articles 10 and 11, the Medicines Steering Group shall monitor supply and demand of medicinal products included on those lists with a view to identifying any potential or actual shortages of those medicinal products. As part of that monitoring, the Medicines Steering Group shall liaise, where relevant, with the Health Security Committee.

**Amendment**

On the basis of the critical medicines lists and the information and data provided in accordance with Articles 10 and 11, the Medicines Steering Group shall monitor supply and demand of medicinal products included on those lists with a view to identifying any potential or actual shortages of those medicinal products. As part of that monitoring, the Medicines Steering Group shall liaise, where relevant, with the Health Security Committee.
established in Article 4 of Regulation (EU) 2020/[…]\(^{19}\) and, in the case of a public health emergency, the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation.

The Medicines Steering Group shall provide the aggregated data and demand forecasts from the digital interoperable platform referred to in Article 1(b) and Article 12(g).

\(^{19}\) [insert reference to adopted text referred to in footnote 4]

Or. en

**Amendment 403**

**Pietro Fiocchi**

**Proposal for a regulation**

**Article 7 – paragraph 1**

*Text proposed by the Commission*

On the basis of the critical medicines lists and the information and data provided in accordance with Articles 10 and 11, the Medicines Steering Group shall monitor supply and demand of medicinal products included on those lists with a view to identifying any potential or actual shortages of those medicinal products. As part of that monitoring, the Medicines Steering Group shall liaise, where relevant, with the Health Security Committee established in Article 4 of Regulation (EU) 2020/[…]\(^{19}\) and, in the case of a public health emergency, the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation.

Amendment

On the basis of the critical medicines lists, the establishment of a two way communication line with industry via the industry single point of contacts (iSPoC) and the information and data provided in accordance with Articles 10 and 11, the Medicines Steering Group shall monitor supply and demand of medicinal products included on those lists with a view to identifying any potential or actual shortages of those medicinal products. As part of that monitoring, the Medicines Steering Group shall liaise, where relevant, with the Health Security Committee established in Article 4 of Regulation (EU) 2020/[…]\(^{19}\) and, in the case of a public health emergency, the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation.

\(^{19}\) [insert reference to adopted text referred to in footnote 4]
On the basis of the critical medicines lists and the information and data provided in accordance with Articles 10 and 11, the Medicines Steering Group shall monitor supply and demand of medicinal products included on those lists with a view to identifying any potential or actual shortages of those medicinal products. As part of that monitoring, the Medicines Steering Group shall liaise, where relevant, with the Health Security Committee established in Article 4 of Regulation (EU) 2020/[…]19 and, in the case of a public health emergency, the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation.

19 [insert reference to adopted text referred to in footnote 4]

There should also be regular structured dialogue with industry, entities involved in
the pharmaceutical supply chain, healthcare professionals and patients’ associations so that any potential or actual shortages of those medicinal products in a public health emergency and/or major event can be managed as effectively as possible.

Or. fr

Amendment 406
Margarita de la Pisa Carrión
Proposal for a regulation
Article 7 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The Medicines Steering Group shall monitor supply and demand of medicinal products included on those across the entire value-chain, from resources to patient;

Or. en

Amendment 407
Tilly Metz
Proposal for a regulation
Article 7 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The Single Point of Contact Network (SPOC) shall be extended to become a reliable monitoring system for shortages of medicines and other medical counter.

Or. en

Justification

The fast-track monitoring system that has been put in place by the EU Executive Steering Group is a welcome initiative. Given that its scope is limited to medicines used for treating
COVID-19, the single point of contact network (SPOC) should be adequately resourced to ensure it is an effective communication tool on other drug supplies affected by the response to the pandemic. The SPOC system, currently being piloted by the European Medicines Agency and the Heads of Medicines Agencies (HMA), should become an established monitoring system thereafter.

Amendment 408
Tilly Metz

Proposal for a regulation
Article 7 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

As shortage of medicines outside of the critical lists established in a public health emergency or a major event are outside of the scope of this Regulation and yet pose a persistent challenge that has been increasingly affecting health and well-being of EU citizens for the past decades, this Regulation should be a first step towards improving the EU response to this long-lasting issue. The Commission shall subsequently propose the expansion of this framework to ensure that the issue of shortages is broadly and permanently tackled in the upcoming revision of Regulation (EC) 726/2004 and Directive 2001/83/EC.

Or. en

Amendment 409
Pietro Fiocchi

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission

Amendment

1. For the duration of a public health emergency or following a request for assistance referred to in Article 4(3) and until its closure, the Medicines Steering
Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article 9(2), and, in particular, signal any potential or actual shortages of medicinal products included on the critical medicines lists.

Amendment 410
Joëlle Mélin

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission

1. For the duration of a public health emergency or following a request for assistance referred to in Article 4(3) and until its closure, the Medicines Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article 9(2), and, in particular, signal any potential or actual shortages of medicinal products included on the critical medicines lists.

Amendment

1. For the duration of a public health emergency or following a request for assistance referred to in Article 4(3) and until its closure, the Medicines Steering Group shall regularly report the results of its monitoring to the Commission, the pharmaceutical industry and the sub-network referred to in Article 9(2), and, in particular, signal any potential or actual shortages of medicinal products included on the critical medicines lists.

Or. en

Amendment 411
Margarita de la Pisa Carrión

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission

1. For the duration of a public health emergency or following a request for assistance referred to in Article 4(3) and until its closure, the Medicines Steering Group shall regularly report the results of

Amendment

1. For the duration of a public health emergency or following a request for assistance referred to in Article 4(3) and until its closure, the Medicines Steering Group shall regularly report the results of national public health authorities and the sub-network referred to in Article 9(2), and, in particular, signal any potential or actual shortages of medicinal products included on the critical medicines lists.

Or. fr
its monitoring to the Commission and the sub-network referred to in Article 9(2), and, in particular, signal any potential or actual shortages of medicinal products included on the critical medicines lists.

its monitoring to the Commission, Member States, the pharmaceutical industry and the sub-network referred to in Article 9(2), and, in particular, signal any potential or actual shortages of medicinal products included on the critical medicines lists.

Or. en

Amendment 412
Stanislav Polčák

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission

1. For the duration of a public health emergency or following a request for assistance referred to in Article 4(3) and until its closure, the Medicines Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article 9(2), and, in particular, signal any potential or actual shortages of medicinal products included on the critical medicines lists.

Amendment

1. For the duration of a public health emergency or following a request for assistance referred to in Article 4(3) and until it is confirmed that its assistance is no longer needed under Article 4(4), the Medicines Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article 9(2), and, in particular, signal any potential or actual shortages of medicinal products included on the critical medicines lists.

Or. cs

Amendment 413
Joanna Kopeińska, Margarita de la Pisa Carrión

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission

1. For the duration of a public health emergency or following a request for assistance referred to in Article 4(3) and until its closure, the Medicines Steering Group shall regularly report the results of

Amendment

1. For the duration of a public health emergency or following a request for assistance referred to in Article 4(3) and until its closure, the Medicines Steering Group shall report on a systematic,
its monitoring to the Commission and the
sub-network referred to in Article 9(2),
and, in particular, signal any potential or
actual shortages of medicinal products
included on the critical medicines lists.

structured, and timely basis the results of
its monitoring to the Commission and the
sub-network referred to in Article 9(2),
and, in particular, signal any potential or
actual shortages of medicinal products
included on the critical medicines lists.

Or. en

Amendment 414
Danilo Oscar Lancini

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission

1. For the duration of a public health
emergency or following a request for
assistance referred to in Article 4(3) and
until its closure, the Medicines Steering
Group shall regularly report the results of
its monitoring to the Commission and the
sub-network referred to in Article 9(2),
and, in particular, signal any potential or
actual shortages of medicinal products
included on the critical medicines lists.

Amendment

1. For the duration of a public health
emergency or following a request for
assistance referred to in Article 4(3) and
until its closure, the Medicines Steering
Group shall regularly report the results of
its monitoring to the Commission, the
pharmaceutical industry and the sub-
network referred to in Article 9(2), and, in
particular, signal any potential or actual
shortages of medicinal products included
on the critical medicines lists.

Or. en

Amendment 415
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ştefănuţă, Susana Solís Pérez,
Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos

Proposal for a regulation
Article 8 – paragraph 1 a (new)

Text proposed by the Commission

1 a. Reports of any potential or actual
shortages of medicinal products included
on the critical medicines lists shall also be
made available to industry and other
entities of the pharmaceutical supply

Amendment

1 a. Reports of any potential or actual
shortages of medicinal products included
on the critical medicines lists shall also be
made available to industry and other
entities of the pharmaceutical supply
chain, where relevant.

Or. en

Amendment 416
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos

Proposal for a regulation
Article 8 – paragraph 2

Text proposed by the Commission

2. Where requested by the Commission or the sub-network referred to in Article 9(2), the Medicines Steering Group shall provide aggregated data and forecasts of demand to substantiate its findings. In that regard, the Medicines Steering Group shall liaise with the European Centre for Disease Prevention and Control to obtain epidemiological data to help forecast medicinal product needs, and with the Executive Steering Group on Shortages of Medical Devices referred to in Article 19 where medicinal products included on the critical medicines lists are administered with a medical device. The aggregated data and forecasts of demand shall also be made available to industry and other entities of the pharmaceutical supply chain, where relevant, with the view to better prevent or mitigate potential or actual shortages.

Amendment

2. Where requested by the Commission or the sub-network referred to in Article 9(2), the Medicines Steering Group shall provide aggregated data and forecasts of demand to substantiate its findings. In that regard, the Medicines Steering Group shall liaise with the European Centre for Disease Prevention and Control to obtain epidemiological data to help forecast medicinal product needs, and with the Executive Steering Group on Shortages of Medical Devices referred to in Article 19 where medicinal products included on the critical medicines lists are administered with a medical device. The aggregated data and forecasts of demand shall also be made available to industry and other entities of the pharmaceutical supply chain, where relevant, with the view to better prevent or mitigate potential or actual shortages.

Or. en

Amendment 417
Tilly Metz

Proposal for a regulation
Article 8 – paragraph 2

Text proposed by the Commission

Amendment

AM\1229960EN.docx 169/324 PE691.443v01-00
2. Where requested by the Commission or the sub-network referred to in Article 9(2), the Medicines Steering Group shall provide aggregated data and forecasts of demand to substantiate its findings. In that regard, the Medicines Steering Group shall liaise with the European Centre for Disease Prevention and Control to obtain epidemiological data to help forecast medicinal product needs, and with the Executive Steering Group on Shortages of Medical Devices referred to in Article 19 where medicinal products included on the critical medicines lists are administered with a medical device.

It shall share its findings and conclusions with Union and national entities engaged with stockpiling of medicinal products and medical devices.

Amendment 418
Cristian-Silviu Bușoi, Radan Kanev

Proposal for a regulation
Article 8 – paragraph 2

Text proposed by the Commission

2. Where requested by the Commission or the sub-network referred to in Article 9(2), the Medicines Steering Group shall provide aggregated data and forecasts of demand to substantiate its findings. In that regard, the Medicines Steering Group shall use data from its interoperable and digitalized platform for reporting and notifying shortages and shall liaise with the European Centre for Disease Prevention and Control to obtain epidemiological data to help forecast medicinal product needs, and with the Executive Steering Group on Shortages of Medical Devices referred to in Article 19 where medicinal products included on the critical medicines lists are administered with a medical device.
with a medical device.

Or. en

Amendment 419
Joëlle Mélin

Proposal for a regulation
Article 8 – paragraph 2

Text proposed by the Commission

2. Where requested by the Commission or the sub-network referred to in Article 9(2), the Medicines Steering Group shall provide aggregated data and forecasts of demand to substantiate its findings. In that regard, the Medicines Steering Group shall liaise with the European Centre for Disease Prevention and Control to obtain epidemiological data to help forecast medicinal product needs, and with the Executive Steering Group on Shortages of Medical Devices referred to in Article 19 where medicinal products included on the critical medicines lists are administered with a medical device.

Amendment

2. Where requested by the Commission, one or more national public health authorities or the sub-network referred to in Article 9(2), the Medicines Steering Group shall provide aggregated data and forecasts of demand to substantiate its findings. In that regard, the Medicines Steering Group shall liaise with the European Centre for Disease Prevention and Control to obtain epidemiological data to help forecast medicinal product needs, and with the Executive Steering Group on Shortages of Medical Devices referred to in Article 19 where medicinal products included on the critical medicines lists are administered with a medical device.

Or. fr

Amendment 420
Joanna Kopcińska, Margarita de la Pisa Carrión

Proposal for a regulation
Article 8 – paragraph 3

Text proposed by the Commission

3. As part of that reporting, the Medicines Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation

Amendment

3. As part of that reporting, the Medicines Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation
holders and other entities, including healthcare professionals and patient organisations, to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, as relevant, with the Health Security Committee and, in the case of a public health emergency, the Advisory Committee on public health emergencies.

Amendment 421
Tilly Metz
Proposal for a regulation
Article 8 – paragraph 3

Text proposed by the Commission

3. As part of that reporting, the Medicines Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, as relevant, with the Health Security Committee and, in the case of a public health emergency, the Advisory Committee on public health emergencies.

Amendment

3. As part of that reporting, the Medicines Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities, including healthcare professionals, consumers and patients, to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, as relevant, with the Health Security Committee and, in the case of a public health emergency, the Advisory Committee on public health emergencies.

Or. en

Amendment 422
Nathalie Colin-Oesterlé
Proposal for a regulation
Article 8 – paragraph 3

Text proposed by the Commission

3. As part of that reporting, the Medicines Steering Group may also

Amendment

3. As part of that reporting, the Medicines Steering Group may also
provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, as relevant, with the Health Security Committee and, in the case of a public health emergency, the Advisory Committee on public health emergencies.

provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities, including healthcare professionals or patients, to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, as relevant, with the Health Security Committee and, in the case of a public health emergency, the Advisory Committee on public health emergencies.

Or. fr

Amendment 423
Dolors Montserrat

Proposal for a regulation
Article 8 – paragraph 3

Text proposed by the Commission

3. As part of that reporting, the Medicines Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, as relevant, with the Health Security Committee and, in the case of a public health emergency, the Advisory Committee on public health emergencies.

Amendment

3. As part of that reporting, the Medicines Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities, including healthcare professionals and patients, to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, as relevant, with the Health Security Committee and, in the case of a public health emergency, the Advisory Committee on public health emergencies.

Or. en

Amendment 424
Sara Cerdas

Proposal for a regulation
Article 8 – paragraph 3
3. As part of that reporting, the Medicines Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, as relevant, with the Health Security Committee and, in the case of a public health emergency, the Advisory Committee on public health emergencies.

Amendment

3. As part of that reporting, the Medicines Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities, including healthcare professionals and patients, to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, as relevant, with the Health Security Committee and, in the case of a public health emergency, the Advisory Committee on public health emergencies.

Or. en

Amendment 425
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos, Ondřej Knotek

Proposal for a regulation
Article 8 – paragraph 3

Text proposed by the Commission

3. As part of that reporting, the Medicines Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, as relevant, with the Health Security Committee and, in the case of a public health emergency, the Advisory Committee on public health emergencies.

Amendment

3. As part of that reporting, the Medicines Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities, including healthcare professionals and patients, to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, as relevant, with the Health Security Committee and, in the case of a public health emergency, the Advisory Committee on public health emergencies.

Or. en

Amendment 426
Kateřina Konečná
Proposal for a regulation
Article 8 – paragraph 3

Text proposed by the Commission

3. As part of that reporting, the Medicines Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, as relevant, with the Health Security Committee and, in the case of a public health emergency, the Advisory Committee on public health emergencies.

Amendment

3. As part of that reporting, the Medicines Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities, including healthcare professionals and patients, to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, as relevant, with the Health Security Committee and, in the case of a public health emergency, the Advisory Committee on public health emergencies.

Or. en

Justification

Concrete mitigation measures for potential and actual shortages should be shared directly with healthcare professionals and patients, using for example the network that EMA has established via its Healthcare Professional Working Party (HCPWP) and the Patients' and Consumers' Working Party (PCWP). By sharing recommendations on measures directly with healthcare professionals and patient organisations it can be ensured that these are taken into account as soon as the measures become known.

Amendment 427
Pernille Weiss

Proposal for a regulation
Article 8 – paragraph 4

Text proposed by the Commission

4. The Medicines Steering Group may, on its own initiative or upon request from the Commission, provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities to ensure preparedness to deal with potential or actual shortages of

Amendment

4. The Medicines Steering Group may, on its own initiative or upon request from the Commission, provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities to ensure preparedness to deal with potential or actual shortages of
medicinal products caused by public health emergencies or major events.

medicinal products caused by public health emergencies or major events. These recommendations may include measures to minimize unnecessary administrative burdens or facilitate flexible supply chains.

Amendment 428
Tilly Metz

Proposal for a regulation
Article 8 – paragraph 4

Text proposed by the Commission

4. The Medicines Steering Group may, on its own initiative or upon request from the Commission, provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities to ensure preparedness to deal with potential or actual shortages of medicinal products caused by public health emergencies or major events.

Amendment

4. The Medicines Steering Group may, on its own initiative or upon request from the Commission, provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities, including healthcare professionals, to ensure preparedness to deal with potential or actual shortages of medicinal products caused by public health emergencies or major events.

Amendment 429
Joëlle Mélin

Proposal for a regulation
Article 8 – paragraph 4

Text proposed by the Commission

4. The Medicines Steering Group may, on its own initiative or upon request from the Commission, provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and

Amendment

4. The Medicines Steering Group may, on its own initiative or upon request from the Commission, provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and
other entities to ensure preparedness to deal with potential or actual shortages of medicinal products caused by public health emergencies or major events.

other entities to ensure preparedness to deal with potential or actual shortages of human and veterinary medicinal products caused by public health emergencies or major events.

Or. fr

Amendment 430
Margarita de la Pisa Carrión

Proposal for a regulation
Article 8 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. Without prejudice to Article 30, reports and recommendations of the Medicines Steering Group will be made available to the public to their greatest extent.

Or. en

Amendment 431
Joanna Kopcińska, Margarita de la Pisa Carrión

Proposal for a regulation
Article 8 – paragraph 5

Text proposed by the Commission

Amendment

5. The Medicines Steering Group may upon request from the Commission coordinate measures, where relevant, between the national competent authorities, the marketing authorisation holders and other entities to prevent or mitigate potential or actual shortages in the context of a major event or public health emergency.

5. The Medicines Steering Group may upon request from the Commission coordinated measures, where relevant, between the national competent authorities, the marketing authorisation holders and other entities, including healthcare professionals and patient organisations, to prevent or mitigate potential or actual shortages in the context of a major event or public health emergency.

Or. en
Amendment 432
Sara Cerdas

Proposal for a regulation
Article 8 – paragraph 5

Text proposed by the Commission

5. The Medicines Steering Group may upon request from the Commission coordinate measures, where relevant, between the national competent authorities, the marketing authorisation holders and other entities to prevent or mitigate potential or actual shortages in the context of a major event or public health emergency.

Amendment

5. The Medicines Steering Group may upon request from the Commission coordinate measures, where relevant, between the national competent authorities, the marketing authorisation holders and other entities, including healthcare professionals and patients, to prevent or mitigate potential or actual shortages in the context of a major event or public health emergency.

Or. en

Amendment 433
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 8 – paragraph 5

Text proposed by the Commission

5. The Medicines Steering Group may upon request from the Commission coordinate measures, where relevant, between the national competent authorities, the marketing authorisation holders and other entities to prevent or mitigate potential or actual shortages in the context of a major event or public health emergency.

Amendment

5. The Medicines Steering Group may upon request from the Commission coordinate measures, where relevant, between the national competent authorities, the marketing authorisation holders and other entities, including healthcare professionals, to prevent or mitigate potential or actual shortages in the context of a major event or public health emergency.

Or. fr

Amendment 434
Proposal for a regulation
Article 8 – paragraph 5

Text proposed by the Commission

5. The Medicines Steering Group may upon request from the Commission coordinate measures, where relevant, between the national competent authorities, the marketing authorisation holders and other entities to prevent or mitigate potential or actual shortages in the context of a major event or public health emergency.

Amendment

5. The Medicines Steering Group may upon request from the Commission coordinate measures, where relevant, between the national competent authorities, the marketing authorisation holders and other entities, **including healthcare professionals**, to prevent or mitigate potential or actual shortages in the context of a major event or public health emergency.

Or. en

Amendment 435
Dolors Montserrat

Proposal for a regulation
Article 8 – paragraph 5

Text proposed by the Commission

5. The Medicines Steering Group may upon request from the Commission coordinate measures, where relevant, between the national competent authorities, the marketing authorisation holders and other entities to prevent or mitigate potential or actual shortages in the context of a major event or public health emergency.

Amendment

5. The Medicines Steering Group may upon request from the Commission coordinate measures, where relevant, between the national competent authorities, the marketing authorisation holders and other entities, **including healthcare professionals**, to prevent or mitigate potential or actual shortages in the context of a major event or public health emergency.

Or. en

Amendment 436
Antoni Comín i Oliveres
Proposal for a regulation
Article 8 – paragraph 5

Text proposed by the Commission

5. The Medicines Steering Group may
upon request from the Commission
coordinate measures, where relevant,
between the national competent authorities,
the marketing authorisation holders and
other entities to prevent or mitigate
potential or actual shortages in the context
of a major event or public health
emergency.

Amendment

5. The Medicines Steering Group may
upon request from the Commission
coordinate measures, where relevant,
between the national, and where
applicable regional, competent authorities,
the marketing authorisation holders and
other entities to prevent or mitigate
potential or actual shortages in the context
of a major event or public health
emergency.

Or. en

Amendment 437
Kateřina Konečná

Proposal for a regulation
Article 8 – paragraph 5

Text proposed by the Commission

5. The Medicines Steering Group may
upon request from the Commission
coordinate measures, where relevant,
between the national competent authorities,
the marketing authorisation holders and
other entities to prevent or mitigate
potential or actual shortages in the context
of a major event or public health
emergency.

Amendment

5. The Medicines Steering Group may
upon request from the Commission
coordinate measures, where relevant,
between the national competent authorities,
the marketing authorisation holders and
other entities, including healthcare
professionals, to prevent or mitigate
potential or actual shortages in the context
of a major event or public health
emergency.

Or. en

Amendment 438
Antoni Comín i Oliveres

Proposal for a regulation
Article 8 – paragraph 5 a (new)
5a. In case any of the aforementioned stakeholders does not give information to the Agency in the time lapse established by the Agency, the Commission shall assist the Agency in obtaining such information, with the prospect of an eventual sanction, which should also be duly informed to the public. This sanction shall be established in an implementing regulation.

Or. en

Amendment 439
Joëlle Mélin, Danilo Oscar Lancini

Proposal for a regulation
Article 8 – paragraph 5 a (new)

Text proposed by the Commission

5a. The measures recommended by the Steering Group to the Commission, Member States, marketing authorisation holders and other stakeholders should include a relaxing of rules to deal with potential shortages.

Or. fr

Amendment 440
Antoni Comín i Oliveres

Proposal for a regulation
Article 8 – paragraph 5 b (new)

Text proposed by the Commission

5b. The Agency, together with the Commission, shall also present recommendations to the Commission to counterbalance smear campaigns and
disinformation on medicines, medical products, devices or applications, in order to ensure proper information to the public.

Amendment 441
Danilo Oscar Lancini

Proposal for a regulation
Article 9 – paragraph 1 – introductory part

Text proposed by the Commission

1. In order to prepare for fulfilling the tasks referred to in Articles 4 to 8, the Agency shall:

Amendment

1. In order to prepare for fulfilling the tasks referred to in Articles 4 to 8 and after having consulted representatives from national competent authorities and from marketing authorisation holder representatives, as well as other stakeholders in the medicines supply chain, the Agency shall:

Or. en

Amendment 442
Joëlle Mélin, Danilo Oscar Lancini

Proposal for a regulation
Article 9 – paragraph 1 – introductory part

Text proposed by the Commission

1. In order to prepare for fulfilling the tasks referred to in Articles 4 to 8, the Agency shall:

Amendment

1. In order to prepare for fulfilling the tasks referred to in Articles 4 to 8, and after consulting representatives of national authorities and marketing authorisation holders, as well as other stakeholders in the pharmaceutical sector, the Agency shall:

Or. fr
Amendment 443
Tilly Metz

Proposal for a regulation
Article 9 – paragraph 1 – point a

Text proposed by the Commission
(a) specify the procedures for establishing the critical medicines lists;

Amendment
(a) specify the procedures for ensuring adequate consultation with healthcare professionals, consumers, patients a high level of transparency in decision-making;

Or. en

Amendment 444
Kateřina Konečná

Proposal for a regulation
Article 9 – paragraph 1 – point a

Text proposed by the Commission
(a) specify the procedures for establishing the critical medicines lists;

Amendment
(a) specify the procedures for ensuring adequate consultation with patients, consumers and healthcare professionals and a high level of transparency;

Or. en

Amendment 445
Dan-Ștefan Motreanu

Proposal for a regulation
Article 9 – paragraph 1 – point a

Text proposed by the Commission
(a) specify the procedures for establishing the critical medicines lists;

Amendment
(a) specify the procedures for ensuring adequate consultation with
consumers, patients and healthcare professionals and a high level of transparency;

Or. en

Amendment 446
Antoni Comín i Oliveres

Proposal for a regulation
Article 9 – paragraph 1 – point a

Text proposed by the Commission

(a) specify the procedures for establishing the critical medicines lists;

Amendment

(a) specify the procedures for establishing the critical medicines lists, ensuring adequate consultation with consumers, patients and healthcare professionals and a high level of transparency;

Or. en

Amendment 447
Tudor Ciuhodaru

Proposal for a regulation
Article 9 – paragraph 1 – point a

Text proposed by the Commission

(a) specify the procedures for establishing the critical medicines lists;

Amendment

(a) specify the procedures for establishing the critical medicines lists and the minimum stock levels required to ensure continuity of medical care;

Or. ro

Amendment 448
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 9 – paragraph 1 – point a
Text proposed by the Commission

(a) specify the procedures for establishing the critical medicines lists;

Amendment

(a) specify the procedures and criteria for establishing the critical medicines lists;

Or. fr

Amendment 449
Cristian-Silviu Bușoi, Radan Kanev

Proposal for a regulation
Article 9 – paragraph 1 – point a

Text proposed by the Commission

(a) specify the procedures for establishing the critical medicines lists;

Amendment

(a) specify the procedures for establishing and reviewing the critical medicines lists;

Or. en

Amendment 450
Dolors Montserrat

Proposal for a regulation
Article 9 – paragraph 1 – point b

Text proposed by the Commission

(b) specify the methods of and criteria for the monitoring, data collection and reporting provided for in Articles 4, 7 and 8;

Amendment

(b) specify the methods of and criteria for the monitoring, data collection and reporting through the European Union of Health digitalized and interoperable early-warning system of shortage of medicines, established in Article 2bis(new), and provided for in Articles 4, 7 and 8;

Or. en

Amendment 451
Aldo Patriciello
Proposal for a regulation
Article 9 – paragraph 1 – point c

Text proposed by the Commission
(c) develop streamlined electronic monitoring and reporting systems;

Amendment
(c) develop streamlined electronic monitoring and reporting systems by implementing and building on existing regulatory infrastructure (EU telematics[1]). This system shall be interoperable with the national shortages reporting to prevent any duplication of the reporting process; the system shall establish a two-way digital communication between the Agency and the national competent authorities, as well as a two-way communication between the Agency and marketing authorisation holders. In case of public health emergency, aggregated information shall be collected by the Agency from national competent authority shortages reporting systems in a harmonised and consolidated way, based on national harmonised data fields and definitions across Member States. The Agency can request additional information directly from the marketing authorisation holders via the industry single point of contact (iSPOC), if this information has not been provided yet to the Member States through the system;

Or. en

Amendment 452
Danilo Oscar Lancini

Proposal for a regulation
Article 9 – paragraph 1 – point c

Text proposed by the Commission
(c) develop streamlined electronic monitoring and reporting systems;

Amendment
(c) develop streamlined electronic monitoring and reporting systems; by implementing and building on existing regulatory infrastructure (EU
telematics[1]). This system shall be interoperable with the national shortages reporting to prevent any duplication of the reporting process; the system should establish a two-way digital communication between the Agency and the national competent authorities, as well as a two-way communication between the Agency and marketing authorisation holders. In case of public health emergency, aggregated information should be collected by the Agency from national competent authority shortages reporting systems in a harmonised and consolidated way, based on harmonised data fields across Member States. The Agency can request additional information directly from the marketing authorisation holders via the industry single point of contact (iSPOC), if this information has not been provided yet to the Member States.

Or. en

Amendment 453
Margarita de la Pisa Carrión

Proposal for a regulation
Article 9 – paragraph 1 – point c

Text proposed by the Commission

(c) develop streamlined electronic monitoring and reporting systems;

Amendment

(c) develop streamlined electronic monitoring and reporting systems, by implementing and building on existing regulatory infrastructure (EU telematics). This system shall be interoperable with the national shortages reporting to prevent any duplication of the reporting process; the system should establish a two-way digital communication between the Agency and the national competent authorities, as well as a two-way communication between the Agency and marketing authorisation holders. In case of public health emergency, aggregated...
information should be collected by the Agency from national competent authority shortages reporting systems in a harmonised and consolidated way, based on harmonised data fields across Member States. The Agency can request additional information directly from the marketing authorisation holders via the industry single point of contact (iSPOC), if this information has not been provided yet to the Member States.

Amendment 454
Pietro Fiocchi

Proposal for a regulation
Article 9 – paragraph 1 – point c

Text proposed by the Commission

(c) develop streamlined electronic monitoring and reporting systems;

Amendment

(c) develop streamlined electronic monitoring and reporting systems; by implementing and building on existing regulatory infrastructure (EU telematics). This system shall be interoperable with the national shortages reporting to prevent any duplication of the reporting process; the system should establish a two-way digital communication between the Agency and the national competent authorities, as well as a two-way communication between the Agency and marketing authorisation holders. In case of public health emergency, aggregated information should be collected by the Agency from national competent authority shortages reporting systems in a harmonised and consolidated way, based on harmonised data fields across Member States. The Agency can request additional information directly from the marketing authorisation holders via the industry single point of contact (iSPOC), if this information has not been provided yet to
Amendment 455
Adam Jarubas

Proposal for a regulation
Article 9 – paragraph 1 – point c

Text proposed by the Commission
(c) develop streamlined electronic monitoring and reporting systems;

Amendment
(c) develop streamlined electronic monitoring and reporting systems, **building upon EU telematics regulatory infrastructure, SPOR, into national shortage reporting interoperable system, based on national harmonised data fields and definitions across Member States, preventing reporting duplication, using international standards (ISO IDMP) and supporting mutual cooperation of the Agency and national competent authorities and via iSPOC with marketing authorisation holders**;

Amendment 456
Cristian-Silviu Buşoi, Radan Kanev

Proposal for a regulation
Article 9 – paragraph 1 – point c

Text proposed by the Commission
(c) develop **streamlined electronic** monitoring **and** reporting systems;

Amendment
(c) develop **an interoperable and digitalized platform for** monitoring, reporting **and notifying**;

Amendment 457
Antoni Comín i Oliveres

Proposal for a regulation
Article 9 – paragraph 1 – point d

Text proposed by the Commission

(d) establish and maintain membership of the working party referred to in Article 3(5) comprised of single points of contacts from national competent authorities for medicinal products;

Amendment

(d) establish and maintain membership of the working party referred to in Article 3(5) comprised of single points of contacts from national, and where applicable regional, competent authorities for medicinal products;

Or. en

Amendment 458
Adam Jarubas

Proposal for a regulation
Article 9 – paragraph 1 – point e

Text proposed by the Commission

(e) establish and maintain a list of single points of contact from marketing authorisation holders for all medicinal products for human use authorised in the Union, through the database provided for in Article 57(1)(l) of Regulation 726/2004;

Amendment

(e) establish and maintain a list of single points of contact from marketing authorisation holders for all medicinal products for human use authorised in the Union, through the database provided for in Article 57(1)(l) of Regulation 726/2004 after updating it by including the industry single point of contacts (iSPOC) maintaining compliance with ISO IDMP;

Or. en

Amendment 459
Danilo Oscar Lancini

Proposal for a regulation
Article 9 – paragraph 1 – point e

Text proposed by the Commission

Amendment
(e) establish and maintain a list of single points of contact from marketing authorisation holders for all medicinal products for human use authorised in the Union, through the database provided for in Article 57(1)(l) of Regulation 726/2004;

(e) update the Article 57(1)(l) of Regulation 726/2004 Data base by including the industry single point of contacts (iSPOC), this database should be digital, regularly updated, and compliant with the standards of the International Organization for Standardization (ISO) for the identification of medicinal products (IDMP);

Or. en

Amendment 460
Pietro Fiocchi

Proposal for a regulation
Article 9 – paragraph 1 – point e

Text proposed by the Commission

(e) establish and maintain a list of single points of contact from marketing authorisation holders for all medicinal products for human use authorised in the Union, through the database provided for in Article 57(1)(l) of Regulation 726/2004;

Amendment

(e) update the Article 57(1)(l) of Regulation 726/2004 Data base by including the industry single point of contacts (iSPOC), this database should be digital, regularly updated, and compliant with the standards of the International Organization for Standardization (ISO) for the identification of medicinal products (IDMP);

Or. en

Amendment 461
Aldo Patriciello

Proposal for a regulation
Article 9 – paragraph 1 – point e

Text proposed by the Commission

(e) establish and maintain a list of single points of contact from marketing authorisation holders for all medicinal products for human use authorised in the Union, through the database provided for

Amendment

(e) update the Article 57(1)(l) of Regulation 726/2004 database by including the industry single point of contact (iSPOC); this database should be digital, regularly updated, and compliant
in Article 57(1)(l) of Regulation 726/2004; with the International Organization for Standardization (ISO) for the identification of medicinal products (IDMP)

Amendment 462
Pietro Fiocchi

Proposal for a regulation
Article 9 – paragraph 1 – point f a (new)

Text proposed by the Commission

Amendment

(fa) update the format and content of the Article 57 database to include the industry Single Point of contact (iSPOC) names as reported by industry. Industry should be able to digitally update the iSPOC names in the article 57 database if needed and compliant with the standards of the International Organization for Standardization (ISO) for the identification of medicinal products (IDMP);

Amendment 463
Kateřina Konečná

Proposal for a regulation
Article 9 – paragraph 1 – point f a (new)

Text proposed by the Commission

Amendment

(fa) The Agency shall publish information referred to in paragraph (1) (a), (b), (f) on its web-portal.
Amendment 464
Tilly Metz

Proposal for a regulation
Article 9 – paragraph 1 – point f a (new)

Text proposed by the Commission

Amendment

(fa) publish information referred to in paragraph (1) (a), (b) and (f) on its web-portal.

Or. en

Amendment 465
Pietro Fiocchi

Proposal for a regulation
Article 9 – paragraph 1 – point f b (new)

Text proposed by the Commission

Amendment

(fb) Include the use of including use of the European Medicines Verification System data for shortages in an epidemiological crisis by enabling national regulators to assess the availability of products versus what has been consumed or parallel exported in their market;

Or. en

Amendment 466
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ţefănuţă, Susana Solis Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos

Proposal for a regulation
Article 9 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. The Agency shall publish the information referred to in paragraph 1 (a), (b), (f) on its web portal without delay.
Proposal for a regulation
Article 9 – paragraph 2 – point a

Text proposed by the Commission

(a) establish and maintain for the duration of the public health emergency or major event, a sub-network of single points of contact from marketing authorisation holders based on the medicinal products included on the critical medicines lists;

Amendment

(a) establish and maintain for the duration of the public health emergency or major event, a sub-network of single points of contact from marketing authorisation holders who can be different from the contacts established under Article 9(1) point (e), and of representatives of other relevant supply chain stakeholders involved in the distribution and supply of medicinal products to the public, based on the medicinal products included on the critical medicines lists;

Proposal for a regulation
Article 9 – paragraph 2 – point b

Text proposed by the Commission

(b) request information from the points of contact included in the sub-network referred to in point (a) and set a deadline for its submission;

Amendment

(b) request information, including on the supply of the list of critical medicinal products, from the points of contact included in the sub-network referred to in point (a) and set a deadline for its submission in the platform;
Cristian-Silviu Bușoi, Radan Kanev

Proposal for a regulation
Article 9 – paragraph 2 – point c

Text proposed by the Commission

(c) request information from the single points of contact from Member States’ national competent authorities based on the set of information agreed on by the Medicines Steering Group and set a deadline for its submission.

Amendment

(c) request information, including on the supply of the list of critical medicinal products, from the single points of contact from Member States’ national competent authorities based on the set of information agreed on by the Medicines Steering Group and set a deadline for its submission in the platform.

Or. en

Amendment 470
Antoni Comín i Oliveres

Proposal for a regulation
Article 9 – paragraph 2 – point c

Text proposed by the Commission

(c) request information from the single points of contact from Member States’ national competent authorities based on the set of information agreed on by the Medicines Steering Group and set a deadline for its submission.

Amendment

(c) request information from the single points of contact from Member States’ national, and where applicable regional, competent authorities based on the set of information agreed on by the Medicines Steering Group and set a deadline for its submission.

Or. en

Amendment 471
Pietro Fiocchi

Proposal for a regulation
Article 9 – paragraph 3 – introductory part

Text proposed by the Commission

3. The information referred to in point

Amendment

3. The information referred to in point
(b) of paragraph 2 shall include at least:

(b) of paragraph 2 (as determined in Article 9(1) (c) and Article 11 (a) shall not include any information available to the Agency via collection of information submitted by industry to the national competent authority shortages systems in a harmonised and consolidated way by means of common data fields for each Member State. The system at the Agency shall be interoperable with the national shortages reporting to prevent any duplication of the reporting process by industry via Industry Single Points of Contact (iSPOC).

Amendment 472
Pernille Weiss

Proposal for a regulation
Article 9 – paragraph 3 – introductory part

Text proposed by the Commission

3. The information referred to in point (b) of paragraph 2 shall include at least:

Amendment

3. The scope of the information referred to in point (b) of paragraph 2 shall be discussed with representatives of the relevant marketing authorisation holders, including to avoid overlaps with information already submitted following Directive 2001/83/EC. Requested information may include:

Or. en

Amendment 473
Adam Jarubas

Proposal for a regulation
Article 9 – paragraph 3 – introductory part

Text proposed by the Commission

3. The information referred to in point

Amendment

3. The information referred to in point

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(b) of paragraph 2 shall include at least:

(b) of paragraph 2, without duplicating information available to the Agency via collection of information submitted by industry to the national competent authority shortages systems, shall include at least:

Or. en

Amendment 474
Tilly Metz

Proposal for a regulation
Article 9 – paragraph 3 – point d

Text proposed by the Commission

(d) details of the potential or actual shortage such as actual or estimated start and end dates and suspected or known cause;

Amendment

(d) details of the potential or actual shortage such as actual or estimated start and end dates and suspected or known cause as well as information on potential bottlenecks in the supply chain;

Or. en

Amendment 475
Tilly Metz

Proposal for a regulation
Article 9 – paragraph 3 – point d a (new)

Text proposed by the Commission

(da) information on active substance manufacturing sites, where relevant;

Amendment

Or. en

Amendment 476
Joëlle Mélin

Proposal for a regulation
Article 9 – paragraph 3 – point e
Text proposed by the Commission  

Amendment

(e) sales and market share data; deleted

Or. fr

Amendment 477
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 9 – paragraph 3 – point e

Text proposed by the Commission  

Amendment

(e) sales, available stock, where relevant, and market share data;

Or. fr

Amendment 478
Pernille Weiss

Proposal for a regulation
Article 9 – paragraph 3 – point f

Text proposed by the Commission  

Amendment

(f) details of available alternative medicinal products where known by the marketing authorisation holder;

Or. en

Amendment 479
Tilly Metz

Proposal for a regulation
Article 9 – paragraph 3 – point g

Text proposed by the Commission  

Amendment

(g) prevention and mitigation plans including but not limited to information

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production and supply capacity; on production and supply capacity, 
production sites of finished 
pharmaceutical products and active 
pharmaceutical ingredients and raw 
materials, potential alternative production 
sites, minimum stock levels; such 
plans shall contain preventative measures 
that help ensure the continued supply of 
critical medicines, such as diversification 
of supply chains;

Justification

To prevent and mitigate shortages, and to organize alternative supply more information on the supply chain is needed, including where medicinal products are produced, the origin of raw materials, as well as possible alternative suppliers of raw materials, API and alternative places of production of finished products if needed.

Amendment 480
Dolors Montserrat

Proposal for a regulation
Article 9 – paragraph 3 – point g

Text proposed by the Commission

(g) mitigation plans including production and supply capacity;

Amendment

(g) prevention and mitigation plans including information on production and supply capacity, production sites of the finished pharmaceutical product and of active pharmaceutical ingredients, potential alternative production sites, minimum stock levels, etc.

Amendment 481
Kateřina Konečná

Proposal for a regulation
Article 9 – paragraph 3 – point g
(g) mitigation plans including production and supply capacity;

Amendment

(g) prevention and mitigation plans including information on production and supply capacity; production sites of the finished pharmaceutical product and of active pharmaceutical ingredients, potential alternative production sites, minimum stock levels, etc;

Or. en

Amendment 482
Sara Cerdas

Proposal for a regulation
Article 9 – paragraph 3 – point g

Text proposed by the Commission

(g) mitigation plans including production and supply capacity;

Amendment

(g) prevention and mitigation plans including information on production and supply capacity; production sites of the finished pharmaceutical product and of active pharmaceutical ingredients, potential alternative production sites, minimum stock levels, etc.

Or. en

Amendment 483
Dan-Ştefan Motreanu

Proposal for a regulation
Article 9 – paragraph 3 – point g

Text proposed by the Commission

(g) mitigation plans including production and supply capacity;

Amendment

(g) mitigation plans including production and supply capacity; these plans shall contain preventative measures that help ensure the continued supply of critical medicines, such as diversification of supply chains;
Amendment 484
Antoni Comín i Oliveres

Proposal for a regulation
Article 9 – paragraph 3 – point g

Text proposed by the Commission

(g) mitigation plans including production and supply capacity;

Amendment

(g) mitigation plans containing preventative measures that help ensure the continued supply of critical medicines, such as diversification of supply chains, as well as including production and supply capacity;

Or. en

Amendment 485
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ştefănuţă, Nils Torvalds, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos

Proposal for a regulation
Article 9 – paragraph 3 – point g

Text proposed by the Commission

(g) mitigation plans including production and supply capacity;

Amendment

(g) mitigation plans, including production and supply capacity, with a view to guarantee continued supply and prevent shortages of medicinal products included on the critical medicines lists;

Or. en

Amendment 486
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 9 – paragraph 3 – point g

Text proposed by the Commission

Amendment
(g) mitigation plans including production and supply capacity;

(g) prevention and mitigation plans including production and supply capacity;

Or. fr

Amendment 487
Pernille Weiss

Proposal for a regulation
Article 9 – paragraph 3 – point g

Text proposed by the Commission

Amendment

(g) mitigation plans including production and supply capacity;

(g) mitigation plans;

Or. en

Amendment 488
Danilo Oscar Lancini

Proposal for a regulation
Article 9 – paragraph 3 – point g a (new)

Text proposed by the Commission

Amendment

(ga) update the format and content of the Article 57 database to include the industry Single Point of contact (iSPOC) names as reported by industry. Industry should be able to digitally update the iSPOC names in the Article 57 database if needed and compliant with the standards of the International Organization for Standardization (ISO) for the identification of medicinal products (IDMP)3;

Or. en

Amendment 489
Sara Cerdas
Proposal for a regulation
Article 9 – paragraph 3 – point h

Text proposed by the Commission

(h) information from the wholesale distributors and legal person entitled to supply the medicinal product to the public.

Amendment

(h) information deleted

Or. en

Amendment 490
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos, Jan Huitema

Proposal for a regulation
Article 9 – paragraph 3 – point h

Text proposed by the Commission

(h) information from the wholesale distributors and legal person entitled to supply the medicinal product to the public.

Amendment

(h) information deleted

Or. en

Justification

Information of a sensitive commercial nature, to be collected by national competent authorities rather.

Amendment 491
Danilo Oscar Lancini

Proposal for a regulation
Article 9 – paragraph 3 – point h

Text proposed by the Commission

(h) information from the wholesale distributors and legal person entitled to supply the medicinal product to the public.

Amendment

(h) information on stock levels from the wholesale distributors and legal person entitled to supply the medicinal product to the public, via their representatives who are part of the sub-network referred to in
point (a) of paragraph 2.

Amendment 492
Sirpa Pietikäinen

Proposal for a regulation
Article 9 – paragraph 3 a (new)

Text proposed by the Commission

3 a. Following the recognition of a public health emergency or a request for assistance referred to in Article 4 (3), the Agency shall establish:

(a) a minimum stock level for wholesale distributors and other legal entities entitled to supply the public with medicinal products included on the critical medicines lists;

(b) an emergency preparedness plan to fast track an increase in the production capacity so that it is sufficient to fulfil Union needs for the medicinal products included on the critical medicines lists.

Amendment 493
Danilo Oscar Lancini

Proposal for a regulation
Article 9 – paragraph 3 a (new)

Text proposed by the Commission

3 a. The information referred to in point (c) of paragraph 2 shall include at least details of (a) available alternative medicinal products; (b) information from the wholesale distributors and legal person entitled to supply the medicinal product to the public.
Amendment 494
Pietro Fiocchi

Proposal for a regulation
Article 9 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. The information referred to in point (c) of paragraph 2 shall include at least details of (a) available alternative medicinal products; (b) information from the wholesale distributors and legal person entitled to supply the medicinal product to the public.

Or. en

Amendment 495
Sirpa Pietikäinen

Proposal for a regulation
Article 9 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

3 b. In normal circumstances the Agency shall establish a minimum stock level for wholesale distributors and other legal entities entitled to supply the public with medicinal products.

Or. en

Amendment 496
Tilly Metz

Proposal for a regulation
Article 10 – title
1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, marketing authorisation holders for medicinal products included on the critical medicines lists shall submit the information referred to in Article 9(3) by the deadline set by the Agency. They shall submit the information through the points of contact designated in accordance with Article 9(2) and using the reporting methods and system established pursuant to Article 9(1). They shall provide updates where necessary. Once uploaded, the information is accessible to the Agency and national competent authorities, ensuring transparency and avoiding duplications of reporting at different levels and enabling the two-way communication with industry and entities of the pharmaceutical supply chain.
Amendment 498
Margarita de la Pisa Carrión

Proposal for a regulation
Article 10 – paragraph 1

Text proposed by the Commission

1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, marketing authorisation holders for medicinal products included on the critical medicines lists shall submit the information referred to in Article 9(3) by the deadline set by the Agency. **They shall submit** the information through the points of contact designated in accordance with Article 9(2) and using the reporting methods and system established pursuant to Article 9(1). **They shall provide updates where necessary.**

Amendment

1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, marketing authorisation holders for medicinal products included on the critical medicines lists shall submit the information referred to in Article 9(3) by the deadline set by the Agency, if the information is not available via the interoperable system connected with the national shortages reporting systems established in Article 9(1) (c).

Amendment 499
Pietro Fiocchi

Proposal for a regulation
Article 10 – paragraph 1

Text proposed by the Commission

1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, marketing authorisation holders for medicinal products included on the critical medicines lists shall submit the information referred to in Article 9(3) by the deadline set by the Agency. **They shall submit** the information through the points of contact designated in accordance with Article 9(2) and using the reporting methods and system established pursuant to Article 9(1). **They shall provide updates where necessary.**

Amendment

1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, marketing authorisation holders for medicinal products included on the critical medicines lists shall submit the information referred to in Article 9(3) by the deadline set by the Agency, if the information is not available via the interoperable system connected with the national shortages reporting systems established in Article 9 (1) (c).
Amendment 500
Joëlle Mélin, Danilo Oscar Lancini

Proposal for a regulation
Article 10 – paragraph 1

Text proposed by the Commission

1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, marketing authorisation holders for medicinal products included on the critical medicines lists shall submit the information referred to in Article 9(3) by the deadline set by the Agency. They shall submit the information through the points of contact designated in accordance with Article 9(2) and using the reporting methods and system established pursuant to Article 9(1). They shall provide updates where necessary.

Amendment

1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, marketing authorisation holders for medicinal products included on the critical medicines lists, and all distributors legally authorised to supply medicines to the public, shall submit the information referred to in Article 9(3) by the deadline set by the Agency. They shall submit the information through the points of contact designated in accordance with Article 9(2) and using the reporting methods and system established pursuant to Article 9(1). They shall provide updates where necessary.

Or. fr

Amendment 501
Pietro Fiocchi

Proposal for a regulation
Article 10 – paragraph 2

Text proposed by the Commission

2. Marketing authorisation holders of medicinal products authorised in the Union shall, within 6 months from the date of application of this Regulation, provide the information required pursuant to Article 9(1)(e) in the form of an electronic submission in the database referred to in Article 57(1)(I) of Regulation (EC) No 726/2004. Those marketing authorisation holders shall update their submission

Amendment

2. Marketing authorisation holders of medicinal products authorised in the Union shall, within 12-24 months from the date of application of this Regulation, provide the information required pursuant to Article 9(1)(e) in the form of an electronic submission in the database referred to in Article 57(1)(I) of Regulation (EC) No 726/2004 and compliant with the standards of the
wherever necessary.

International Organization for Standardization (ISO) for the identification of medicinal products (IDMP). Those marketing authorisation holders shall update their submission wherever necessary.

Amendment 502
Aldo Patriciello

Proposal for a regulation
Article 10 – paragraph 2

Table 1: Amendment to Text proposed by the Commission

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Marketing authorisation holders of medicinal products authorised in the Union shall, within 6 months from the date of application of this Regulation, provide the information required pursuant to Article 9(1)(e) in the form of an electronic submission in the database referred to in Article 57(1)(l) of Regulation (EC) No 726/2004. Those marketing authorisation holders shall update their submission wherever necessary.</td>
<td>2. Marketing authorisation holders of medicinal products authorised in the Union shall, within 6 months from the date of application of this Regulation, provide the information required pursuant to Article 9(1)(e) in the form of an electronic submission in the database referred to in Article 57(1)(l) of Regulation (EC) No 726/2004 and compliant with ISO IDMP standards for the identification of human medicines. Those marketing authorisation holders shall update their submission wherever necessary.</td>
</tr>
</tbody>
</table>

Amendment 503
Joanna Kopcińska

Proposal for a regulation
Article 10 – paragraph 3

Table 1: Amendment to Text proposed by the Commission

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Marketing authorisation holders shall justify the absence of any requested information and any delays in providing it by the deadline set by the Agency.</td>
<td>deleted</td>
</tr>
</tbody>
</table>

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Justification

It is unclear how exactly this information will be used by the Medicines Steering Group when issuing recommendations. Moreover, medical device manufacturers and notified bodies may not always be willing to provide the Agency with the requested information, particularly in view of confidentiality provisions and the absence of any punitive sanctions, as disclosure could undermine the economic interest or competitive position of the owner of the information.

Amendment 504
Aldo Patriciello

Proposal for a regulation
Article 10 – paragraph 3

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Marketing authorisation holders shall justify the absence of any requested information and any delays in providing it by the deadline set by the Agency.</td>
<td>3. Marketing authorisation holders of medicinal products authorised in the Union shall, within 6 months from the date of application of this Regulation, provide the information required pursuant to Article 9(1)(e) in the form of an electronic submission in the database referred to in Article 57(1)(l) of Regulation (EC) No 726/2004 and compliant with ISO IDMP standards for the identification of human medicines. Those marketing authorisation holders shall update their submission wherever necessary.</td>
</tr>
</tbody>
</table>

Amendment 505
Tilly Metz

Proposal for a regulation
Article 10 – paragraph 3

<table>
<thead>
<tr>
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<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Marketing authorisation holders shall justify the absence of any requested</td>
<td>3. Marketing authorisation holders shall justify the absence of any requested</td>
</tr>
</tbody>
</table>

Or. en
Marketing authorisation holders failing to comply with their reporting obligations shall be subject to proportionate sanctions set by the Commission in a delegated act.

Or. en

Amendment 506
Margarita de la Pisa Carrión

Proposal for a regulation
Article 10 – paragraph 3

Text proposed by the Commission

3. Marketing authorisation holders shall justify the absence of any requested information and any delays in providing it by the deadline set by the Agency.

Amendment

3. Marketing authorisation holders shall justify the absence of any requested information and any delays in providing it by the deadline set by the Agency after consultation and agreement with industry on a case by case scenario.

Or. en

Amendment 507
Pietro Fiocchi

Proposal for a regulation
Article 10 – paragraph 3

Text proposed by the Commission

3. Marketing authorisation holders shall justify the absence of any requested information and any delays in providing it by the deadline set by the Agency.

Amendment

3. Marketing authorisation holders shall justify the absence of any requested information and any delays in providing it by the deadline set by the Agency after consultation and agreement with industry on a case by case scenario.

Or. en
Amendment 508
Joëlle Mélin

Proposal for a regulation
Article 10 – paragraph 4

Text proposed by the Commission

4. Where marketing authorisation holders for medicinal products included on the critical medicines lists indicate that the submitted information contains information of a commercially confidential nature, they shall identify the relevant parts and clarify the reasons for such an indication. The Agency shall assess the merits of each request and protect commercially confidential information against unjustified disclosure.

Amendment

4. Where marketing authorisation holders for medicinal products included on the critical medicines lists indicate that the submitted information contains information of a commercially confidential nature, they shall identify the relevant parts and clarify the reasons for such an indication. The Agency shall assess the merits of each request and protect commercially confidential information against unjustified disclosure, in accordance with Article 30 of this Regulation.

Or. fr

Amendment 509
Pietro Fiocchi

Proposal for a regulation
Article 10 – paragraph 4

Text proposed by the Commission

4. Where marketing authorisation holders for medicinal products included on the critical medicines lists indicate that the submitted information contains information of a commercially confidential nature, they shall identify the relevant parts and clarify the reasons for such an indication. The Agency shall assess the merits of each request and protect commercially confidential information against unjustified disclosure.

Amendment

4. Where marketing authorisation holders for medicinal products included on the critical medicines lists indicate that the submitted information contains information of a commercially confidential nature, they shall identify the relevant parts and clarify the reasons for such an indication. It should be determined upfront what information is commercially confident, based on this the Agency shall assess the merits of each request and protect commercially confidential information against unjustified disclosure.

Or. en
Amendment 510
Cristian-Silviu Bușoi, Radan Kanev

Proposal for a regulation
Article 10 – paragraph 4

Text proposed by the Commission

4. Where marketing authorisation holders for medicinal products included on the critical medicines lists indicate that the submitted information contains information of a commercially confidential nature, they shall identify the relevant parts and clarify the reasons for such an indication. The Agency shall assess the merits of each request and protect commercially confidential information against unjustified disclosure.

Amendment

4. Where marketing authorisation holders for medicinal products included on the critical medicines lists indicate that the submitted information requested by the Agency and the national competent authorities contains information of a commercially confidential nature, they shall identify the relevant parts and clarify the reasons for such an indication. The Agency shall assess the merits of each request and protect commercially confidential information against unjustified disclosure.

Or. en

Amendment 511
Antoni Comín i Oliveres

Proposal for a regulation
Article 10 – paragraph 5

Text proposed by the Commission

5. Where marketing authorisation holders for medicinal products included on the critical medicines lists are in possession of any additional information, which provides evidence of a potential or actual shortage they shall immediately provide such information to the Agency.

Amendment

5. Where marketing authorisation holders for medicinal products included on the critical medicines lists are in possession of any additional information, which provides evidence of a potential or actual shortage they shall immediately provide such information to the Agency. National, or where applicable regional, competent authorities shall facilitate patient and consumer reporting of medicine shortages through the digital interoperable database referred to in Article 1(b) and Article 12(g). Aggregated data from these reports
shall be shared by the sub-network of single points of contact from national, or where applicable regional, competent authorities referred to in Article 3(5) with the Steering Group to inform recommendations on medicine shortage management.

Amendment 512
Kateřina Konečná

Proposal for a regulation
Article 10 – paragraph 5

Text proposed by the Commission

5. Where marketing authorisation holders for medicinal products included on the critical medicines lists are in possession of any additional information, which provides evidence of a potential or actual shortage they shall immediately provide such information to the Agency.

Amendment

5. Where marketing authorisation holders for medicinal products included on the critical medicines lists are in possession of any additional information, which provides evidence of a potential or actual shortage they shall immediately provide such information to the Agency. In the absence of notification of essential information, the Agency, the Commission and Member States should enact sanctions, e.g. financial penalties, extending compulsory license or removing intellectual property rights to allow that other actors can minimise the shortage.

Justification

Sanctions should be foreseen in case of non-respect of provision of essential information. The sanctions and/or removal of intellectual property rights aim to enable the production of essential health products by other producers.

Amendment 513
Cristian-Silviu Bușoi, Radan Kanev

Proposal for a regulation
Article 10 – paragraph 5

Text proposed by the Commission

5. Where marketing authorisation holders for medicinal products included on the critical medicines lists are in possession of any additional information, which provides evidence of a potential or actual shortage they shall immediately provide such information to the Agency.

Amendment

5. Where marketing authorisation holders for medicinal products included on the critical medicines lists and/or other relevant entities of the pharmaceutical supply chain, are in possession of any additional information, which provides evidence of a potential or actual shortage they shall immediately provide such information to the Agency.

Or. en

Amendment 514
Joëlle Mélin

Proposal for a regulation
Article 10 – paragraph 6 – point a

Text proposed by the Commission

(a) provide any comments they have to the Agency;

Amendment

(a) provide any comments they have to the Agency, in accordance with Article 30 of this Regulation;

Or. fr

Amendment 515
Cristian-Silviu Buşoi, Radan Kanev

Proposal for a regulation
Article 10 – paragraph 6 – point c

Text proposed by the Commission

(c) inform the Medicines Steering Group of any measures taken and report on the results of those measures, including information on the resolution of the potential or actual shortage.

Amendment

(c) inform the Medicines Steering Group of any measures taken and report on the monitoring and results of those measures, including information on the resolution of the potential or actual shortage.
Amendment 516
Tilly Metz
Proposal for a regulation
Article 10 – paragraph 6 a (new)

Text proposed by the Commission

6 a. In order to supplement the shortage prevention and mitigation plans of critical products, the Agency and national competent authorities may request additional information from wholesale distributors and other relevant actors regarding any logistical challenges incurred by the wholesale supply chain.

Amendment

Or. en

Amendment 517
Dan-Ştefan Motreanu
Proposal for a regulation
Article 10 – paragraph 6 a (new)

Text proposed by the Commission

6 a. 6 a. The Commission and Member States shall lay down rules on sanctions for non-compliance with the obligations established under this Article. These sanctions shall be dissuasive.

Amendment

Or. en

Amendment 518
Kateřina Konečná
Proposal for a regulation
Article 10 – paragraph 6 a (new)
6 a. The Commission and Member States shall lay down rules on sanctions for non-compliance with the obligations established under this Article. These sanctions shall be dissuasive.

Justification

The Regulation should require that the European Commission and Member States lay down rules on sanctions for non-compliance by companies with their obligations.

Amendment 519
Tilly Metz

Proposal for a regulation
Article 10 – paragraph 6 b (new)

Text proposed by the Commission

6 b. The Commission shall exercise its power to lay down rules on sanctions for non-compliance with the obligations established under this Article in a delegated act.

Or. en

Amendment 520
Pietro Fiocchi

Proposal for a regulation
Article 11 – paragraph 1 – introductory part

Text proposed by the Commission

1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, Member States shall, by the deadline set by the Agency:

1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, Member States shall, by the deadline set by the Agency, where relevant, following the creation of a harmonized pan-European interoperable and digital National Competent
Authorities (NCAs) shortages reporting system based on common data fields (a) submit the set of information requested by the Agency in Chapter 2 Article 9 (4) including available and estimated data on volume of demand, through its designated point of contact and using the reporting methods and system established pursuant to Article 9(1);

Or. en

Amendment 521
Aldo Patriciello

Proposal for a regulation
Article 11 – paragraph 1 – introductory part

Text proposed by the Commission

1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, Member States shall, by the deadline set by the Agency:

Amendment

1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, Member States shall, by the deadline set by the Agency, submit the following, if not already available in the harmonised pan-European interoperable and digitalized shortages reporting and notification system:

Or. en

Amendment 522
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 11 – paragraph 1 – introductory part

Text proposed by the Commission

1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, Member States shall, by the deadline set by the Agency:

Amendment

1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, Member States or any national competent authority shall,
by the deadline set by the Agency:

*(Amendment 523)*

Danilo Oscar Lancini

Proposal for a regulation
Article 11 – paragraph 1 – point a

*Text proposed by the Commission*

(a) submit the set of information requested by the Agency including available and estimated data on volume of demand, through its designated point of contact and using the reporting methods and system established pursuant to Article 9(1);

*Amendment*

(a) In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, Member States shall, by the deadline set by the Agency, where relevant, following the creation of a harmonized pan-European interoperable and digital National Competent Authorities (NCAs) shortages reporting system based on common data fields (a) submit the set of information requested by the Agency in Chapter 2 Article 9 (4) including available and estimated data on volume of demand, through its designated point of contact and using the reporting methods and system established pursuant to Article 9(1);

*(Amendment 524)*

Aldo Patriciello

Proposal for a regulation
Article 11 – paragraph 1 – point a

*Text proposed by the Commission*

(a) submit the set of information requested by the Agency including available and estimated data on volume of demand, through its designated point of contact and using the reporting methods and system established pursuant to Article

*Amendment*

(a) submit the set of additional information requested by the Agency in Chapter 2 Article 9 (3) including available and estimated data on volume of demand, through its designated point of contact and using the reporting methods and system
established pursuant to Article 9(1);

**Amendment 525**  
Joanna Kopcińska

Proposal for a regulation  
Article 11 – paragraph 1 – point a

*Text proposed by the Commission*

(a) submit the set of information requested by the Agency including available and estimated data on volume of demand, through its designated point of contact and using the reporting methods and system established pursuant to Article 9(1);

*Amendment*

(a) submit the set of available information to Member States requested by the Agency including estimated data on volume of demand, through its designated point of contact and using the reporting methods and system established pursuant to Article 9(1);

**Amendment 526**  
Cristian-Silviu Bușoi, Radan Kanev

Proposal for a regulation  
Article 11 – paragraph 1 – point a

*Text proposed by the Commission*

(a) submit the set of information requested by the Agency including available and estimated data on volume of demand, through its designated point of contact and using the reporting methods and system established pursuant to Article 9(1);

*Amendment*

(a) submit the set of information requested by the Agency including available and estimated data on volume of demand, through its designated point of contact and using the reporting methods, system and platform established pursuant to Article 9(1);

**Amendment 527**  
Joanna Kopcińska
Proposal for a regulation
Article 11 – paragraph 2

Text proposed by the Commission

2. Where necessary to fulfil their reporting obligations set out in paragraph 1, Member States, with the support of the Agency, shall gather information and data on stock levels from wholesale distributors and other legal entities entitled to supply the public with medicinal products included on the critical medicines lists.

Amendment

deleted

Justification

The obligation on manufacturers, authorised representatives and importers to provide inventory reporting is already required under EUDAMED, and it is unnecessary to include this under an additional system. Furthermore, it is questionable whether the competent authority, at the request of the Agency, will be able to contact all manufacturers, authorised representatives, importers and distributors in a timely and relevant manner in acquiring this information.

Amendment 528
Aldo Patriciello

Proposal for a regulation
Article 11 – paragraph 2

Text proposed by the Commission

2. Where necessary to fulfil their reporting obligations set out in paragraph 1, Member States, with the support of the Agency, shall gather information and data on stock levels from wholesale distributors and other legal entities entitled to supply the public with medicinal products included on the critical medicines lists.

Amendment

2. Where necessary to fulfil their reporting obligations set out in paragraph 1, Member States, with the support of the Agency, shall gather information and data on stock levels from wholesale distributors and other legal entities entitled to supply the public with medicinal products included on the critical medicines lists, when not yet available or accessible in the harmonised pan-European interoperable and digitalized shortages reporting and notification system.
Amendment 529
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 11 – paragraph 2

Text proposed by the Commission

2. Where necessary to fulfil their reporting obligations set out in paragraph 1, Member States, with the support of the Agency, shall gather information and data on stock levels from wholesale distributors and other legal entities entitled to supply the public with medicinal products included on the critical medicines lists.

Amendment

2. Where necessary to fulfil their reporting obligations set out in paragraph 1, Member States, with the support of the Agency, shall gather information and data on stock levels from marketing authorisation holders, wholesale distributors, community and hospital pharmacies, and other legal entities entitled to supply the public with medicinal products included on the critical medicines lists.

Amendment 530
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 11 – paragraph 2 a (new)

Text proposed by the Commission

2a. Where necessary to fulfil their reporting obligations set out in paragraph 1, Member States, with the support of the Agency, shall gather information and data on unmet demands from wholesale distributors, community and hospital pharmacies, and other legal entities entitled to supply the public with medicinal products included on the critical medicines lists.

Amendment

2a. Where necessary to fulfil their reporting obligations set out in paragraph 1, Member States, with the support of the Agency, shall gather information and data on unmet demands from wholesale distributors, community and hospital pharmacies, and other legal entities entitled to supply the public with medicinal products included on the critical medicines lists.
Amendment 531
Aldo Patriciello

Proposal for a regulation
Article 11 – paragraph 3

Text proposed by the Commission

3. Where Member States are in possession of any additional information on volume of sales and volumes of prescriptions, including data based on Article 23a of Directive 2001/83/EC, which provides evidence of a potential or actual shortage of a medicinal product included on the critical medicines lists, they shall immediately provide such information to the Medicines Steering Group through their designated points of contact.

Amendment

3. Where Member States are in possession of any additional information on volume of sales and volumes of prescriptions, including data based on Article 23a of Directive 2001/83/EC, which provides evidence of a potential or actual shortage of a medicinal product included on the critical medicines lists, they shall immediately provide such information to the Medicines Steering Group through their designated points of contact via the harmonised pan-European interoperable and digitalized shortages reporting and notification system.

Or. en

Amendment 532
Joanna Kopcińska

Proposal for a regulation
Article 11 – paragraph 4 – point a

Text proposed by the Commission

(a) take into account any recommendations and guidelines and comply with any measures taken at Union-level pursuant to Article 12;

Amendment

(a) acknowledge any recommendations and guidelines and comply with any measures taken at Union-level pursuant to Article 12;

Or. en

Amendment 533
Dan-Ștefan Motreanu
Proposal for a regulation
Article 11 – paragraph 4 – subparagraph 1 (new)

Text proposed by the Commission

Amendment

Member States shall facilitate patient and consumer reporting of medicine shortages through the provision of alternative reporting formats in addition to web-based formats. Aggregated data from these reports shall be shared by the sub-network of single points of contact from national competent authorities referred to in Article 3 (5) with the Steering Group to inform recommendations on medicine shortage management.

Or. en

Amendment 534
Tilly Metz

Proposal for a regulation
Article 11 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. National medicines agencies in Member States shall facilitate patient and consumer reporting of medicine shortages through the provision of alternative reporting formats in addition to web-based formats. Aggregated data from these reports shall be shared by the sub-network of single points of contact from national competent authorities referred to in Article 3 (5) with the Medicines Steering Group to inform recommendations on medicine shortage impact and management.

Or. en

Justification

Medicine shortages can lead to disease worsening, side effects from alternative treatments and even hospitalisation. Consumers/patients might also face extra costs due to alternative
medicines being more expensive or not reimbursed. To better understand the implications of medicine shortages, and minimise their impact, public authorities should collect and process information about medicine users’ experience with shortages.

Amendment 535
Kateřina Konečná

Proposal for a regulation
Article 11 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. Member States shall facilitate patient and consumer reporting of medicine shortages through the provision of alternative reporting formats in addition to web-based formats. Aggregated data from these reports shall be shared by the sub-network of single points of contact from national competent authorities referred to in Article 3 (5) with the Steering Group to inform recommendations on medicine shortage management.

Or. en

Justification

Drug shortages can lead to disease worsening, side effects from alternative treatments and even hospitalisation. Consumers might also face extra costs due to alternative medicines being more expensive or not reimbursed. To better understand the implications of drug shortages, and minimise their impact on consumers, public authorities should collect and process information about medicine users’ experience with shortages.

Amendment 536
Aldo Patriciello

Proposal for a regulation
Article 12 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

The Commission shall take into account the information from and recommendations

The Commission shall take into account the aggregated data from the harmonised pan-European interoperable and
of the Medicines Steering Group and shall: **digitalized shortages reporting and notification system, as well as** information from and recommendations of the Medicines Steering Group and shall:

Amendment 537
Pietro Fiocchi

Proposal for a regulation
Article 12 – paragraph 1 – point a a (new)

*Text proposed by the Commission*

(aa) The European Commission shall facilitate the coordination between manufacturers and other relevant stakeholders to address demand surges adapting with relevant European legislation including competition, internal market and pharmaceutical regulation.

Amendment

(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities, including healthcare professionals, to support them in their work and in the communication with patients;

Amendment 538
Tilly Metz

Proposal for a regulation
Article 12 – paragraph 1 – point b

*Text proposed by the Commission*

(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities;

Amendment

(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities, including healthcare professionals, to support them in their work and in the communication with patients;

Amendment 539
Sara Cerdas

Proposal for a regulation
Article 12 – paragraph 1 – point b

Text proposed by the Commission

(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities;

Amendment

(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities, including healthcare professionals to support them in their work and in the communication with patients;

Or. en

Amendment 540
Kateřina Konečná

Proposal for a regulation
Article 12 – paragraph 1 – point b

Text proposed by the Commission

(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities;

Amendment

(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities, including healthcare professionals to support them in their work and in the communication with patients;

Or. en

Amendment 541
Dolors Montserrat

Proposal for a regulation
Article 12 – paragraph 1 – point b

Text proposed by the Commission

(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities;

Amendment

(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities, including healthcare professionals to support them in their work and in the communication with patients;
support them in their work and in the communication with patients;

Amendment 542
Joanna Kopcińska, Margarita de la Pisa Carrión

Proposal for a regulation
Article 12 – paragraph 1 – point b

Text proposed by the Commission

(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities;

Amendment

(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities, including healthcare professionals, in order to support their work and communication with patients;

Or. en

Amendment 543
Joëlle Mélin

Proposal for a regulation
Article 12 – paragraph 1 – point b

Text proposed by the Commission

(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities;

Amendment

(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities where this is proportionate, justified and necessary;

Or. fr

Amendment 544
Cristian-Silviu Buşoi, Radan Kanev

Proposal for a regulation
Article 12 – paragraph 1 – point b
Proposal for a regulation
Article 12 – paragraph 1 – point b

Text proposed by the Commission
(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities;

Amendment
(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities including from the pharmaceutical supply chain;

Or. en

Amendment 545
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos, Ondřej Knotek

Proposal for a regulation
Article 12 – paragraph 1 – point b

Text proposed by the Commission
(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities;

Amendment
(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities including healthcare professionals;

Or. en

Amendment 546
Aldo Patriciello

Proposal for a regulation
Article 12 – paragraph 1 – point b

Text proposed by the Commission
(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities;

Amendment
(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities of the pharmaceuticals supply chain

Or. en

Amendment 547
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 12 – paragraph 1 – point b

Text proposed by the Commission
(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities;

Amendment
(b) consider the need for guidelines and recommendations addressed to Member States, marketing authorisation holders, and other entities;

Or. fr

Amendment 548
Pietro Fiocchi

Proposal for a regulation
Article 12 – paragraph 1 – point c

Text proposed by the Commission
(c) inform the Medicines Steering Group of any measures taken and report on the results;

Amendment
(c) inform the Medicines Steering Group and industry (via the trade associations) of any measures taken and report on the results;

Or. en

Amendment 549
Aldo Patriciello

Proposal for a regulation
Article 12 – paragraph 1 – point c

Text proposed by the Commission
(c) inform the Medicines Steering Group of any measures taken and report on the results;

Amendment
(c) inform the Medicines Steering Group and industry of any measures taken and report on the results;

Or. en
Amendment 550
Antoni Comín i Oliveres
Proposal for a regulation
Article 12 – paragraph 1 – point f a (new)

Text proposed by the Commission

(fa) assist the Agency in building the digital and interoperable database referred to in Article 1(b) and Article 12(g), with the following main tasks:

i. facilitate the prevention, monitoring and reporting of shortages of medicinal products, devices and applications,

ii. track and follow medicinal products, devices and applications throughout the supply chain,

iii. determine the volume of stock, the capabilities of all stakeholders linked in the supply chain or chains, the actual, current and foreseeable level of demand obtain,

iv. record and share information about innovative medicinal products, devices, applications or developments that are still not harmonised throughout the Union, such as plasma-derived products.

Or. en

Amendment 551
Antoni Comín i Oliveres
Proposal for a regulation
Article 12 – paragraph 1 – point f b (new)

Text proposed by the Commission

(fb) sanction those marketing authorisation holders, manufacturers or Member States that do not comply with the demands of information by the Agency;
Amendment 552
Margarita de la Pisa Carrión

Proposal for a regulation
Article 12 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The Commission shall provide answers to (priority) written questions from Members of the European Parliament within the deadline;

Or. en

Amendment 553
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos

Proposal for a regulation
Article 12 a (new)

Text proposed by the Commission

Amendment

Article 12 a

European medicines supply database

1. The Agency shall, in collaboration with the Commission and Member States, set up, maintain and manage the European medicines supply database (EUMSD) for the following purposes:

(a) to enable the monitoring of supply and demand of medicinal products at Union and Member State level;

(b) to enable the monitoring and reporting of shortages of medicinal products at Union and Member State level;

(c) to enable marketing authorisation holders and wholesale distributors to comply with the information obligations laid down in Article 10;
(d) to enable the Commission, the national competent authorities and the Agency to carry out their tasks relating to this Regulation on a well-informed basis and to enhance the cooperation between them.

The EUMSD, which shall be functional not only during public health emergencies and major events but also under normal circumstances, shall function as an interoperable and harmonised Union database, based on the data reported through the national electronic platforms established pursuant to paragraph 2. The database shall allow the national competent authorities and the Agency to simultaneously access and share the information provided in the database.

2. Each Member State shall develop an electronic platform for real-time monitoring of the supply of medicinal products, capable of determining the volume of supply existing at any given moment, and detecting, predicting and preventing shortages of medicinal products. Those platforms, which shall be managed by the national competent authorities, shall be fully operational at Member State level by [30 months after the date of entry into force of this Regulation].

Data on supply and demand shall be reported at Member State level by the following entities:

(a) marketing authorisation holders
(b) wholesale distributors
(c) community and hospital pharmacies

3. In addition to paragraph 2, the electronic platforms shall provide the national competent authorities with real-time access to unmet demands from wholesale distributors, community pharmacies and hospital pharmacies at national level. Those platforms shall also allow marketing authorisation holders to report any medicinal products supply
problems, including manufacturing problems.

4. Member State platforms shall be interoperable and shall replicate their information in the EUMSD managed by the Agency, thus preventing any duplication of the reporting process by the single points of contact established in Article 9(2).

5. The data generated by the Member State platforms and consequently by the EUMSD shall make it possible to identify any supply problems along the supply chain and, through the application of big data techniques and, where appropriate, artificial intelligence, shall be able to forecast supply problems in advance.

6. The data submitted shall be compliant with the International Organization for Standardization for the identification of medicinal products standards for the identification and description of medicinal products for human use and be based on the four domains of master data in pharmaceutical regulatory processes: substance, product, organisation and referential data.

7. The Agency shall, in collaboration with the Commission and Member States, draw up the functional specifications for the database, together with a plan for the implementation of the EUMSD and the Member State platforms by... [6 months after the entry into force of this Regulation] . That plan shall seek to ensure that the EUMSD is fully functional by...[48 months after the date of entry into force of this Regulation] .

8. Where a national competent authority indicates that the submitted information contains information of a commercially confidential nature, it shall identify the relevant parts and clarify the reasons for such an indication. The Agency shall assess the merits of each request and protect commercially confidential information against unjustified
disclosure.

9. Considering the commercially sensitive data provided in the EUMSD, access to the database shall be limited to the Commission, the Agency, national competent authorities reporting the data to the database and the Medicines Steering Group.

Justification

While supporting the Rapporteur's proposal for a streamlined and single platform to monitor, detect, predict and prevent shortages of medicinal products so as to be immediately operational in preparation for or during a health crisis, the tracking and tracing system appears too costly, burdensome for pharmacies, hospitals and self-dispensing doctors. We therefore propose to amend his proposal to rely on volumes of stocks throughout the supply chain rather than a tracking-and-tracing system of individual medicinal products.

Amendment 554
Tilly Metz

Proposal for a regulation
Article 13 – paragraph -1 (new)

Text proposed by the Commission

Amendment

-1 The Agency shall establish an early warning system to inform relevant stakeholders, including doctors and community and hospital pharmacists of any supply problems and potential or actual shortages of medicines included on the critical medicines list.

Amendment 555
Tilly Metz

Proposal for a regulation
Article 13 – paragraph 1
The Agency shall, via its web-portal and other appropriate means, in conjunction with national competent authorities, inform the public and interest groups with regard to the work of the Medicines Steering Group.

Or. en

Proposal for a regulation
Article 13 – paragraph 1

The Agency shall, via its web-portal and other appropriate means, in conjunction with national, or where applicable regional, competent authorities, inform the public and interest groups with regard to the work of the Medicines Steering Group, ensuring the sharing of information by the Patients’ and Consumers’ Working Party as well as a representative of the Healthcare Professionals’ Working Party as observers. The Agency shall assess the transparency of the undertakings of the Medicines Steering Group, taking into account principles of transparency and accountability.
Amendment 557
Kateřina Konečná

Proposal for a regulation
Article 13 – paragraph 1

**Text proposed by the Commission**

The Agency shall, via its web-portal and other appropriate means, in conjunction with national competent authorities, inform the public and interest groups with regard to the work of the Medicines Steering Group.

**Amendment**

The Agency shall, via its web-portal and other appropriate means, in conjunction with national competent authorities, inform the public and interest groups with regard to the work of the Medicines Steering Group, and ensure adequate consultation with the Patients’ and Consumers’ Working Party and the Healthcare Professionals’ Working Party.

Or. en

Amendment 558
Dan-Ştefan Motreanu

Proposal for a regulation
Article 13 – paragraph 1

**Text proposed by the Commission**

The Agency shall, via its web-portal and other appropriate means, in conjunction with national competent authorities, inform the public and interest groups with regard to the work of the Medicines Steering Group.

**Amendment**

The Agency shall, via its web-portal and other appropriate means, in conjunction with national competent authorities, inform the public and interest groups with regard to the work of the Medicines Steering Group, and ensure adequate consultation with the Patients’ and Consumers’ Working Party and the Healthcare Professionals’ Working Party.

Or. en

Amendment 559
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos

Proposal for a regulation
Article 13 – paragraph 1

Text proposed by the Commission

The Agency shall, via its web-portal and other appropriate means, in conjunction with national competent authorities, inform the public and interest groups with regard to the work of the Medicines Steering Group.

Amendment

The Agency shall, via its web-portal and other appropriate means, in conjunction with national competent authorities, inform without delay the public and interest groups with regard to the work of the Medicines Steering Group, and respond to disinformation as appropriate.

Or. en

Amendment 560
Danilo Oscar Lancini

Proposal for a regulation
Article 14 – paragraph 1

Text proposed by the Commission

1. The Emergency Task Force is hereby established as part of the Agency. It shall be convened during public health emergencies, either in person or remotely. The Agency shall provide its secretariat.

Amendment

1. The Emergency Task Force is hereby established as a permanent structure as part of the Agency. It shall be convened during public health emergencies, either in person or remotely. The Agency shall provide its secretariat. The Emergency Task Force shall work with scientific committees, working parties and scientific advisory groups of the Agency in the area of pandemic preparedness and response. It shall cooperate with Union bodies and agencies, the World Health Organization, third countries, and international scientific organisations on scientific and technical issues related to pandemic preparedness. The Agency, in collaboration with the Member States, shall, in parallel, proactively foster expertise building to avoid a shortage of expertise due to a public health emergency, in areas which are unrelated to the public health emergency.

Or. en
Amendment 561
Carlo Calenda

Proposal for a regulation
Article 14 – paragraph 1

Text proposed by the Commission

1. The Emergency Task Force is hereby established as part of the Agency. It shall be convened during public health emergencies, either in person or remotely. The Agency shall provide its secretariat.

Amendment

1. The permanent Emergency Task Force is hereby established as part of the Agency. It shall be convened during public health emergencies, either in person or remotely. The Agency shall provide its secretariat. The Emergency Task Force shall cooperate with EU bodies and agencies, the World Health Organization, third countries and international scientific organisations in preparing timely and appropriate responses to health emergencies. The Agency, working together with the Member States, shall undertake to develop the protocols and expertise necessary for a timely and appropriate response to health crises, including for sectors other than the health sector, in order to improve crisis response capacity.

Or. it

Amendment 562
Tudor Ciuhodaru

Proposal for a regulation
Article 14 – paragraph 1

Text proposed by the Commission

1. The Emergency Task Force is hereby established as part of the Agency. It shall be convened during public health emergencies, either in person or remotely. The Agency shall provide its secretariat.

Amendment

1. The Emergency Task Force is hereby established as part of the Agency. It shall be convened as often as needed during public health emergencies, either in person or remotely. The Agency shall provide its secretariat.
Amendment 563
Tilly Metz

Proposal for a regulation
Article 14 – paragraph 1

Text proposed by the Commission

1. The Emergency Task Force is hereby established as part of the Agency. It shall be convened during public health emergencies, either in person or remotely. The Agency shall provide its secretariat.

Amendment

1. The Emergency Task Force is hereby established as part of the Agency. It shall be convened in preparation for and during public health emergencies, either in person or remotely. The Agency shall provide its secretariat.

Or. en

Amendment 564
Joëlle Mélin

Proposal for a regulation
Article 14 – paragraph 1

Text proposed by the Commission

1. The Emergency Task Force is hereby established as part of the Agency. It shall be convened during public health emergencies, either in person or remotely. The Agency shall provide its secretariat.

Amendment

1. The Emergency Task Force is hereby established as part of the Agency. It shall be convened only during public health emergencies, either in person or remotely. The Agency shall provide its secretariat.

Or. fr

Amendment 565
Joëlle Mélin

Proposal for a regulation
Article 14 – paragraph 2 – point a

Text proposed by the Commission

1. The Emergency Task Force is hereby established as part of the Agency. It shall be convened during public health emergencies, either in person or remotely. The Agency shall provide its secretariat.

Amendment

1. The Emergency Task Force is hereby established as part of the Agency. It shall be convened only during public health emergencies, either in person or remotely. The Agency shall provide its secretariat.
(a) providing scientific advice and reviewing the available scientific data on medicinal products with the potential to address the public health emergency, including requesting data from developers and engaging with them in preliminary discussions;

(b) reviewing clinical trial protocols and providing advice to developers on clinical trials to be conducted in the Union for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency, in accordance with Article 15;

**Amendment 566**
Dan-Ştefan Motreanu

**Proposal for a regulation**
**Article 14 – paragraph 2 – point b**

*Text proposed by the Commission*

(b) reviewing clinical trial protocols and providing advice to developers on clinical trials to be conducted in the Union for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency, in accordance with Article 15;

*Amendment*

(b) reviewing clinical trial protocols and providing advice to developers on clinical trials to be conducted in the Union, in particular on large multicentre clinical trials, for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency, in accordance with Article 15;

**Amendment 567**
Tilly Metz

**Proposal for a regulation**
**Article 14 – paragraph 2 – point b**

*Text proposed by the Commission*

(b) reviewing clinical trial protocols and providing advice to developers on clinical trials to be conducted in the Union for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency, in accordance with Article 15;

*Amendment*

(b) reviewing clinical trial protocols and providing advice to developers on clinical trials to be conducted in the Union, in particular on large multi-centre trials, for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency, in accordance with Article 15;
Amendment 568
Kateřina Konečná

Proposal for a regulation
Article 14 – paragraph 2 – point b

Text proposed by the Commission
(b) reviewing clinical trial protocols and providing advice to developers on clinical trials to be conducted in the Union for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency, in accordance with Article 15;

Amendment
(b) reviewing clinical trial protocols and providing advice to developers on clinical trials to be conducted in the Union, in particular on large multicentre clinical trials, for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency, in accordance with Article 15;

Justification

During the COVID-19 pandemic, there has been a large mobilisation of resources to fund clinical trials for the development of vaccines and treatments. However, there has not been sufficient coordination among the various initiatives leading most likely to redundancies and delays. To avoid that, the Regulation should explicitly require in Article 14 that the Task Force that will be set up to promote the development of medicines that can help address public health emergencies supports coordinated multicentre trials.

Amendment 569
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 14 – paragraph 2 – point e

Text proposed by the Commission
(e) providing scientific recommendations with regard to the use of any medicinal product, which may have the potential to address public health emergencies, in accordance with Article 16;

Amendment
(e) providing scientific recommendations with regard to the use of any medicinal product, and in particular alternative medicinal products, which may have the potential to address public health emergencies, in accordance with Article 16;
Proposal for a regulation
Article 14 – paragraph 2 – point e

Text proposed by the Commission

(e) providing scientific recommendations with regard to the use of any medicinal product, which may have the potential to address public health emergencies, in accordance with Article 16;

Amendment

(e) providing scientific recommendations with regard to the use of any human or veterinary medicinal product, which may have the potential to address public health emergencies, in accordance with Article 16;

Proposal for a regulation
Article 14 – paragraph 2 – point e a (new)

Text proposed by the Commission

(ea) collecting information from national competent authorities and defining a pan-European list of alternative products for use to address public health emergencies. Such list shall be accessible for relevant healthcare stakeholders;

Amendment

Proposal for a regulation
Article 14 – paragraph 2 – point f
(f) cooperating with Union bodies and agencies, the World Health Organization, third countries, and international scientific organisations on scientific and technical issues relating to the public health emergency and to medicinal products which may have the potential to address public health emergencies, as necessary.

(Or. fr) Amendment 573
Kateřina Konečná

Proposal for a regulation
Article 14 – paragraph 3

Text proposed by the Commission

3. The Emergency Task Force shall be composed of representatives of the scientific committees, working parties, and staff members of the Agency, the coordination group established in accordance with Article 27 of Directive 2001/83/EC, and the Clinical Trials Coordination and Advisory Group established in accordance with Article 85 of Regulation (EU) 536/2014.\(^\text{21}\) External experts may be appointed and representatives of other Union bodies and agencies be invited on an ad hoc basis, as necessary. It shall be chaired by the Agency.

Amendment

3. The Emergency Task Force shall be composed of representatives of the scientific committees, working parties, including a representative of the Patients’ and Consumers’ Working Party and a representative of the Healthcare Professionals’ Working Party, and staff members of the Agency, the coordination group established in accordance with Article 27 of Directive 2001/83/EC, and the Clinical Trials Coordination and Advisory Group established in accordance with Article 85 of Regulation (EU) 536/2014.\(^\text{21}\) External experts may be appointed and representatives of other Union bodies and agencies be invited on an ad hoc basis, as necessary. It shall be chaired by the Agency.

Proposal for a regulation

Article 14 – paragraph 3

Text proposed by the Commission

3. The Emergency Task Force shall be composed of representatives of the scientific committees, working parties, and staff members of the Agency, the coordination group established in accordance with Article 27 of Directive 2001/83/EC, and the Clinical Trials Coordination and Advisory Group established in accordance with Article 85 of Regulation (EU) 536/2014. External experts may be appointed and representatives of other Union bodies and agencies be invited on an ad hoc basis, as necessary. It shall be chaired by the Agency.

Amendment

3. The Emergency Task Force shall be composed of representatives of the scientific committees, working parties, including a representative of the Patients’ and Consumers’ Working Party and a representative of the Healthcare Professionals’ Working Party, and staff members of the Agency, the coordination group established in accordance with Article 27 of Directive 2001/83/EC, and the Clinical Trials Coordination and Advisory Group established in accordance with Article 85 of Regulation (EU) 536/2014. External experts may be appointed and representatives of other Union bodies and agencies be invited on an ad hoc basis, as necessary. It shall be chaired by the Agency.

Proposal for a regulation
Article 14 – paragraph 3

Text proposed by the Commission

3. The Emergency Task Force shall be composed of representatives of the scientific committees, working parties, and staff members of the Agency, the coordination group established in accordance with Article 27 of Directive 2001/83/EC, and the Clinical Trials Coordination and Advisory Group established in accordance with Article 85 of Regulation (EU) 536/2014. External experts may be appointed and representatives of other Union bodies and agencies be invited on an ad hoc basis, as necessary. It shall be chaired by the Agency.

Amendment

3. The Emergency Task Force shall be composed of representatives of the Member States, of the scientific committees, working parties, and staff members of the Agency, the coordination group established in accordance with Article 27 of Directive 2001/83/EC, and the Clinical Trials Coordination and Advisory Group established under Heads of Medicines Agencies. Each Member State may appoint one representative. A Member State may delegate its tasks in the Emergency Task Force to another Member State. External experts may be appointed and representatives of other Union bodies and agencies be invited on an ad hoc basis, as necessary. It shall be chaired by the Agency.


Amendment 576
Tilly Metz

Proposal for a regulation
Article 14 – paragraph 3

Text proposed by the Commission

3. The Emergency Task Force shall be composed of representatives of the scientific committees, working parties, and staff members of the Agency, the coordination group established in

Amendment

3. The Emergency Task Force shall be composed of representatives of the scientific committees, working parties, namely representatives of the Patients’ and Consumers’ Working Party
accordance with Article 27 of Directive 2001/83/EC, and the Clinical Trials Coordination and Advisory Group established in accordance with Article 85 of Regulation (EU) 536/2014. 21 External experts may be appointed and representatives of other Union bodies and agencies be invited on an ad hoc basis, as necessary. It shall be chaired by the Agency.


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**Amendment 577**

Margarita de la Pisa Carrión

Proposal for a regulation

Article 14 – paragraph 3 a (new)

*Text proposed by the Commission*

**Amendment**

3 a. The Emergency Task Force shall be empowered to coordinate and exchange information and best practices with the health authorities of the Member States and the pharmaceutical industry in order to generate new synergies.

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**Amendment 578**

Joëlle Mélin

Proposal for a regulation
Article 14 – paragraph 5

Text proposed by the Commission

5. The Chair may invite representatives of Member States, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, and interest groups representing patients and healthcare professionals to attend its meetings.

Amendment

5. The Chair shall invite, to Emergency Task Force meetings throughout the public health emergency, representatives of Member States, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, and interest groups representing patients and healthcare professionals, in order to provide the Emergency Task Force with the broadest and most detailed view of the situation at all times throughout the public health emergency.

Or. fr

Amendment 579
Sara Cerdas

Proposal for a regulation
Article 14 – paragraph 5

Text proposed by the Commission

5. The Chair may invite representatives of Member States, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, and interest groups representing patients and healthcare professionals to attend its meetings.

Amendment

5. The Chair may invite representatives of Member States, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, independent clinical trial experts and researchers, and interest groups representing patients and healthcare professionals to attend its meetings.
Amendment 580  
Tilly Metz  

Proposal for a regulation  
Article 14 – paragraph 5  

Text proposed by the Commission  

5. The Chair may invite representatives of Member States, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, and interest groups representing patients and healthcare professionals to attend its meetings.  

Amendment  

5. The Chair may invite representatives of Member States, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, independent clinical trials experts and researchers, and interest groups representing patients and healthcare professionals to attend its meetings.  

Justification  

The Covid-19 pandemic has shown that independent clinical trials experts had been among the first to point out the weaknesses in clinical trial protocols. The EMA emergency Task Force should have the possibility to take the advice of independent clinical trials experts.  

Amendment 581  
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Nils Torvalds, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos, Ondřej Knotek  

Proposal for a regulation  
Article 14 – paragraph 5  

Text proposed by the Commission  

5. The Chair may invite representatives of Member States, members of scientific committees of the Agency and working parties, and third  

Amendment  

5. The Chair may invite representatives of Member States, members of scientific committees of the Agency and working parties, and third
parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, and interest groups representing patients and healthcare professionals to attend its meetings.

Amendment 582
Kateřina Konečná

Proposal for a regulation
Article 14 – paragraph 5

Text proposed by the Commission

5. The Chair may invite representatives of Member States, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, and interest groups representing patients and healthcare professionals to attend its meetings.

Amendment

5. The Chair may invite representatives of Member States, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, independent clinical trial experts and researchers, and interest groups representing patients and healthcare professionals to attend its meetings.

Justification

The Covid-19 pandemic has shown that independent clinical trials experts had been among the first to point out the weaknesses in clinical trial protocols. The EMA emergency Task Force should have the possibility to take the advice of independent clinical trials experts.

Amendment 583
Kateřina Konečná
Proposal for a regulation
Article 14 – paragraph 6

Text proposed by the Commission

6. The Emergency Task Force shall establish its rules of procedure including rules on the adoption of recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.

Amendment

6. The Emergency Task Force shall establish its rules of procedure including rules on the adoption of recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency. The rules of procedure including rules on the adoption of recommendations as well as the opinions should be made public on the Agency web-portal. The agenda and minutes of the Task Force shall be made public via the Agency web-portal.

Amendment 584
Tilly Metz

Proposal for a regulation
Article 14 – paragraph 6

Text proposed by the Commission

6. The Emergency Task Force shall establish its rules of procedure including rules on the adoption of recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.

Amendment

6. The Emergency Task Force shall establish its rules of procedure including rules on the adoption of recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency. The rules of procedure including rules on the adoption of recommendations, as well as the opinions meeting minutes and agendas should be made public on the Agency web-portal.

Or. en

Amendment 585
Joëlle Mélin

Proposal for a regulation
Article 14 – paragraph 6

Text proposed by the Commission

6. The Emergency Task Force shall establish its rules of procedure including rules on the adoption of recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.

Amendment

6. The Emergency Task Force shall establish its rules of procedure, which shall include rules relating to its formation, structure and confidentiality, including potential conflicts of interest. These rules of procedure shall also include rules on the adoption of recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.

Or. fr

Amendment 586
Joanna Kopcińska, Margarita de la Pisa Carrión

Proposal for a regulation
Article 14 – paragraph 6

Text proposed by the Commission

6. The Emergency Task Force shall establish its rules of procedure including rules on the adoption of recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.

Amendment

6. The Emergency Task Force shall establish its rules of procedure including rules on the adoption of recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency. The agenda and minutes of the Task Force shall be made public through the Agency’s online portal.

Or. en

Amendment 587
Tudor Ciuhodaru

Proposal for a regulation
Article 14 – paragraph 9 a (new)

Text proposed by the Commission

9a. The Agency shall use traditional and social media to issue periodic communications, agreed by all Member States, to keep the general public informed, using accessible language and providing explanations that can be understood by all;

Amendment

Or. ro

Amendment 588
Antoni Comín i Oliveres

Proposal for a regulation
Article 15 – paragraph 1

Text proposed by the Commission

1. During a public health emergency, the Emergency Task Force shall review clinical trial protocols submitted or intended to be submitted in a clinical trial application by developers of medicinal products as part of an accelerated scientific advice process.

Amendment

1. During a public health emergency, the Emergency Task Force shall review clinical trial protocols submitted or intended to be submitted in a clinical trial application by developers of medicinal products as part of an accelerated scientific advice process, taking into account possible innovative medicinal products, devices, applications or developments that are still not harmonised throughout the Union, such as plasma-derived products.

Or. en

Amendment 589
Margarita de la Pisa Carrión

Proposal for a regulation
Article 15 – paragraph 3

Text proposed by the Commission

3. The Emergency Task Force shall

Amendment

3. The Emergency Task Force shall
establish procedures for the request and submission of the set of information and data required, including information on the Member State or States where an application for authorisation of a clinical trial is submitted or is intended to be submitted.

establish procedures for the request and submission of the set of information and data required, in cooperation with the Member States where an application for authorisation of a clinical trial is submitted or is intended to be submitted in accordance with Article 4 of the Regulation 536/2014 on clinical trials on medicinal products for human use.

Or. en

Amendment 590
Stanislav Polčák

Proposal for a regulation
Article 15 – paragraph 4

Text proposed by the Commission

4. The Emergency Task Force shall involve representatives of the Member State or States where an application for authorisation of a clinical trial is submitted or is intended to be submitted in the preparation of the scientific advice.

Amendment

4. For the purposes of this Article, the Emergency Task Force shall involve representatives of the Member State or States where an application for authorisation of a clinical trial is submitted or is intended to be submitted in the preparation of the scientific advice.

Or. cs

Amendment 591
Ondřej Knotek

Proposal for a regulation
Article 15 – paragraph 5

Text proposed by the Commission

5. When authorising a clinical trial application for which scientific advice has been given, Member States shall take that advice duly into account.

Amendment

5. When authorising a clinical trial application for which scientific advice has been given, Member States shall take that advice duly into account. The scientific advice provided by the Emergency Task Force and endorsed by the Committee for Medicinal Products for Human Use
referred to in paragraph 2 shall have no binding force on the opinion of an independent Ethics Committee issued within authorisation of a clinical trial application.

Amendment 592
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Nils Torvalds, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos, Jan Huitema

Proposal for a regulation
Article 15 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. Where a clinical trial reviewed as part of an accelerated scientific advice process is authorised, the developer of the clinical trial shall:

(a) publish the study protocol at the start of the trial through the European Union clinical trials register;

(b) publish the summary of the results of the trial through the European Union clinical trials register by a deadline set by the Agency shorter than that laid down in Article 37 of Regulation (EU) No 536/2014, taking into consideration the public interest and nature of the health emergency.

Justification

The WHO has recommended that the deadline for reporting study results be shorter than the general 12 months in situations of public health emergency. See :

Amendment 593
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Susana Solís Pérez,
Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos

Proposal for a regulation
Article 15 – paragraph 5 b (new)

Text proposed by the Commission

5 b. Where a clinical trial took part in an accelerated scientific advice process and the related medicinal product receives a marketing authorisation, the Agency shall:

(a) publish the European Public Assessment Reports in full within 7 days of authorisation by the Commission;

(b) publish the clinical data submitted to the Agency in support of the application within two months of authorisation by the Commission, and after personal data have been anonymised and commercially confidential information redacted;

(c) publish the Risk Management Plan in full, and any updated version.

Or. en

Amendment 594
Joëlle Mélin

Proposal for a regulation
Article 16 – paragraph 1

Text proposed by the Commission

1. Following the recognition of a public health emergency, the Emergency Task Force shall undertake a review of the available scientific data on medicinal products, which may have the potential to be used to address the public health emergency. The review shall be regularly updated during the public health emergency.

Amendment

1. Following the recognition of a public health emergency, the Emergency Task Force shall undertake a review of the available scientific data on human or veterinary medicinal products, which may have the potential to be used to address the public health emergency. The review shall be regularly updated during the public health emergency.

Or. fr
Amendment 595
Tilly Metz

Proposal for a regulation
Article 16 – paragraph 2

*Text proposed by the Commission*

2. In preparation of the review, the Emergency Task Force may request information and data from marketing authorisation holders and from developers and engage with them in preliminary discussions. The Emergency Task Force may also, where available, make use of observational studies of health data generated outside of clinical studies taking into account their reliability.

*Amendment*

2. In preparation of the review, the Emergency Task Force may request information and data from marketing authorisation holders and from developers and engage with them in preliminary discussions. The Emergency Task Force may also, where available, make use of observational studies of health data generated outside of clinical studies taking into account their reliability. The Emergency Task Force shall liaise with medicine agencies of third countries for additional information and data exchange.

Or. en

Amendment 596
Joëlle Mélin

Proposal for a regulation
Article 16 – paragraph 2

*Text proposed by the Commission*

2. In preparation of the review, the Emergency Task Force *may* request information and data from marketing authorisation holders and from developers and engage with them in preliminary discussions. The Emergency Task Force may also, where available, make use of observational studies of health data generated outside of clinical studies taking into account their reliability.

*Amendment*

2. In preparation of the review, the Emergency Task Force *shall* request information and data from marketing authorisation holders and from developers and engage with them in preliminary discussions. The Emergency Task Force may also, where available, make use of observational studies of health data generated outside of clinical studies taking into account their reliability.

Or. fr
Amendment 597
Joëlle Mélin

Proposal for a regulation
Article 16 – paragraph 3 – introductory part

**Text proposed by the Commission**

3. Based on a request from one or more Member States, or the Commission, the Emergency Task Force shall provide recommendations to the Committee for Medicinal Products for Human Use for an opinion in accordance with paragraph 4 on the following:

**Amendment**

3. Based on a request from one or more Member States, or the Commission, the Emergency Task Force shall provide recommendations to the Committee for Medicinal Products for Human and Veterinary Use for an opinion in accordance with paragraph 4 on the following:

Or. fr

Amendment 598
Joëlle Mélin

Proposal for a regulation
Article 16 – paragraph 3 – point a

**Text proposed by the Commission**

(a) the compassionate use of medicinal products falling under the scope of Directive 2001/83/EC or Regulation (EC) No 726/2004;

**Amendment**

(a) the compassionate use of medicinal products falling under the scope of Directive 2001/83/EC or Regulation (EC) No 726/2004 and the whole production and distribution chain, as well as the adapted prescription by carers in accordance with Article 83(8) of Regulation (EC) No 726/2004;

Or. fr

Amendment 599
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos

Proposal for a regulation
Article 16 – paragraph 4

Text proposed by the Commission

4. Following receipt of the recommendation, the Committee for Medicinal Products for Human Use shall adopt an opinion on the conditions for use, the conditions for distribution and the patients targeted. The opinion shall be updated where necessary.

Amendment

4. Following receipt of the recommendation, the Committee for Medicinal Products for Human Use shall adopt an opinion on the conditions for use, the conditions for distribution and the patients targeted. The opinion shall be updated where necessary, and made public on the Agency's web-portal.

Or. en

Amendment 600
Joanna Kopcińska

Proposal for a regulation
Article 16 – paragraph 6

Text proposed by the Commission

6. In the preparation of its recommendations provided pursuant to paragraphs 3, the Emergency Task Force may consult the concerned Member State and request it to provide any information and data, which informed the Member State’s decision to make the medicinal product available for compassionate use. Following such a request, the Member State shall provide all of the requested information.

Amendment

6. In the preparation of its recommendations provided pursuant to paragraphs 3, the Emergency Task Force may consult the concerned Member State and request it to provide any information and data, which informed the Member State’s decision to make the medicinal product available for compassionate use. Following such a request, the Member State shall provide all of the best available requested information.

Or. en

Justification

Evidently, recommendations cannot impose binding obligations on Member States. However, in the event that a Member State considers it inappropriate to follow a recommendation, it should be obliged to state the reasons for any non-compliance in order to better understand the Member States’ respective situations.

Amendment 601
Ondřej Knotek

Proposal for a regulation
Article 16 – paragraph 7

Text proposed by the Commission

7. The Agency shall publish the opinions adopted pursuant to paragraph 4 including any updates on its web-portal.

Amendment

7. The Agency shall publish the recommendations provided pursuant to paragraph 3 and the opinions adopted pursuant to paragraph 4 including any updates on its web-portal.

Or. en

Amendment 602
Kateřina Konečná

Proposal for a regulation
Article 16 – paragraph 7

Text proposed by the Commission

7. The Agency shall publish the opinions adopted pursuant to paragraph 4 including any updates on its web-portal.

Amendment

7. The Agency shall publish the recommendations provided pursuant to paragraph 3 and opinions adopted pursuant to paragraph 4 including any updates on its web-portal

Or. en

Justification

Wording of Article 16 is not clear as regards the procedure following a potential negative opinion of ETF. If ETF does not recommend a medicinal product for rolling review, it should inform all Member States thereof and subsequent opinion of CHMP should be published in line with para 7. Wording of paragraph 4 implies that paragraph 7 refers only to “positive” recommendations. For the sake of transparency, the public should be informed also of negative outcomes of assessment by ETF and CHMP.

Amendment 603
Margarita de la Pisa Carrión

Proposal for a regulation
Article 16 – paragraph 7 a (new)
7a. Marketing authorisation holders or developers may suggest medicinal products which may have the potential to be used to address the public health emergency. The Emergency Taskforce shall take these suggestions into account and, given that the suggestion is accompanied with sufficient scientific data that the medicinal products have the potential to halt the public health emergency, give an appropriate reaction to the suggestion. The reaction shall be public.

Or. en

Amendment 604
Tilly Metz

Proposal for a regulation
Article 17 – paragraph 1

Text proposed by the Commission

The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Emergency Task Force.

Or. en

Amendment 605
Kateřina Konečná

The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Emergency Task Force, and ensure adequate consultation with the Patients’ and Consumers’ Working Party and the Healthcare Professionals’ Working Party. The list of the members of the Emergency Task Force, the rules of procedure, agendas and minutes of the meetings and recommendations shall be published on the Agency’s web-portal.
Proposal for a regulation  
Article 17 – paragraph 1

Text proposed by the Commission

The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Emergency Task Force.

Amendment

The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Emergency Task Force, and ensure adequate consultation with the Patients’ and Consumers’ Working Party and the Healthcare Professionals’ Working Party.

Or. en

Amendment 606  
Dan-Ștefan Motreanu

Proposal for a regulation  
Article 17 – paragraph 1

Text proposed by the Commission

The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Emergency Task Force.

Amendment

The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Emergency Task Force, and ensure adequate consultation with the Patients’ and Consumers’ Working Party and the Healthcare Professionals’ Working Party.

Or. en

Amendment 607  
Tudor Ciuhodaru

Proposal for a regulation  
Article 17 – paragraph 1
The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Emergency Task Force.

The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Emergency Task Force, as well as its decisions, proposals and recommendations to the national and European authorities.

Or. ro

Amendment 608
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ştefănuţă, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos

Proposal for a regulation
Article 17 – paragraph 1

Text proposed by the Commission

The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Emergency Task Force.

Amendment

The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Emergency Task Force, and respond to disinformation as appropriate.

Or. en

Amendment 609
Aldo Patriciello

Proposal for a regulation
Article 18 – paragraph 1 – introductory part

Text proposed by the Commission

To prepare for and support the work of the Emergency Task Force during public health emergencies, the Agency shall:

Amendment

To prepare for and support the work related to the reporting and notification obligations defined in this Regulation, as
well as the tasks of the Agency bodies established, including of the Emergency Task Force during public health emergencies, the Agency shall:

Or. en

Amendment 610
Aldo Patriciello

Proposal for a regulation
Article 18 – paragraph 1 – point a

Text proposed by the Commission

(a) develop and maintain electronic tools for the submission of information and data, including electronic health data generated outside the scope of clinical studies;

Amendment

(a) develop and maintain pan-European interoperable and digitalized electronic tools for the submission of information and data, including electronic health data generated outside the scope of clinical studies, as well as for the harmonised pan-European interoperable and digitalized shortages reporting and notification system, based on ISO IDMP standards for the identification of human medicines and based on a harmonized data collection model with interoperability with SPOR data, as well as on the EUDAMED IT platform for medical devices. Those platforms shall be accessible to relevant authorities at EU and national level to ensure the transparency needed to take actions to prevent and mitigate cross border shortages, as well as to avoid duplications of reporting at different levels;

Or. en

Amendment 611
Joëlle Mélin

Proposal for a regulation
Article 18 – paragraph 1 – point a
Text proposed by the Commission

(a) develop and maintain electronic tools for the submission of information and data, including electronic health data generated outside the scope of clinical studies;

Amendment

(a) develop and maintain European-designed electronic tools for the submission of information and data, including electronic health data generated outside the scope of clinical studies, in strict compliance with Union law on personal data and the GDPR;

Or. fr

Amendment 612
Cristian-Silviu Buşoi, Radan Kanev

Proposal for a regulation
Article 18 – paragraph 1 – point a

Text proposed by the Commission

(a) develop and maintain electronic tools for the submission of information and data, including electronic health data generated outside the scope of clinical studies;

Amendment

(a) develop and maintain electronic tools, including an interoperable and digitalized platform, for the submission of information and data, including electronic health data generated outside the scope of clinical studies;

Or. en

Amendment 613
Kateřina Konečná

Proposal for a regulation
Article 18 – paragraph 1 – point a

Text proposed by the Commission

(a) develop and maintain electronic tools for the submission of information and data, including electronic health data generated outside the scope of clinical studies;

Amendment

(a) develop and maintain electronic tools for the submission of information and data, including electronic health data generated outside the scope of interventional clinical studies;

Or. en
develop and maintain electronic tools for the submission of information and data, including electronic health data generated outside the scope of interventional clinical studies.

Amendment 614
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Nils Torvalds, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos

Proposal for a regulation
Article 18 – paragraph 1 – point b

Text proposed by the Commission

(b) coordinate independent **vaccine** effectiveness and safety monitoring studies using relevant data held by public authorities. Such coordination shall be conducted jointly with the European Centre for Disease Prevention and Control and notably through a new vaccine monitoring platform;

Amendment

(b) coordinate independent **utilisation**, effectiveness and safety monitoring studies **of medicinal products intended to treat, prevent or diagnose a disease** using relevant data held by public authorities; for **vaccines**, such coordination shall be conducted jointly with the European Centre for Disease Prevention and Control and notably through a new vaccine monitoring platform;

Or. en

Amendment 615
Joëlle Mélin

Proposal for a regulation
Article 18 – paragraph 1 – point c

Text proposed by the Commission

(c) as part of its regulatory tasks, make use of digital infrastructures or tools, to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of clinical studies, and the exchange of such data between Member States, the Agency, and other Union bodies;

Amendment

(c) as part of its regulatory tasks, make use of digital infrastructures or tools, to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of clinical studies, and the exchange of such data between Member States, the Agency, and other Union bodies, **in strict compliance with Union law on personal data and the GDPR**;
Amendment 616
Aldo Patriciello

Proposal for a regulation
Article 18 – paragraph 1 – point c

Text proposed by the Commission

(c) as part of its regulatory tasks, make use of digital infrastructures or tools, to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of clinical studies, and the exchange of such data between Member States, the Agency, and other Union bodies;

Amendment

(c) as part of its regulatory tasks, make use of digital infrastructures or tools, as referred to in point (a), to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of clinical studies, and the exchange of such data between Member States, the Agency, and other Union bodies;

Amendment 617
Kateřina Konečná

Proposal for a regulation
Article 18 – paragraph 1 – point c

Text proposed by the Commission

(c) as part of its regulatory tasks, make use of digital infrastructures or tools, to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of clinical studies, and the exchange of such data between Member States, the Agency, and other Union bodies;

Amendment

(c) as part of its regulatory tasks, make use of digital infrastructures or tools, to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of interventional clinical studies, and the exchange of such data between the Member States, the Agency, and the other Union bodies.

Justification

There is no definition of “data generated outside the scope of clinical trials” in the Proposal, for better clarity this concept should be defined. Namely, it should be specified whether it...
applies only to interventional clinical trials or also to observational (non-interventional) studies where no common rules for data sharing exist.

Amendment 618
Ondřej Knotek

Proposal for a regulation
Article 18 – paragraph 1 – point c

_text proposed by the Commission_

(c) as part of its regulatory tasks, make use of digital infrastructures or tools, to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of clinical studies, and the exchange of such data between Member States, the Agency, and other Union bodies;

_text proposed by the Commission_

(c) as part of its regulatory tasks, make use of digital infrastructures or tools, to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of interventional clinical studies, and the exchange of such data between Member States, the Agency, and other Union bodies;

Or. en

Amendment 619
Adam Jarubas

Proposal for a regulation
Article 18 – paragraph 1 – point d a (new)

_text proposed by the Commission_

(da) develop IT tools interoperable with harmonized shortages reporting systems of National Competent Authorities (NCAs) by building on the existing digital regulatory infrastructure and ongoing projects on data management and implement AI technics to among others forecast crisis development, prepare responses and proactively initiate optimisation of resources management.

_text proposed by the Commission_

(da) develop IT tools interoperable with harmonized shortages reporting systems of National Competent Authorities (NCAs) by building on the existing digital regulatory infrastructure and ongoing projects on data management and implement AI technics to among others forecast crisis development, prepare responses and proactively initiate optimisation of resources management.

Or. en
Amendment 620
Tilly Metz

Proposal for a regulation
Article 18 – paragraph 1 – point d a (new)

Text proposed by the Commission

(da) take urgent and appropriate measures to ensure the protection of health data from attacks against information systems. These measures should be built on combination of regular penetration testing, decentralised solutions and security by design principles.

Or. en

Amendment 621
Traian Băsescu

Proposal for a regulation
Article 18 – paragraph 1 – point d a (new)

Text proposed by the Commission

(da) develop, implement and coordinate an online European platform where consumers, pharmacists, medical professionals and all other European citizens can report shortages of medicinal products or medical devices in any of the Member States;

Or. ro

Amendment 622
Danilo Oscar Lancini

Proposal for a regulation
Article 18 – paragraph 1 – point d a (new)

Text proposed by the Commission
(da) develop IT tools interoperable with harmonized shortages reporting systems of National Competent Authorities (NCAs) by building on the existing digital regulatory infrastructure and ongoing projects on data management.

Amendment 623
Pietro Fiocchi

Proposal for a regulation
Article 18 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(da) develop IT tools interoperable with harmonized shortages reporting systems of National Competent Authorities (NCAs) by building on the existing digital regulatory infrastructure and ongoing projects on data management.

Amendment 624
Joëlle Mélin

Proposal for a regulation
Article 18 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(da) ensure that it has the necessary resources to secure and protect the data flow within the Agency, and in particular to resist and/or counter cyberattacks and human leaks of documentation;

Amendment 625
Antoni Comín i Oliveres

Proposal for a regulation
Article 18 – paragraph 1 – point d a (new)

Amendment
(da) build the digital and interoperable database as referred to in Article 1(b) and Article 12(g).

Or. en

Amendment 626
Tudor Ciuhodaru

Proposal for a regulation
Article 18 – paragraph 1 a (new)

Amendment
ensure enhanced protection of electronic tools and disseminated data against cyberattacks, deciding in conjunction with the Member States how the data in question can be accessed (users with access, data access period, data retention period);

Or. ro

Amendment 627
Kateřina Konečná

Proposal for a regulation
Article 18 a (new)

Amendment

Article 18 a

Public information about clinical trials and marketing authorisation decisions

1. For the duration of a public health emergency, the sponsors of clinical trials
conducted in the EU shall:
(a) publish the study protocol at the start of the trial through the EU clinical trials register;
(b) publish the summary of the results through the EU clinical trials register within a timeline set by the Agency that is shorter than the timeline laid down in Article 37 of Regulation (EU) No 536/2014.

2. The Agency shall publish:
(a) the European Public Assessment Reports as soon as possible and ideally within seven days of marketing authorisation;
(b) the full body of the Risk Management Plan and any updated versions.

Justification
Public health emergency situations require higher standards for the reporting of clinical trials. As recommended by the WHO, the deadline for reporting study results in these situations should be much shorter than the general rule of 12 months. Likewise, building on the transparency measures implemented during the COVID-19 pandemic, the EMA should provide enhanced information on marketing authorisation decisions. As such, the Regulation should require that the Agency publishes European Public Assessment Reports much quicker and Risk Management Plans in full.

Amendment 628
Dan-Ştefan Motreanu
Proposal for a regulation
Article 18 a (new)

Text proposed by the Commission

Amendment

Article 18 a
new Article 19

1. For the duration of a public health emergency, the sponsors of clinical trials conducted in the EU shall:
1. The Executive Steering Group on Medical Devices (‘the Medical Devices Steering Group’) is hereby established as part of the Agency. It shall meet either in person or remotely, in preparation for or during a public health emergency. The Agency shall provide its secretariat.

Amendment 629
Tudor Ciuhodaru

Proposal for a regulation
Article 19 – paragraph 1

Text proposed by the Commission

1. The Executive Steering Group on Medical Devices (‘the Medical Devices Steering Group’) is hereby established as part of the Agency. It shall meet as often as needed, either in person or remotely, in preparation for or during a public health emergency. The Agency shall provide its secretariat.

Amendment

1. The Executive Steering Group on Medical Devices (‘the Medical Devices Steering Group’) is hereby established as part of the Agency. It shall meet as often as needed, either in person or remotely, in preparation for or during a public health emergency. The Agency shall provide its secretariat.

Or. ro

Amendment 630
Antoni Comín i Oliveres

Proposal for a regulation
Article 19 – paragraph 2
2. The Medical Devices Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields. The Steering Group shall also include a representative of the Patients' and Consumers' Working Party as well as a representative of the Healthcare Professionals’ Working Party as observers. The Agency shall assess the transparency of the undertakings of the Executive Steering Group on Medical Devices, taking into account principles of transparency and accountability.

Proposal for a regulation
Article 19 – paragraph 2

Text proposed by the Commission

2. The Medical Devices Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields.
Amendment 632
Dan-Ștefan Motreanu

Proposal for a regulation
Article 19 – paragraph 2

2. The Medical Devices Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields.

Amendment
2. The Medical Devices Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields. The Steering Group shall also include a representative the Patients’ and Consumers’ Working Party and a representative of the Healthcare Professionals’ Working Party.

Amendment 633
Kateřina Konečná

Proposal for a regulation
Article 19 – paragraph 2

2. The Medical Devices Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields.

Amendment
2. The Medical Devices Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields. The Steering Group shall also include a representative the Patients’ and Consumers’ Working Party.

Or. en

Amendment 634
Tudor Ciuhodaru

Proposal for a regulation
Article 19 – paragraph 2

Text proposed by the Commission

2. The Medical Devices Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields.

Amendment

2. The Medical Devices Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one senior representative per Member State, including one alternate in case of unforeseen circumstances. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields.

Or. ro

Amendment 635
Tilly Metz

Proposal for a regulation
Article 19 – paragraph 2 a (new)

Text proposed by the Commission

2 a. Members of the Medical Devices Steering Group must have no financial or other interests that could affect their impartiality. They shall act in the public interest and in an independent manner and make an annual declaration of their financial interests. All indirect interests which could relate to the industry shall be entered in a register held by the Agency and be accessible to the public, upon request.

Amendment

2 a. Members of the Medical Devices Steering Group must have no financial or other interests that could affect their impartiality. They shall act in the public interest and in an independent manner and make an annual declaration of their financial interests. All indirect interests which could relate to the industry shall be entered in a register held by the Agency and be accessible to the public, upon request.

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Amendment 636
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 19 – paragraph 3

Text proposed by the Commission

3. The Medical Devices Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medical device interest groups to attend its meetings.

Amendment

3. The Medical Devices Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medical device interest groups, any other entity in the relevant pharmaceutical supply chain, healthcare professionals and patients’ associations, to attend its meetings to ensure transparent and effective dialogue between all stakeholders in the supply chain and the relevant authorities.

Amendment 637
Antoni Comín i Oliveres

Proposal for a regulation
Article 19 – paragraph 3

Text proposed by the Commission

3. The Medical Devices Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medical device interest groups to attend its meetings.

Amendment

3. The Medical Devices Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medical device interest groups to attend its meetings ensuring the sharing of information by the Patients’ and Consumers’ Working Party as well as a representative of the Healthcare Professionals’ Working Party as observers.

Or. fr

Or. en
Amendment 638
Tilly Metz

Proposal for a regulation
Article 19 – paragraph 3

Text proposed by the Commission

3. The Medical Devices Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medical device interest groups to attend its meetings.

Amendment

3. The Medical Devices Steering Group shall be chaired by the Agency. All members of the Medicines Steering Group may propose to the Chair to invite third parties, including representatives of medical device interest groups, in particular healthcare professionals, consumers and patients, to attend its meetings when their contribution may inform the discussions of the Steering Group.

Or. en

Amendment 639
Kateřina Konečná

Proposal for a regulation
Article 19 – paragraph 3

Text proposed by the Commission

3. The Medical Devices Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medical device interest groups to attend its meetings.

Amendment

3. The Medical Devices Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medical device interest groups and representatives of patients, consumers and healthcare professionals to attend its meetings.

Or. en

Amendment 640
Dan-Ștefan Motreanu
Proposal for a regulation
Article 19 – paragraph 3

Text proposed by the Commission

3. The Medical Devices Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medical device interest groups to attend its meetings.

Amendment

3. The Medical Devices Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medical device interest groups and representatives of patients, consumers and healthcare professionals to attend its meetings.

Or. en

Amendment 641
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos, Ondřej Knotek

Proposal for a regulation
Article 19 – paragraph 3

Text proposed by the Commission

3. The Medical Devices Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medical device interest groups to attend its meetings.

Amendment

3. The Medical Devices Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medical device interest groups, representatives of patients and healthcare professionals, to attend its meetings.

Or. en

Amendment 642
Joëlle Mélin

Proposal for a regulation
Article 19 – paragraph 3 a (new)

Text proposed by the Commission

3a. The Medical Devices Steering Group shall regularly invite representatives of medicinal product

Amendment

3a. The Medical Devices Steering Group shall regularly invite representatives of medicinal product
interest groups and marketing authorisation holders, as well as other stakeholders in the pharmaceutical industry, to discuss the situation of drug production in Europe and worldwide. On the basis of these exchanges, the Medical Devices Steering Group shall draw up strategic recommendations which it shall address to the Member States during the public health emergency period.

Amendment 643
Tilly Metz

Proposal for a regulation
Article 19 – paragraph 4

_text proposed by the Commission_

4. The Medical Devices Steering Group shall establish its rules of procedure including procedures relating to the working party referred to in paragraph 5, and on the adoption of lists, sets of information and recommendations. The rules of procedures shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.

-Amendment-

4. The Medical Devices Steering Group shall establish its rules of procedure including procedures relating to the working party referred to in paragraph 5, and on the adoption of lists, sets of information and recommendations. The rules of procedures shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency. **Agendas and minutes of the Steering Group as well as the rules of procedure and recommendations should be made available to the public via the Agency web-portal.**

Or. en

Amendment 644
Antoni Comín i Oliveres

Proposal for a regulation
Article 19 – paragraph 5
5. The Medical Devices Steering Group shall be supported in its work by a working party comprised of single points of contact from national competent authorities for medical devices established in accordance with Article 23(1).

Amendment 645
Joanna Kopcińska

Proposal for a regulation
Article 19 – paragraph 5

Text proposed by the Commission

5. The Medical Devices Steering Group **shall** be supported in its work by a working party comprised of single points of contact from national competent authorities for medical devices established in accordance with Article 23(1).

Amendment

5. The Medical Devices Steering Group **may** be supported in its work by a working party comprised of single points of contact from national competent authorities for medical devices established in accordance with Article 23(1).

Or. en

**Justification**

The national competent authorities for medical devices supervise the safety and effectiveness of medical devices; they do not supervise and monitor medical entities and therefore are unaware of their needs for medical devices. Moreover, manufacturers, importers and distributors, do not supervise the users of such devices, as this would be an obvious conflict of interest. It is therefore unclear where the competent authorities will obtain the data on the volume of demand included in the above-mentioned inventory, and why these authorities should provide such data to the EMA.

Amendment 646
Margarita de la Pisa Carrión

Proposal for a regulation
Article 19 – paragraph 5 a (new)
5 a. The Medical Devices Steering Group will establish the basis for strengthened cooperation with national health authorities and the pharmaceutical industry.

Or. en

Amendment 647
Kateřina Konečná

Proposal for a regulation
Article 19 – paragraph 6 a (new)

Text proposed by the Commission

6 a. The members of the Medicines Steering Group must have no financial or other interests that could affect their impartiality. The list of members shall be published on the Agency website.

Or. en

Amendment 648
Dan-Ștefan Motreanu

Proposal for a regulation
Article 19 – paragraph 6 a (new)

Text proposed by the Commission

6 a. The members of the Medicines Steering Group must have no financial or other interests that could affect their impartiality. The list of members shall be published on the Agency website.

Or. en

Amendment 649
Joëlle Mélin

Proposal for a regulation
Article 20 – paragraph 1

Text proposed by the Commission

1. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medical Devices Steering Group shall adopt a list of medical devices which it considers as critical during the public health emergency (‘the public health emergency critical devices list’). The list shall be updated whenever necessary until the termination of the recognition of the public health emergency.

Amendment

1. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medical Devices Steering Group, after consulting marketing authorisation holders and representatives of stakeholders in the sector, shall adopt a list of medical devices which it considers as critical during the public health emergency (‘the public health emergency critical devices list’). The list shall be updated whenever necessary until the termination of the recognition of the public health emergency, and shall cease to apply at the end of the public health emergency.

Or. fr

Amendment 650
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 20 – paragraph 1

Text proposed by the Commission

1. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medical Devices Steering Group shall adopt a list of medical devices which it considers as critical during the public health emergency (‘the public health emergency critical devices list’). The list shall be updated whenever necessary until the termination of the recognition of the public health emergency.

Amendment

1. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medical Devices Steering Group, in coordination with stakeholders in the sector, shall adopt a list of medical devices which it considers as critical during the public health emergency (‘the public health emergency critical devices list’). The list shall be updated whenever necessary until the termination of the recognition of the public health emergency.

Or. fr
Amendment 651
Tudor Ciuhodaru

Proposal for a regulation
Article 20 – paragraph 1

Text proposed by the Commission

1. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medical Devices Steering Group shall adopt a list of medical devices which it considers as critical during the public health emergency (‘the public health emergency critical devices list’). The list shall be updated whenever necessary until the termination of the recognition of the public health emergency.

Amendment

1. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medical Devices Steering Group shall adopt a list of medical devices which it considers as critical during the public health emergency (‘the public health emergency critical devices list’) as well as minimum necessary stock levels. The list shall be updated whenever necessary until the termination of the recognition of the public health emergency.

Or. ro

Amendment 652
Joanna Kopcińska

Proposal for a regulation
Article 20 – paragraph 2

Text proposed by the Commission

2. The Medical Devices Steering Group shall adopt a set of information necessary to monitor the supply and demand of medical devices included on the public health emergency critical devices list and inform its working party thereof.

Amendment

2. The Medical Devices Steering Group shall adopt a set of information necessary to only monitor data for the long-term safety assessment of medical devices included on the public health emergency critical devices list.

Or. en

Amendment 653
Joëlle Mélin
Proposal for a regulation
Article 20 – paragraph 3

Text proposed by the Commission

3. The Agency shall publish the public health emergency critical devices list and any updates to that list on its web-portal.

Amendment

3. The Agency shall publish the public health emergency critical devices list and any updates to that list on its web-portal. This list shall be published in a clear and accessible way so that Member States, actors in the pharmaceutical supply chain and all stakeholders can easily access this information and, where appropriate, can easily report possible changes or publication problems.

Or. fr

Amendment 654
Joëlle Mélin

Proposal for a regulation
Article 20 – paragraph 3 a (new)

Text proposed by the Commission

3a. The Agency, in cooperation with the Commission and the national competent authorities of the Member States, shall work with representatives of the European medical device industry to ensure that medical devices included on the critical devices list made available in one Member State are equally available in all Member States, in one form or another, and in particular in smaller Member States.

Amendment

3a. The Agency, in cooperation with the Commission and the national competent authorities of the Member States, shall work with representatives of the European medical device industry to ensure that medical devices included on the critical devices list made available in one Member State are equally available in all Member States, in one form or another, and in particular in smaller Member States.

Or. fr

Amendment 655
Tilly Metz

Proposal for a regulation
Article 20 – paragraph 3 a (new)
Text proposed by the Commission

3 a. The Agency shall report about the shortage of public health emergency critical devices through the database referred to in Article 6 (4a).

Amendment

Or. en

Amendment 656
Dan-Ştefan Motreanu

Proposal for a regulation
Article 20 – paragraph 3 a (new)

Text proposed by the Commission

3 a. The Agency shall report about the shortage of public health emergency critical devices through the database referred to in Article 6(5).

Amendment

Or. en

Amendment 657
Kateřina Konečná

Proposal for a regulation
Article 20 – paragraph 3 a (new)

Text proposed by the Commission

3 a. The Agency shall report about the shortage of public health emergency critical devices through the database referred to in Article 6(5).

Amendment

Or. en

Amendment 658
Joëlle Mélin
Proposal for a regulation
Article 21 – paragraph 1

Text proposed by the Commission

1. On the basis of the public health emergency critical devices list and the information and data provided in accordance with Articles 24 and 25, the Medical Devices Steering Group shall monitor supply and demand of medical devices included on that list with a view to identifying any potential or actual shortages of those medical devices. As part of that monitoring, the Medical Devices Steering Group shall liaise, where relevant, with the Health Security Committee established in Article 4 of Regulation (EU) 2020/…[1] and the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation.

22 [insert reference to adopted text referred to in footnote 4]

Amendment

1. On the basis of the public health emergency critical devices list and the information and data provided in accordance with Articles 24 and 25 of this Regulation, the Medical Devices Steering Group shall meet regularly throughout the major event or public health emergency with the working group of designated national contact points for medicines shortages within the national competent authorities for medicines and with representatives of the medicines production and distribution sectors in order to monitor supply and demand of medical devices included on that list with a view to identifying any potential or actual shortages of those medical devices and to adapt the list as best as possible throughout the major event or emergency. As part of that monitoring, the Medical Devices Steering Group shall liaise, where relevant, with the Health Security Committee established in Article 4 of Regulation (EU) 2020/…[1] and the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation.

[1] [insérer référence au texte adopté mentionné à la note de bas de page 4]

Amendment 659
Joanna Kopcińska

Proposal for a regulation
Article 21 – paragraph 1

Text proposed by the Commission

Amendment

Or. fr
1. On the basis of the public health emergency critical devices list and the information and data provided in accordance with Articles 24 and 25, the Medical Devices Steering Group shall monitor supply and demand of medical devices included on that list with a view to identifying any potential or actual shortages of those medical devices. As part of that monitoring, the Medical Devices Steering Group shall liaise, where relevant, with the Health Security Committee established in Article 4 of Regulation (EU) 2020/ [...] and the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation.

22 [insert reference to adopted text referred to in footnote 4]

Justification

It should be noted that as a result of the ongoing COVID-19 pandemic, a list of diagnostic medical devices to be observed as critical in a public health emergency has already been developed by the MDCG, established pursuant to Article 103 of Regulation (EU) 2017/745 and Article 98 of Regulation (EU) 2017/746.

Amendment 660
Joanna Kopcińska

Proposal for a regulation
Article 21 – paragraph 2

Text proposed by the Commission
Amendment

2. As part of the monitoring, the Medical Devices Steering Group may also make use of data from device registries and databanks where such data is available to the Agency. In so doing, the Medical Devices Steering Group shall take into account the data generated pursuant to Article 108 of Regulation

Justification

The registers and databases do not and will not contain any data useful for the assessment of supply and demand, as they only gather data used to assess the long-term safety and performance of medical devices. Up-to-date information on medical devices, their manufacturers, authorised representatives and importers will already be included in the EUDAMED database referred to in Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices. The obligation of inventories should be reported by manufacturers, authorised representatives and importers should be part of EUDAMED.

Amendment 661
Joëlle Mélin

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission

1. For the duration of the public health emergency, the Medical Devices Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article 23(1)(b), and, in particular, signal any potential or actual shortages of medical devices included on the public health emergency critical devices list.

Amendment

1. For the duration of the public health emergency, the Medical Devices Steering Group shall regularly report the results of its monitoring to the Commission, national public health authorities and the sub-network referred to in Article 23(1)(b), and, in particular, signal any potential or actual shortages of medical devices included on the public health emergency critical devices list.

Amendment 662
Joëlle Mélin

Proposal for a regulation
Article 22 – paragraph 2

Text proposed by the Commission

Amendment
2. Where requested by the Commission or the sub-network referred to in Article 23(2)(b), the Medical Devices Steering Group shall provide aggregated data and forecasts of demand to support its findings. In that regard, the Steering Group shall liaise with the European Centre for Disease Prevention and Control to obtain epidemiological data to help forecast medical device needs, and with the Medicines Steering Group referred to in Article 3 where medical devices included on the public health emergency critical devices list are used jointly with a medicinal product.

Amendment 663
Joanna Kopcińska

Proposal for a regulation
Article 22 – paragraph 3

Text proposed by the Commission

3. As part of the reporting referred to in paragraphs 1 and 2, the Medical Devices Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, medical device manufacturers, notified bodies and other entities to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, where relevant, with the Health Security Committee and the Advisory Committee on public health emergencies.

Amendment

deleted

Justification

As registers and databases only gather data used to assess the long-term safety and performance of medical devices, this provision should be deleted. Up-to-date information on medical devices, their manufacturers, authorised representatives and importers will already

Amendment 664
Joanna Kopcińska

Proposal for a regulation
Article 22 – paragraph 4

Text proposed by the Commission

4. The Medical Devices Steering Group may, on its own initiative or upon request from the Commission, provide recommendations on measures which may be taken by the Commission, Member States, medical device manufacturers, notified bodies and other entities to ensure preparedness to deal with potential or actual shortages of medical devices caused by public health emergencies.

Or. en

Justification

The national competent authorities for medical devices supervise the safety and effectiveness of medical devices; they do not supervise and monitor medical entities and therefore are unaware of their needs for medical devices. Moreover, manufacturers, importers and distributors, do not supervise the users of such devices, as this would be an obvious conflict of interest. It is therefore unclear where the competent authorities will obtain the data on the volume of demand included in the above-mentioned inventory, and why these authorities should provide such data to the EMA.

Amendment 665
Antoni Comin i Oliveres

Proposal for a regulation
Article 22 – paragraph 5

Text proposed by the Commission

5. The Medical Devices Steering Group may, upon request from the Commission coordinate measures, where relevant, between the national competent

5. The Medical Devices Steering Group may, upon request from the Commission coordinate measures, where relevant, between the national, and where
authorities, manufacturers of medical devices, notified bodies, and other entities to prevent or mitigate potential or actual shortages in the context of a public health emergency.

applicable regional, competent authorities, manufacturers of medical devices, notified bodies, and other entities to prevent or mitigate potential or actual shortages in the context of a public health emergency.

Amendment 666
Joëlle Mélin

Proposal for a regulation
Article 22 – paragraph 5 a (new)

Text proposed by the Commission

5a. The measures recommended by the Steering Group to the Commission, Member States, marketing authorisation holders and other stakeholders should include a relaxing of rules to deal with potential shortages.

Amendment

1. In order to prepare for fulfilling the tasks referred to in Articles 20, 21 and 22, the Agency shall:

Or. fr

Amendment 667
Joëlle Mélin

Proposal for a regulation
Article 23 – paragraph 1 – introductory part

Text proposed by the Commission

1. In order to prepare for fulfilling the tasks referred to in Articles 20, 21 and 22, and after consulting representatives of national authorities and marketing authorisation holders, as well as other stakeholders in the pharmaceutical sector, the Agency shall:

Or. fr
Amendment 668
Tilly Metz

Proposal for a regulation
Article 23 – paragraph 1 – point a

Text proposed by the Commission
(a) specify the procedures for establishing the public health emergency critical devices list;

Amendment
(a) specify the procedures for establishing the public health emergency critical devices list, ensuring adequate consultation with healthcare professionals, consumers, patients and a high level of transparency in decision-making;

Or. en

Amendment 669
Dan-Ștefan Motreanu

Proposal for a regulation
Article 23 – paragraph 1 – point a

Text proposed by the Commission
(a) specify the procedures for establishing the public health emergency critical devices list;

Amendment
(a) specify the procedures for establishing the public health emergency critical devices list, ensuring adequate consultation with consumers, patients and healthcare professionals and a high level of transparency;

Or. en

Amendment 670
Kateřina Konečná

Proposal for a regulation
Article 23 – paragraph 1 – point a

Text proposed by the Commission
(a) specify the procedures for establishing the public health emergency critical devices list;

Amendment
(a) specify the procedures for establishing the public health emergency critical devices list.
critical devices list; critical devices list, ensuring adequate consultation with consumers, patients and healthcare professionals and a high level of transparency;

Amendment 671
Antoni Comín i Oliveres

Proposal for a regulation
Article 23 – paragraph 1 – point a

Text proposed by the Commission

(a) specify the procedures for establishing the public health emergency critical devices list;

Amendment

(a) specify the procedures for establishing the public health emergency critical devices list, ensuring adequate consultation with consumers, patients and healthcare professionals and a high level of transparency;

Or. en

Amendment 672
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 23 – paragraph 1 – point a

Text proposed by the Commission

(a) specify the procedures for establishing the public health emergency critical devices list;

Amendment

(a) specify the procedures and criteria for establishing the public health emergency critical devices list;

Or. fr

Amendment 673
Tudor Ciuhodaru

Proposal for a regulation
Article 23 – paragraph 1 – point b
Text proposed by the Commission

(b) develop streamlined electronic monitoring and reporting systems;

Amendment

(b) develop streamlined electronic monitoring and reporting systems, including for existing or potential stock levels;

Or. ro

Amendment 674
Antoni Comín i Oliveres

Proposal for a regulation
Article 23 – paragraph 1 – point c

Text proposed by the Commission

(c) establish and maintain membership of the working party referred to in Article 19(5) comprised of single points of contact from Member States’ national competent authorities for medical devices;

Amendment

(c) establish and maintain membership of the working party referred to in Article 19(5) comprised of single points of contact from Member States’ national, and where applicable regional, competent authorities for medical devices;

Or. en

Amendment 675
Tilly Metz

Proposal for a regulation
Article 23 – paragraph 1 – point d

Text proposed by the Commission

(d) establish and maintain a list of single points of contact from medical device manufacturers, authorised representatives and notified bodies;

Amendment

(d) establish and maintain a list of single points of contact from medical device manufacturers, authorised representatives and notified bodies;

Or. en

Justification

It will be extremely difficult for the Agency to manually set-up and maintain a list of contact
points for medical devices manufacturers, authorised representatives and NBs as proposed in article 23.1(d) since the EMA does not hold any information with regard to these stakeholders. However, since there exists a database of medical device manufacturers i.e. EUDAMED, it would be much more efficient to include such contact details in the EUDAMED database. It is therefore proposed to remove requirement (d) from Article 23.1 and to add a reference to EUDAMED in Article 23.2.

**Amendment 676**

**Tilly Metz**

**Proposal for a regulation**

**Article 23 – paragraph 2 – point a**

**Text proposed by the Commission**

(a) establish and maintain for the duration of the public health emergency, a sub-network of single points of contact from medical device manufacturers and notified bodies based on the medical devices included on the public health emergency critical devices list;

**Amendment**

(a) establish and maintain for the duration of the public health emergency, a sub-network of single points of contact from medical device manufacturers and notified bodies based on the medical devices included on the public health emergency critical devices list based on single points of contact to be included for all medical device manufacturers in the database referred to in Article 33 of Regulation (EU) 2017/745 and Article 30 of Regulation (EU) 2017/746;

Or. en

**Amendment 677**

**Antoni Comín i Oliveres**

**Proposal for a regulation**

**Article 23 – paragraph 2 – point c**

**Text proposed by the Commission**

(c) request information from the single points of contact from Member States’ national competent authorities based on the set of information agreed on by the Medical Devices Steering Group and set a deadline for its submission.

**Amendment**

(c) request information from the single points of contact from Member States’ national, and where applicable regional, competent authorities based on the set of information agreed on by the Medical Devices Steering Group and set a deadline for its submission.
Amendment 678
Joëlle Mélin

Proposal for a regulation
Article 23 – paragraph 3 – point e

Text proposed by the Commission

Amendment

(e) sales and market share data; deleted

Or. fr

Amendment 679
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 23 – paragraph 3 – point e

Text proposed by the Commission

Amendment

(e) sales and market share data; (e) sales, stock, where relevant, and market share data;

Or. fr

Amendment 680
Tilly Metz

Proposal for a regulation
Article 23 – paragraph 3 – point f

Text proposed by the Commission

Amendment

(f) mitigation plans including production and supply capacity; (f) prevention and mitigation plans including production and supply capacity; such plans shall contain preventative measures that help ensure the continued supply of critical medical devices;

Or. en
Amendment 681
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Nils Torvalds, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos

Proposal for a regulation
Article 23 – paragraph 3 – point f

Text proposed by the Commission

(f) mitigation plans including production and supply capacity;

Amendment

(f) mitigation plans including production and supply capacity, with a view to guarantee continued supply and prevent shortages of medicinal products included on the critical medicines lists;

Or. en

Amendment 682
Dan-Ștefan Motreanu

Proposal for a regulation
Article 23 – paragraph 3 – point f

Text proposed by the Commission

(f) mitigation plans including production and supply capacity;

Amendment

(f) mitigation plans including production and supply capacity; these plans shall contain preventative measures that help ensure the continued supply of critical medical devices;

Or. en

Amendment 683
Kateřina Konečná

Proposal for a regulation
Article 23 – paragraph 3 – point f

Text proposed by the Commission

(f) mitigation plans including production and supply capacity;

Amendment

(f) mitigation plans including production and supply capacity; these plans shall contain preventative measures
that help ensure the continued supply of critical medical devices;

Or. en

Amendment 684
Antoni Comín i Oliveres

Proposal for a regulation
Article 23 – paragraph 3 – point f

Text proposed by the Commission

(f) mitigation plans including production and supply capacity;

Amendment

(f) mitigation plans, containing preventative measures to ensure the continued supply of critical medical devices as well as including production and supply capacity;

Or. en

Amendment 685
Tudor Ciuhodaru

Proposal for a regulation
Article 23 – paragraph 3 – point f

Text proposed by the Commission

(f) mitigation plans including production and supply capacity;

Amendment

(f) mitigation plans including production and supply capacity, so as to ensure the minimum stock levels required;

Or. ro

Amendment 686
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 23 – paragraph 3 – point f

Text proposed by the Commission

Amendment
(f) prevention and mitigation plans including production and supply capacity;

Amendment 687
Joëlle Mélin

Proposal for a regulation
Article 24 – paragraph 1

Text proposed by the Commission

1. In order to facilitate the monitoring referred to in Article 21 and following a request from the Agency, medical device manufacturers of the medical devices included on the public health emergency critical devices list and, where necessary, concerned notified bodies, shall submit the information requested by the deadline set by the Agency. They shall submit the information requested through the points of contact designated in accordance with Article 23(2) and using the reporting methods and system established pursuant to Article 23(1). They shall provide updates wherever necessary.

Amendment

1. In order to facilitate the monitoring referred to in Article 21 and following a request from the Agency, medical device manufacturers of the medical devices included on the public health emergency critical devices list, and all distributors legally authorised to supply medical devices to the public and, where necessary, concerned notified bodies, shall submit the information requested by the deadline set by the Agency. They shall submit the information requested through the points of contact designated in accordance with Article 23(2) and using the reporting methods and system established pursuant to Article 23(1). They shall provide updates wherever necessary.

Amendment 688
Joanna Kopcińska

Proposal for a regulation
Article 24 – paragraph 4

Text proposed by the Commission

4. Where manufacturers of medical devices included on the public health emergency critical devices list and concerned notified bodies are in

Amendment

deleted
possession of any additional information, which provides evidence of a potential or actual shortage, they shall immediately provide such information to the Agency.

Or. en

Justification

The marketing departments of manufacturers, either directly or through importers and distributors, monitor the needs of healthcare facilities, in addition to cooperating with procurement departments, management and outlet staff. Furthermore, their development and production departments also take account of supply chain requirements and their technological capabilities. In this regard, manufacturers are already active and prepared in times of crisis in the supply of medical devices.

Amendment 689
Kateřina Konečná

Proposal for a regulation
Article 24 – paragraph 6 a (new)

.Text proposed by the Commission

Amendment

6 a. The Commission and Member States shall lay down rules on sanctions for non-compliance with the obligations established under this Article. These sanctions shall be dissuasive.

Or. en

Amendment 690
Dan-Ştefan Motreanu

Proposal for a regulation
Article 24 – paragraph 6 a (new)

.Text proposed by the Commission

Amendment

6 a. The Commission and Member States shall lay down rules on sanctions for non-compliance with the obligations established under this Article. These sanctions shall be dissuasive.
Amendment 691
Tilly Metz

Proposal for a regulation
Article 24 – paragraph 6 a (new)

Text proposed by the Commission
Amendment

6 a. The Commission shall exercise its power to lay down rules on sanctions for non-compliance with the obligations established under this Article in a delegated act.

Amendment 692
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 25 – paragraph 1 – introductory part

Text proposed by the Commission
Amendment

1. In order to facilitate the monitoring referred to in Article 21 and following a request from the Agency, Member States shall, by the deadline set by the Agency:

1. In order to facilitate the monitoring referred to in Article 21 and following a request from the Agency, Member States or any national competent authority shall, by the deadline set by the Agency:

Amendment 693
Joëlle Mélin

Proposal for a regulation
Article 25 – paragraph 1 – point b

Text proposed by the Commission
Amendment

(b) indicate the existence of any commercially confidential information,

(b) indicate the existence of any commercially confidential information,
and, clarify the reasons for such an indication;

and, clarify the reasons for such an indication, in accordance with Article 30 of this Regulation;

Or. fr

Amendment 694
Antoni Comín i Oliveres

Proposal for a regulation
Article 25 – paragraph 1 – point c a (new)

Text proposed by the Commission

(ca) regional authorities with devolved health policy competences shall also comply with Article 25 and provide this information both to the national competent authority and to the Agency.

Amendment

Or. en

Amendment 695
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ştefănuţă, Susana Solis Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos, Ondřej Knotek

Proposal for a regulation
Article 25 – paragraph 4 – point a

Text proposed by the Commission

(a) consider the need to provide for temporary exemptions at Member State level pursuant to Article 59(1) of Regulation (EU) 2017/745 or Article 54(1) of Regulation (EU) 2017/746 with a view to mitigating potential or actual shortages of medical devices included on the public health emergency critical devices list;

Amendment

(a) consider the need to provide for temporary exemptions at Member State level pursuant to Article 59(1) of Regulation (EU) 2017/745 or Article 54(1) of Regulation (EU) 2017/746 with a view to mitigating potential or actual shortages of medical devices included on the public health emergency critical devices list, while at the same time ensuring a high level of patient and product safety;

Or. en
Amendment 696
Dolors Montserrat

Proposal for a regulation
Article 25 – paragraph 4 – point a

Text proposed by the Commission

(a) consider the need to provide for temporary exemptions at Member State level pursuant to Article 59(1) of Regulation (EU) 2017/745 or Article 54(1) of Regulation (EU) 2017/746 with a view to mitigating potential or actual shortages of medical devices included on the public health emergency critical devices list;

Amendment

(a) consider the need to provide for temporary exemptions at Member State level pursuant to Article 59(1) of Regulation (EU) 2017/745 or Article 54(1) of Regulation (EU) 2017/746 with a view to mitigating potential or actual shortages of medical devices included on the public health emergency critical devices list, while at the same time ensuring both patient and product safety;

Or. en

Amendment 697
Tilly Metz

Proposal for a regulation
Article 25 – paragraph 4 – point a

Text proposed by the Commission

(a) consider the need to provide for temporary exemptions at Member State level pursuant to Article 59(1) of Regulation (EU) 2017/745 or Article 54(1) of Regulation (EU) 2017/746 with a view to mitigating potential or actual shortages of medical devices included on the public health emergency critical devices list;

Amendment

(a) consider the need to provide for temporary exemptions at Member State level pursuant to Article 59(1) of Regulation (EU) 2017/745 or Article 54(1) of Regulation (EU) 2017/746 with a view to mitigating potential or actual shortages of medical devices included on the public health emergency critical devices list, while at the same time ensuring both patient and product safety;

Or. en

Justification

Temporary exemption from the conformity assessment procedure should only be considered in exceptional circumstances. Before allowing for such a derogation the considerations should take into account both the safety of patients/citizens using the device and the safety of the
product. Only if both can be ensured even without a conformity assessment procedure and the benefits for safeguarding supply outweigh the risks a temporary exemption could be offered.

Amendment 698
Kateřina Konečná

Proposal for a regulation
Article 25 – paragraph 4 – point a

Text proposed by the Commission
(a) consider the need to provide for temporary exemptions at Member State level pursuant to Article 59(1) of Regulation (EU) 2017/745 or Article 54(1) of Regulation (EU) 2017/746 with a view to mitigating potential or actual shortages of medical devices included on the public health emergency critical devices list;

Amendment
(a) consider the need to provide for temporary exemptions at Member State level pursuant to Article 59(1) of Regulation (EU) 2017/745 or Article 54(1) of Regulation (EU) 2017/746 with a view to mitigating potential or actual shortages of medical devices included on the public health emergency critical devices list while at the same time ensuring both patient and product safety;

Or. en

Justification

Temporary exemption from the conformity assessment procedure should only be considered in exceptional circumstances. Before allowing for such a derogation the considerations should take into account both the safety of patients/citizens using the device and the safety of the product. Only if both can be ensured even without a conformity assessment procedure and the benefits for safeguarding supply outweigh the risks a temporary exemption could be offered.

Amendment 699
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos, Ondřej Knotek

Proposal for a regulation
Article 26 – paragraph 1 – point a

Text proposed by the Commission
(a) take all necessary action within the limits of the powers conferred on it, with a view to mitigating potential or actual shortages of medical devices included on the public health emergency critical devices list;

Amendment
(a) take all necessary action within the limits of the powers conferred on it, with a view to mitigating potential or actual shortages of medical devices included on the public health emergency critical devices list;
devices list, including, where necessary, granting temporary exemptions at Union level pursuant to Article 59(3) of Regulation (EU) 2017/745 or Article 54(3) of Regulation (EU) 2017/746; devices list, including, where necessary, granting temporary exemptions at Union level pursuant to Article 59(3) of Regulation (EU) 2017/745 or Article 54(3) of Regulation (EU) 2017/746, while at the same time ensuring a high level of patient and product safety;

Or. en

Amendment 700
Sara Cerdas

Proposal for a regulation
Article 26 – paragraph 1 – point a

Text proposed by the Commission

(a) take all necessary action within the limits of the powers conferred on it, with a view to mitigating potential or actual shortages of medical devices included on the public health emergency critical devices list, including, where necessary, granting temporary exemptions at Union level pursuant to Article 59(3) of Regulation (EU) 2017/745 or Article 54(3) of Regulation (EU) 2017/746;

Amendment

(a) take all necessary action within the limits of the powers conferred on it, with a view to mitigating potential or actual shortages of medical devices included on the public health emergency critical devices list, including, where necessary, granting temporary exemptions at Union level pursuant to Article 59(3) of Regulation (EU) 2017/745 or Article 54(3) of Regulation (EU) 2017/746, while at the same time ensuring both patient and product safety;

Or. en

Amendment 701
Dolors Montserrat

Proposal for a regulation
Article 26 – paragraph 1 – point a

Text proposed by the Commission

(a) take all necessary action within the limits of the powers conferred on it, with a view to mitigating potential or actual shortages of medical devices included on

Amendment

(a) take all necessary action within the limits of the powers conferred on it, with a view to mitigating potential or actual shortages of medical devices included on
the public health emergency critical devices list, including, where necessary, granting temporary exemptions at Union level pursuant to Article 59(3) of Regulation (EU) 2017/745 or Article 54(3) of Regulation (EU) 2017/746; the public health emergency critical devices list, including, where necessary, granting temporary exemptions at Union level pursuant to Article 59(3) of Regulation (EU) 2017/745 or Article 54(3) of Regulation (EU) 2017/746, while at the same time ensuring both patient and product safety;

**Amendment 702**
Kařeřina Konečná

**Proposal for a regulation**
**Article 26 – paragraph 1 – point a**

*Text proposed by the Commission*

(a) take all necessary action within the limits of the powers conferred on it, with a view to mitigating potential or actual shortages of medical devices included on the public health emergency critical devices list, including, where necessary, granting temporary exemptions at Union level pursuant to Article 59(3) of Regulation (EU) 2017/745 or Article 54(3) of Regulation (EU) 2017/746;

*Amendment*

(a) take all necessary action within the limits of the powers conferred on it, with a view to mitigating potential or actual shortages of medical devices included on the public health emergency critical devices list, including, where necessary, granting temporary exemptions at Union level pursuant to Article 59(3) of Regulation (EU) 2017/745 or Article 54(3) of Regulation (EU) 2017/746 while at the same time ensuring both patient and product safety;

**Justification**

Extensions of the temporary exemption from the conformity assessment procedure should only be considered in exceptional circumstances. Before allowing for such a derogation the considerations should take into account both the safety of patients/citizens using the device and the safety of the product. Only if both can be ensured even without a conformity assessment procedure and the benefits for safeguarding supply outweigh the risks a temporary exemption could be offered.

**Amendment 703**
Joëlle Mélin
Proposal for a regulation
Article 26 – paragraph 1 – point b

(b) consider the need for guidelines addressed to Member States, medical device manufacturers, notified bodies and other entities;  

(b) consider the need for guidelines addressed to Member States, medical device manufacturers, notified bodies and other entities where this is proportionate, justified and necessary;

Or. fr

Amendment 704
Joanna Kopcińska, Margarita de la Pisa Carrión

Proposal for a regulation
Article 26 – paragraph 1 – point d a (new)

(da) work in conjunction with the European Centre for Disease Prevention and Control (ECDC) to categorise and establish different priority levels for the medicinal products identified as critical.

Or. en

Amendment 705
Tilly Metz

Proposal for a regulation
Article 27 – paragraph -1 (new)

-1 The Agency shall establish an early warning system to inform relevant stakeholders, including healthcare professionals of any supply problems and potential or actual shortages of medicinal products included on the critical products list.
Amendment 706  
Tilly Metz

Proposal for a regulation  
Article 27 – paragraph 1

*Text proposed by the Commission*

The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Medical Devices Steering Group.

*Amendment*

The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Medical Devices Steering Group, and ensure adequate consultation with the Patients’ and Consumers’ Working Party and the Healthcare Professionals’ Working Party. The list of the members of the Medical Devices Steering Group, the rules of procedure, agendas and minutes of the meetings and recommendations shall be published on the Agency’s web-portal.

Amendment 707  
Kateřina Konečná

Proposal for a regulation  
Article 27 – paragraph 1

*Text proposed by the Commission*

The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Medical Devices Steering Group.

*Amendment*

The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Medical Devices Steering Group and ensure adequate consultation with the Patients’ and Consumers’ Working Party and the Healthcare Professionals’
Working Party.

Amendment 708
Dan-Ștefan Motreanu

Proposal for a regulation
Article 27 – paragraph 1

Text proposed by the Commission

The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Medical Devices Steering Group.

Amendment

The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Medical Devices Steering Group and ensure adequate consultation with the Patients’ and Consumers’ Working Party and the Healthcare Professionals’ Working Party.

Or. en

Amendment 709
Tudor Ciuhodaru

Proposal for a regulation
Article 27 – paragraph 1

Text proposed by the Commission

The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Medical Devices Steering Group.

Amendment

The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Medical Devices Steering Group and its proposals and recommendations.

Or. ro
Amendment 710
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos

Proposal for a regulation
Article 27 – paragraph 1

*Text proposed by the Commission*

The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Medical Devices Steering Group.

*Amendment*

The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform *without delay* the public and relevant interest groups with regard to the work of the Medical Devices Steering Group, *and respond to disinformation*.

Or. en

Amendment 711
Tilly Metz

Proposal for a regulation
Article 28 – paragraph 1 – introductory part

*Text proposed by the Commission*

The Agency shall, on behalf of the Commission, from 1 March 2022 onwards, provide the secretariat of the expert panels designated in accordance with Implementing Decision (EU) 2019/1396 and provide the support necessary to ensure that those panels can efficiently perform their tasks as set out in Article 106(9) and (10) of Regulation (EU) 2017/745. The Agency shall:

*Amendment*

The Agency shall, on behalf of the Commission, provide the secretariat of the expert panels designated in accordance with Implementing Decision (EU) 2019/1396 and provide the support necessary to ensure that those panels can efficiently perform their tasks as set out in Article 106(9) and (10) of Regulation (EU) 2017/745. The Agency shall:

Or. en

Amendment 712
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos

Proposal for a regulation
Article 28 – paragraph 1 – introductory part

Text proposed by the Commission

The Agency shall, on behalf of the Commission, from 1 March 2022 onwards, provide the secretariat of the expert panels designated in accordance with Implementing Decision (EU) 2019/1396 and provide the support necessary to ensure that those panels can efficiently perform their tasks as set out in Article 106(9) and (10) of Regulation (EU) 2017/745. The Agency shall:

Amendment

The Agency shall, on behalf of the Commission, provide the secretariat of the expert panels designated in accordance with Implementing Decision (EU) 2019/1396 and provide the support necessary to ensure that those panels can efficiently perform their tasks as set out in Article 106(9) and (10) of Regulation (EU) 2017/745. The Agency shall:

Or. en

Justification

To be consistent and avoid confusion with the date of application of Chapter IV.

Amendment 713

Tilly Metz

Proposal for a regulation

Article 28 – paragraph 1 – point a

Text proposed by the Commission

(a) provide administrative and technical support to the expert panels for the provision of scientific opinions, views and advice;

Amendment

(a) provide administrative, scientific and technical support to the expert panels for the provision of scientific opinions, views and advice;

Or. en

Justification

It is appropriate to reflect also EMA’s scientific support to the expert panels, by analogy to the Agency’s support that is provided to EMA’s main scientific committees, pursuant to article 56(f) of Regulation (EC) No 726/2004.

Amendment 714

Margarita de la Pisa Carrión

Proposal for a regulation

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Article 29 – paragraph 1 a (new)

Text proposed by the Commission

1 a. The purpose of this Regulation is to increase cooperation between the European Medicines Agency, the European Commission, the Member States and stakeholders. Highlights that under no circumstances this Regulation should establish a sanctions regime.

Amendment

Or. en

Amendment 715
Aldo Patriciello

Proposal for a regulation
Article 29 – paragraph 3

Text proposed by the Commission

3. In agreement with the Chairs, joint meetings of the Medicines and Medical Devices Steering Groups may be held.

3. In agreement with the Chairs, the Medicines and Medical Devices Steering Groups shall be maintained and deployed beyond crisis situations for the management of medicines shortage, ensuring proportionality of their actions compared to emergency situations.

Amendment

Or. en

Amendment 716
Margarita de la Pisa Carrión, Joanna Kopcińska

Proposal for a regulation
Article 29 – paragraph 3 a (new)

Text proposed by the Commission

3 a. The Commission shall carry out an impact assessment prior to the entry into force of this Regulation.

Amendment

Or. en
Proposal for a regulation
Article 29 a (new)

Text proposed by the Commission

Amendment

Article 29 a

Transparency and publication of clinical data

1. For the duration of a public health emergency, the sponsors of clinical trials related to products linked to the disease in question, shall:

(a) publish the study protocol at the start of the trial through the EU clinical trials register;

(b) publish the summary of the results through the EU clinical trials register within two months after marketing authorisation.

2. The Agency shall implement exceptional measures with regard to medicinal products, including vaccines, and medical devices falling under the scope of this Regulation, strengthening transparency measures and speeding up standard publication timelines and providing more information. These measures include:

(a) Publication of the product information with details of the conditions of use at the time of marketing authorisation;

(b) Expedited publication of the full European Public Assessment Reports (EPAR), within 7 days after marketing authorisation. The EPARs should include a description of received scientific advice;

(c) Expedited publication, within a period of 2 months after marketing authorisation, of clinical data submitted to the Agency in support of the applications for medicines, after personal
data have been anonymised and any commercially confidential information redacted. Access shall be provided to all independent individual participant level data along with protocols and analytic codes;

(d) Publication of the full risk management plan for authorised medicines;

(e) Publication of news announcements within 1 day of the start of initial rolling reviews or the evaluation of new evidence or applications for extension of indication.

3. The Agency shall make agendas and minutes of all meetings public, as well as the recommendations, opinions and decisions from the Steering Groups and the Emergency Task Force on its web-portal.

4. The membership of the Emergency Task Force, Steering Groups and Working Parties shall be made public. Members of the Emergency Task Force, Steering Groups and experts shall not have financial or other interests in the pharmaceutical or medical device industry which could affect their impartiality. They shall act in the public interest in an independent manner and shall make an annual declaration of their financial interests. All indirect interests which could relate to the industry shall be entered in a register held by the Agency, which is accessible to the public, upon request. Members of the Emergency Task Force, Steering Groups and Working Parties, and experts who participate in meetings or working groups of the Agency shall declare, at each meeting, any specific interests which could be considered to be prejudicial to their independence with respect to the items on the agenda. These declarations shall be made available to the public.

Or. en
Amendment 718
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos

Proposal for a regulation
Article 29 a (new)

Text proposed by the Commission

Article 29 a

Protection against cyber-attacks
The Agency shall be equipped with a high level of security controls and processes against cyber-attacks to ensure the normal functioning of the Agency at all time, and especially during public health emergencies and major events at Union level. To that end, the Agency shall actively pursue and implement best cybersecurity practices within Union institutions and bodies to prevent, detect, mitigate, and respond to cyber-attacks.

Or. en

Justification

EMA is already cooperation with the Computer Emergency Response Team for the Union Institutions, bodies, and agencies. We therefore propose to broaden the Rapporteur's proposal to a higher level of requirement.

Amendment 719
Tilly Metz

Proposal for a regulation
Article 30 – title

Text proposed by the Commission

Confidentiality

Confidentiality and data privacy

Or. en
Amendment 720
Tilly Metz

Proposal for a regulation
Article 30 – paragraph 1 – introductory part

Text proposed by the Commission

1. Unless otherwise provided for in this Regulation and without prejudice to Regulation (EC) No 1049/2001 and existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:


Amendment

1. Unless otherwise provided for in this Regulation and without prejudice to Regulation (EC) No 1049/2001 and on the legal protection of persons who report breaches of Union law, and existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:


Or. en

Justification

The concept of confidentiality would need to be balanced from the start in the article’s ‘chapeau’.

The Whistleblower (WB) Directive cannot be added after the reference to Regulation on Access to Docs. The MS practices on confidentiality can include flexibilities/exceptions but legal protection of WB is a distinct set of rules

Amendment 721
Joëlle Mélin

Proposal for a regulation
Article 30 – paragraph 1 – introductory part

Text proposed by the Commission

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EN
1. Unless otherwise provided for in this Regulation and without prejudice to Regulation (EC) No 1049/2001\(^{24}\) and existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:


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**Amendment 722**

Tilly Metz

Proposal for a regulation

Article 30 – paragraph 1 – point a

*Text proposed by the Commission*

(a) personal data in accordance with Article 32;

*Amendment*

(a) personal data in accordance with the definitions contained in Article 4(1) of Regulation (EU) 2016/679 (GDPR) and Article 3(1) of Regulation (EU) 2018/1725 (EUDPR);

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**Amendment 723**

Joëlle Mélin

Proposal for a regulation

Article 30 – paragraph 1 – point a

*Text proposed by the Commission*

*Amendment*
(a) personal data in accordance with Article 32;

(a) personal data as defined in Article 4(1) of the GDPR;

Or. fr

Amendment 724
Tilly Metz

Proposal for a regulation
Article 30 – paragraph 1 – point b

Text proposed by the Commission

(b) commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights;

Amendment

(b) commercially confidential information and trade secrets of a natural or legal person in accordance with Directive 2016/943 and without prejudice to Directive 2019/1937, as well as intellectual property rights, unless there is an overriding public interest in disclosure;

Or. en

Justification

IP rights and commercially confidential information are not the same and need to be distinguished in the text. IP rights should not be considered as commercially confidential information.

Amendment 725
Dan-Ştefan Motreanu

Proposal for a regulation
Article 30 – paragraph 1 – point b

Text proposed by the Commission

(b) commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights;

Amendment

(b) commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights, unless there is an overriding public interest in disclosure;

Or. en
Amendment 726
Kateřina Konečná

Proposal for a regulation
Article 30 – paragraph 1 – point b

Text proposed by the Commission
(b) commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights;

Amendment
(b) commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights, unless there is an overriding public interest in disclosure;

Justification
The proposed Article on confidentiality should contain stronger language on transparency, to ensure that information on medicines and medical devices that is relevant to patients, consumers and healthcare professionals is made publicly available.

Amendment 727
Kateřina Konečná

Proposal for a regulation
Article 30 – paragraph 5

Text proposed by the Commission
5. The Commission, the Agency, and Member States may exchange commercially confidential information and, where necessary to protect public health, personal data, with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

Amendment
5. The Commission, the Agency, and the Member States may exchange commercially confidential information and, where necessary to protect public health, anonymised and aggregated personal and sensitive personal data, with regulatory authorities of the third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

Justification
The need for sharing personal data of the EU citizens with the third countries is not justified,
proper reflection on the Formal Comments of the European Data Protection Supervisor on the Proposal as regards lack of provision on the applicability of the EU data protection rules, should be included. When exchanged with regulatory authorities of the third countries, any personal data and especially personal sensitive data should be anonymised and aggregated.

Amendment 728
Tilly Metz

Proposal for a regulation
Article 30 – paragraph 5

Text proposed by the Commission

5. The Commission, the Agency, and Member States may exchange commercially confidential information and, where necessary to protect public health, personal data, with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

Amendment

5. The Commission, the Agency, and Member States may, in compliance with Chapter V of the EUDPR, exchange commercially confidential information and, where necessary to protect public health, anonymised and aggregated sensitive personal data, with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

Or. en

Amendment 729
Ondřej Knotek

Proposal for a regulation
Article 30 – paragraph 5

Text proposed by the Commission

5. The Commission, the Agency, and Member States may exchange commercially confidential information and, where necessary to protect public health, personal data, with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

Amendment

5. The Commission, the Agency, and Member States may exchange commercially confidential information and, where necessary to protect public health, anonymised and aggregated sensitive personal data, with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

Or. en
Amendment 730
Tilly Metz

Proposal for a regulation
Article 30 – paragraph 5 a (new)

Text proposed by the Commission

Amendment
5 a. All parties involved in the application of this Regulation shall ensure that the concept of commercially confidential information is interpreted narrowly, and information of public interest is, to the extent possible, proactively disclosed.

Or. en

Amendment 731
Kateřina Konečná

Proposal for a regulation
Article 30 – paragraph 5 a (new)

Text proposed by the Commission

Amendment
5 a. All parties involved in the application of this Regulation shall ensure that the concept of commercially confidential information is interpreted narrowly, and information of public interest is, to the extent possible, proactively disclosed.

Or. en

Amendment 732
Dan-Ștefan Motreanu

Proposal for a regulation
Article 30 – paragraph 5 a (new)

Text proposed by the Commission

Amendment
5 a. All parties involved in the application of this Regulation shall ensure that the concept of commercially confidential information is interpreted narrowly, and information of public interest is, to the extent possible, proactively disclosed.

Amendment 733
Tilly Metz

Proposal for a regulation
Article 30 – paragraph 5 b (new)

Text proposed by the Commission

5 b. This Regulation shall be without prejudice to the obligations of Member States relating to their processing of personal data under Regulation (EU) No 2016/679 and Directive 2002/58/EC on privacy and electronic communications, or the obligations of the Agency and the Commission relating to their processing of personal data under Regulation (EU) No 2018/1725, when fulfilling their responsibilities.

Amendment 734
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ştefănuţă, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos

Proposal for a regulation
Article 31 – title

Text proposed by the Commission

31 Entry into Force

31 Entry into Force and date of application
Amendment 735
Tilly Metz

Proposal for a regulation
Article 31 – title

Text proposed by the Commission

Amendment

31 Entry into Force

31 Entry into Force and application

Or. en

Amendment 736
Frédérique Ries, Véronique Trillet-Lenoir, Nicolae Ștefănuță, Susana Solís Pérez, Andreas Glück, Martin Hojsík, María Soraya Rodríguez Ramos

Proposal for a regulation
Article 31 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Chapters IV shall apply from… [date of entry into force + 12 months].

Or. en

Amendment 737
Tilly Metz

Proposal for a regulation
Article 31 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

Chapters I, II and III shall apply from [date of entry into force].

Chapter IV shall apply from [date of entry into force + 3 months].

Or. en