AMENDMENTS
65 - 322

Draft opinion
Joëlle Mélin
(PE689.565v01-00)

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

Proposal for a regulation
Amendment 65
Aldo Patriciello, Ioan-Rareș Bogdan, Cristian-Silviu Bușoi, Massimiliano Salini, Antonio Tajani, Maria da Graça Carvalho

Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission

(1 a) According to Article 4(2) of the TFEU, common safety concerns in public health matters is amongst the shared competences of the EU;

Or. en

Amendment 66
Aldo Patriciello, Massimiliano Salini, Ioan-Rareș Bogdan, Cristian-Silviu Bușoi, Antonio Tajani, Maria da Graça Carvalho

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.

(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 in a harmonised way between authorities, industry and other stakeholders of the pharmaceuticals supply chain. Europe needs to give a higher priority to health not with standing the competences of the Member States in the area of healthcare, to have health systems ready to provide state of the art care, and to be prepared to cope with epidemics and other unforeseeable health threats in line with the International Health Regulations. 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 67
Ivo Hristov, Nicolás González Casares, Maria-Manuel Leitão-Marques, Lina Gálvez Muñoz, Romana Jerković, Carlos Zorrinho, Robert Hajšel, Tsvetelina Penkova, Josianne Cutajar, Alicia Homs Ginel

Proposal for a regulation
Recital 2

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<thead>
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<th>Text proposed by the Commission</th>
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<td>(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. The pandemic has also shown the necessity of having an innovative and research based pharmaceutical industry that works closely with EMA in order to be better prepared for future health crisis and disruptions in the supply chain. COVID-19 also underlined the need for more transparency on medicines pricing and EU marketing authorisation.</td>
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Amendment 68
Marc Botenga, Marisa Matias, Manuel Bompard, Giorgos Georgiou, Sira Rego
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 must be more effective and transparent 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 austerity measures affecting public health services, insufficient public control on production, and by the absence of a clearly defined legal framework for managing its response to the pandemic, also by the limited degree of Union preparedness in case of a public health emergency impacting a majority of Member States.

Or. en

Amendment 69
Jutta Paulus
on behalf of the Verts/ALE Group

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

Amendment

(2) The unprecedented experience of the COVID-19 pandemic has demonstrated that the Union must 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 and Member States preparedness in

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case of a public health emergency impacting a majority of Member States.

Amendment 70
Aldo Patriciello, Ioan-Răzesc Bogdan, Cristian-Silviu Bușoi, Massimiliano Salini, Antonio Tajani, Maria da Graça Carvalho

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) The COVID-19 pandemic has exacerbated the already existing difficulty 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.

Amendment 71
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 to be taken by the EMA;

Or. fr

Amendment 72
Joëlle Mélin

Proposal for a regulation
Recital 3 b (new)

Text proposed by the Commission

(3b) the essential free movement of goods must be possible with a revised border management;

Amendment

Or. fr

Amendment 73
Jutta Paulus
on behalf of the Verts/ALE Group

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 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 as well as discussions under recent Presidencies of the Council of the European Union.

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

Or. en
Amendment 74
Ivo Hristov, Nicolás González Casares, Maria-Manuel Leitão-Marques, Lina Gálvez Muñoz, Romana Jerković, Carlos Zorrinho, Robert Hajšel, Tsvetelina Penkova, Alicia Homs Ginel

Proposal for a regulation
Recital 4 a (new)

Text proposed by the Commission

(4 a) The COVID-19 pandemic is a clear example of the need to reinforce the application of the One Health approach in the EU to achieve better public health outcomes, since, as stated in the EU4Health Programme, human health is connected to animal health and the environment and actions to tackle threats to health should take into account those three dimensions.

Or. en

Amendment 75
Jutta Paulus
on behalf of the Verts/ALE Group

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.

(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 and the Member States’ ability to rapidly and effectively react to such challenges during public health crises.

Or. en

Amendment 76
Aldo Patriciello, Ioan-Rareş Bogdan, Cristian-Silviu Buşoi, Massimiliano Salini, Antonio Tajani, Maria da Graça Carvalho
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.

Or. en

Amendment 77
Jutta Paulus
on behalf of the Verts/ALE Group

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 personal protective equipments and 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.
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Or. en

Amendment 78
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a regulation
Recital 6 a (new)

Text proposed by the Commission

(6 a) 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 EU and Member States to combat future health emergencies or serious events;

Or. en

Amendment 79
Ivars Ijabs, Izaskun Bilbao Barandica, Mauri Pekkarinen, Christophe Grudler

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

(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 80**

Jutta Paulus

on behalf of the Verts/ALE Group

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 as well as lead to the need for temporary export transparency and export authorisation mechanisms.

**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 as well as lead to the need for temporary export transparency and export authorisation mechanisms.
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 81
Jutta Paulus
on behalf of the Verts/ALE Group

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

Amendment

(8) Safe and efficacious medicinal products that treat, prevent or diagnose diseases which cause public health emergencies, should be developed, if necessary, and made available within the Union as soon as possible during such emergencies. The COVID-19 pandemic
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.

has also highlighted lacking coordination and decision-making as regards multinational clinical trials, and missing 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.

Or. en

Amendment 82
Aldo Patriciello, Ioan-Rareș Bogdan, Cristian-Silviu Bușoi, Massimiliano Salini, Antonio Tajani, Maria da Graça Carvalho

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 stakeholders 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 83
Ivo Hristov, Nicolás González Casares, Maria-Manuel Leitão-Marques, Lina Gálvez Muñoz, Romana Jerković, Carlos Zorrinho, Robert Hajšel, Tsvetelina Penkova, Josianne Cutajar, Alicia Homs Ginel

Proposal for a regulation
Recital 9 a (new)
(9 a) The outbreak of COVID-19 and the subsequent health crisis revealed the need for a more coordinated European approach in crisis management. Although the emergency of the situation explains the lack of an impact assessment, sufficient allocation of resources in terms of staff and funding needs to be secured, taking into account the specificities of the health sector in the different Member States.

Amendment 84
Ivo Hristov, Nicolás González Casares, Maria-Manuel Leitão-Marques, Lina Gálvez Muñoz, Romana Jerković, Carlos Zorrinho, Robert Hajšel, Tsvetelina Penkova, Josianne Cutajar, Alicia Homs Ginel

Proposal for a regulation
Recital 10

(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.

Highlights in this respect the necessity of developing analytics to predict emerging risks, including the use of alternative data sources.

Amendment 85
Jutta Paulus  
on behalf of the Verts/ALE Group

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. 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

(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, but quality, safety and efficacy of medical products should be a paramount priority. 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.

Or. en

Amendment 86  
Jutta Paulus  
on behalf of the Verts/ALE Group

Proposal for a regulation  
Recital 11 a (new)

Text proposed by the Commission

(11 a) 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 is a persistent problem

Amendment

(11 a) 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 is a persistent problem
that affects health and lives of EU citizens between emergencies as well. Therefore, the Commission should subsequently propose the expansion of this framework to ensure that the problem of shortages is tackled on a permanent basis.

Amendment 87
Jutta Paulus
on behalf of the Verts/ALE Group

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 and on experiences and examples in other countries.

Amendment 88
Aldo Patriciello, Ioan-Rareș Bogdan, Cristian-Silviu Bușoi, Massimiliano Salini, Antonio Tajani, Maria da Graça Carvalho

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

Amendment

(13) A harmonised system, based on common data fields, of monitoring of shortages of medicinal products, personal protective equipments and medical devices
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.

should be established, which will facilitate appropriate access for relevant national and EU 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 telematic 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 Agency should be able to ask and obtain additional information and data, not already in the system, from the concerned marketing authorisation holders, manufacturers and Member States who all have the obligation to provide complete information and data through designated points of contact.

Or. en

Amendment 89
Jutta Paulus
on behalf of the Verts/ALE Group

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

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 90
Jutta Paulus
on behalf of the Verts/ALE Group

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.

 Amendement

(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 general list of critical medicinal products applicable to any major event or public health emergency, such as those related to emergency care, surgical operations and intensive medical care. This list would serve as the basis for more specific lists of critical medicinal products, applicable in specific health crises to ensure monitoring of those products. The Steering Group 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 91
Aldo Patriciello, Ioan-Rareş Bogdan, Cristian-Silviu Buşoi, Massimiliano Salini, Antonio Tajani, Maria da Graça Carvalho

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 shall establish list 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.

Amendment 92
Marc Botenga, Marisa Matias, Manuel Bompard, Giorgos Georgiou, Sira Rego

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

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 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 93
Jutta Paulus
on behalf of the Verts/ALE Group

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 medicinal products, which have the potential to address public health emergencies, can be developed, if necessary, 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 development of such medicinal products.

Amendment 94
Marc Botenga, Marisa Matias, Manuel Bompard, Giorgos Georgiou, Sira Rego

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) While guaranteeing the independence of any subsequent evaluations, 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 driven only by science and public-health needs and not by other interests, 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 95
Jutta Paulus
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 18

Text proposed by the Commission

(18) The work of the Emergency Task Force

Amendment

(18) The work of the Emergency Task Force
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.

**Justification**

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

**Amendment 96**

Aldo Patriciello, Ioan-Răceş Bogdan, Cristian-Silviu Buşoi, Massimiliano Salini, Maria da Graça Carvalho

**Proposal for a regulation**

Recital 19

**Text proposed by the Commission**

(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.

**Amendment**

(19) The establishment of the emergency task force is committed to overcome the divergencies among the individual regulatory frameworks, placing itself as guarantee and protection for EU citizens. The 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 ongoing basis, of emerging evidence to allow a more efficient assessment of medical products including vaccines during public health emergencies.
Amendment 97
Marc Botenga, Marisa Matias, Manuel Bompard, Giorgos Georgiou, Sira Rego

Proposal for a regulation
Recital 19

Text proposed by the Commission

(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.

Amendment

(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, the transparency of related activities, including the rapid publishing clinical data for the products in question, 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.

Amendment 98
Jutta Paulus
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 19 a (new)

Text proposed by the Commission

(19 a) Experience with clinical trials during the COVID-19 pandemic revealed a tremendous amount of duplication, plethora of small trials, underrepresentation of important population groups and the lack of collaboration that increased the risk of research waste. To improve the clinical research agenda, there is a need for robust evidence on quality, efficacy and
safety of medicinal products through well-designed, well-supported, large, randomised and controlled trials. Clinical results and data of trials need to be made public.

Amendment 99
Ivo Hristov, Nicolás González Casares, Maria-Manuel Leitão-Marques, Lina Gálvez Muñoz, Romana Jerković, Carlos Zorrinho, Robert Hajšel, Tsvetelina Penkova, Josianne Cutajar, Alicia Homs Ginel

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 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

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, while encouraging the collaboration with external experts including academia, and target recruitment of data scientists, omics specialists, biostatisticians, epidemiologists, and experts in advanced analytics and AI, as well as to promote harmonisation and avoid subsequent delays in integrating the results of research to a marketing authorisation. A Union sponsor
trials established by Union or international public health or research organisations.

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 100

Jutta Paulus

on behalf of the Verts/ALE Group

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 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.

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 or other non-commercial entities.

Amendment 101
Jutta Paulus
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 20 a (new)

Text proposed by the Commission

Amendment

(20 a) The Emergency Task Force should review clinical trial protocols and advice developers on clinical trials that are conducted in the Union. The Emergency Task Force should define the most clinically relevant performance targets for vaccines and treatments to be measured in clinical trials, so that they can meet the criteria for effective public health interventions.

Amendment 102
Jutta Paulus
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 21

Text proposed by the Commission

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./issues of medical devices, and to establish a list of critical devices for the most probable cases of public health emergencies.

Or. en

Amendment 103
Marc Botenga, Marisa Matias, Manuel Bompard, Giorgos Georgiou, Sira Rego

Proposal for a regulation
Recital 22

Text proposed by the Commission

(22) This Regulation also provides the Agency with a role to support the expert panels on medical devices designated under Commission Implementing Decision (EU) 2019/1396\(^\text{12}\) to provide independent scientific and technical assistance to the Member States, the Commission, the Medical Device Coordination Group (MDCG), notified bodies and manufacturers.

Amendment

(22) This Regulation also provides the Agency with a role to support the expert panels on medical devices designated under Commission Implementing Decision (EU) 2019/1396\(^\text{12}\) to provide independent scientific and technical assistance to the Member States, the Commission, the Medical Device Coordination Group (MDCG), notified bodies and manufacturers, while upholding maximum transparency as a condition for fostering trust and confidence in the EU regulatory system.


Or. en

Amendment 104
Jutta Paulus
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 23 a (new)

Text proposed by the Commission

(23 a) Temporary exemption from the conformity assessment procedure for medical devices should only be considered in exceptional circumstances. Before allowing for such a derogation, the considerations should take into account both the safety of 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.

Or. en

Amendment 105
Jutta Paulus
on behalf of the Verts/ALE Group

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

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 that are 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
Union, which should remain clearly distinct from the one 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.

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 a recital of this regulation.

Amendment 106
Ivo Hristov, Nicolás González Casares, Maria-Manuel Leitão-Marques, Lina Gálvez Muñoz, Romana Jerković, Carlos Zorrinho, Robert Hajšel, Tsvetelina Penkova, Alicia Homs Ginel

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 through further implementing acts with a view to outlining the roles of the actors involved in the processing of personal data 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 and Data Analysis and Real World Interrogation Network - DARWIN. 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, while enabling data discoverability.
Amendment 107
Aldo Patriciello, Ioan-Rareş Bogdan, Cristian-Silviu Buşoi, Maria da Graça Carvalho

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 the use of the European Medicines Verification System (set up in the context of the Falsified Medicines FMD) data for preventing medicines 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, as well as the Substance, product, organisation and referential (SPOR) master management\(^1a\) for human medicines and the EUDAMED IT platform for medical devices.

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Amendment 108
Margarita de la Pisa Carrión
on behalf of the ECR Group
Pietro Fiocchi

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.

Or. en

Amendment 109
Ivo Hristov, Nicolás González Casares, Maria-Manuel Leitão-Marques, Lina Gálvez Muñoz, Romana Jerković, Carlos Zorrinho, Robert Hajšel, Tsvetelina Penkova, Josianne Cutajar, Alicia Homs Ginel

Proposal for a regulation
Recital 25 a (new)

Text proposed by the Commission

(25 a) Underlines the potential of Big Data to complement the evidence from clinical trials and fill knowledge gaps on medicines, as well as to help to better characterise diseases, treatments and the performance of medicines in individual healthcare systems. The global pandemic has also shown how High Performance Computing, in combination with Big Data and AI, can be of critical importance in the global fight against COVID-19.

Or. en
Amendment 110
Patrizia Toia

Proposal for a regulation
Recital 25 a (new)

Text proposed by the Commission

(25 a) Calling upon the NCAs to establish a reliable and harmonized pan-European interoperable and digital reporting system consisting of harmonized and common data fields and able to operate with other systems like SPOR, EMA systems and iSPOC and operate in a digital environment and having and effective alert system to discriminate between national and/or pan-European shortages and preventing duplication of shortages reporting.

Or. en

Amendment 111
Ivo Hristov, Nicolás González Casares, Maria-Manuel Leitão-Marques, Lina Gálvez Muñoz, Romana Jerković, Carlos Zorrinho, Robert Hajšel, Tsvetelina Penkova, Alicia Homs Giné

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, such as electronic health records, insurance claims data and data from patient registries, 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, while ensuring the applicability of the GDPR and EUDPR, and the respect of the principles relating to the processing of
personal data (as per Article 5 GDPR and 4 EUDPR).

Amendment 112
Aldo Patriciello, Ioan-Răceș Bogdan, Cristian-Silviu Bușoi, Massimiliano Salini, Maria da Graça Carvalho

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. 
It shall allow as well the definition of programs and data collection systems relating to outcomes, results, adverse and undesirable events usable for all developers.

Or. en

Amendment 113
Jutta Paulus
on behalf of the Verts/ALE Group

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

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. It is of utmost importance to ensure that health data is used in full respect to the provisions of the GDPR on personal data protection.

Or. en

Amendment 114
Marc Botenga, Marisa Matias, Manuel Bompard, Giorgos Georgiou, Sira Rego

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 when generated with appropriate quality criteria, real world data i.e. health data generated outside of clinical studies, can be essential as supportive evidence or signal-eliciting evidence 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.

Or. en

Amendment 115
Jutta Paulus
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission  
(26 a) It is imperative to have in place

Amendment
(26 a) It is imperative to have in place
robust transparency measures and standards regarding the Agency’s regulatory activities on treatments, vaccines 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, having taken due regard to protection of personal data protection and commercially confidential information. The Agency should make public the recommendations, opinions and decisions from the steering groups. The membership of the steering groups and working parties should be made public. Members of the steering groups and experts should not have financial or other interests in the pharmaceutical industry which could affect their impartiality;

Amendment 116
Ivo Hristov, Nicolás González Casares, Maria-Manuel Leitão-Marques, Lina Gálvez Muñoz, Romana Jerković, Carlos Zorrinho, Robert Hajšel, Tsvetelina Penkova, Alicia Homs Ginel

Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission

(26 a) The handling of sensitive health data requires a high level of protection against cyber-attacks. The Agency was the target of a cyber-attack that resulted in some of the unlawfully accessed documents related to COVID-19 medicines and vaccines belonging to third parties. Highlights in this respect the need for a high level of security against cyber-attacks, and particularly cyber-espionage, at all times and especially during public health emergencies;

Or. en
Amendment 117
Ivo Hristov, Nicolás González Casares, Maria-Manuel Leitão-Marques, Lina Gálvez Muñoz, Romana Jerković, Carlos Zorrinho, Robert Hajšel, Tsvetelina Penkova, Alicia Homs Ginel

Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission

(26 a) Calls for the swift implementation of binding rules on security information and cybersecurity in line with the Security Union Strategy. Urges the Member States to accelerate the work towards completing the implementation of the main 5G Toolbox measures by the second quarter of 2021;

Or. en

Amendment 118
Aldo Patriciello, Ioan-Rareş Bogdan, Cristian-Silviu Bușoi, Massimiliano Salini, Antonio Tajani, Maria da Graça Carvalho

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 – which should provide forecasts in a timely manner to relevant actor of the pharmaceutical supply chain - 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;

Amendment 119
Aldo Patriciello, Ioan-Raş Bogdan, Cristian-Silviu Buşoi, Massimiliano Salini, Antonio Tajani, Maria da Graça Carvalho

Proposal for a regulation
Recital 28

Text proposed by the Commission

(28) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States alone due to the cross-border dimension of public health emergencies and major events and can, therefore, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

Amendment

(28) As stressed out as well by EU4Health Programme recently adopted by the EU, since the objectives of this Regulation cannot be sufficiently achieved by the Member States alone due to the cross-border dimension of public health emergencies and major events and can, therefore, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
Amendment 120
Margarita de la Pisa Carrión
on behalf of the ECR Group
Proposal for a regulation
Recital 29 a (new)

Text proposed by the Commission

(29 a) In order to ensure that the democratic oversight on EMA is maintained, especially in times of crisis, the Commission commits to answer questions asked by Members of the European Parliament before the deadline expires;

Or. en

Amendment 121
Margarita de la Pisa Carrión
on behalf of the ECR Group
Proposal for a regulation
Recital 31 a (new)

Text proposed by the Commission

(31 a) To enable the Agency to be better prepared for the consequences of major events for human or veterinary medicinal products and public health emergencies, it is necessary to establish an European High Level Forum composed by health and pharmaceutical experts, Agency members and other interested parties with the purpose of sharing useful information, exchanging different points of view and finding appropriate solutions.

Or. en

Amendment 122
Patrizia Toia
Proposal for a regulation
Recital 31 a (new)

Text proposed by the Commission

(31 a) 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 should include identification of bottlenecks in the supply chain;

Or. en

Amendment 123
Aldo Patriciello, Ioan-Rareș Bogdan, Cristian-Silviu Bușoi, Massimiliano Salini, Antonio Tajani, Maria da Graça Carvalho

Proposal for a regulation
Recital 31 a (new)

Text proposed by the Commission

(31 a) Recalls the applicability of the GDPR and EUDPR and the respect of the principles relating to the processing of personal data (as per Article 5 GDPR and 4EUDPR);

Or. en

Amendment 124
Margarita de la Pisa Carrión
on behalf of the ECR Group
Pietro Fiocchi

Proposal for a regulation
Recital 31 b (new)

Text proposed by the Commission

(31 b) Calling upon the National Competent Authorities (NCAs) to 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 need to 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 125
Patrizia Toia

Proposal for a regulation
Recital 31 b (new)

Text proposed by the Commission

(31 b) During COVID-19’s emergency, the regulatory flexibility allowed by the Commission has proven to be a tool for industry to prevent shortages. Such regulatory flexibilities should also be feasible outside of a crisis to help manufacturers to prevent shortages;

Or. en

Amendment 126
Margarita de la Pisa Carrión
on behalf of the ECR Group
Pietro Fiocchi
Proposal for a regulation
Recital 31 c (new)

Text proposed by the Commission

(31 c) 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 the standards of the International Organization for Standardization (ISO) for the identification of medicinal products (IDMP);

Amendment 127
Margarita de la Pisa Carrión on behalf of the ECR Group
Pietro Fiocchi

Proposal for a regulation
Recital 31 d (new)

Text proposed by the Commission

(31 d) acknowledges 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;

Amendment 128
Margarita de la Pisa Carrión on behalf of the ECR Group
Pietro Fiocchi

Proposal for a regulation
Recital 31 e (new)
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;

Amendment 129
Margarita de la Pisa Carrión
on behalf of the ECR Group
Pietro Fiocchi
Proposal for a regulation
Recital 31 f (new)

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.

Amendment 130
Margarita de la Pisa Carrión
on behalf of the ECR Group
Proposal for a regulation
Article 1 – paragraph 1 – point b
(b) monitor and report to prevent on shortages of medicinal products for human use and medical devices;

Amendment 131
Jutta Paulus
on behalf of the Verts/ALE Group

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

Text proposed by the Commission

This Regulation shall not prejudice the potential expansion of this framework by subsequent legislation in order to be applicable on a permanent basis beyond public health emergencies and major events.

Or. en

Amendment 132
Aldo Patriciello, Ioan-Rareș Bogdan, Cristian-Silviu Bușoi, Massimiliano Salini, Antonio Tajani, Maria da Graça Carvalho

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 […] ; arising from a threat of human, animal, plant, food or environmental origin having a health dimension which requires urgent action by Authorities.
Amendment 133
Margarita de la Pisa Carrión
on behalf of the ECR Group
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/[…][17];

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/[…][17] and the Agency will define upfront the actual criteria to capture the drivers of such an emergency in Article 3.

Amendment 134
Jutta Paulus
on behalf of the Verts/ALE Group

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

Text proposed by the Commission
(d) ‘shortage’ means that supply of a

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; medicinal product for human use or a medical device does not meet patients' demand plus appropriate buffer stock for that medicinal product or medical device at national level;

Amendment 135
Margarita de la Pisa Carrión
on behalf of the ECR Group

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 136
Patrizia Toia

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 and healthcare actors’ needs for that medicinal product or medical device at national level;

Or. en

Amendment 137
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 need, no matter the cause;

Or. en

Amendment 138
Aldo Patriciello, Ioan-Rareș Bogdan, Cristian-Silviu Bușoi, Massimiliano Salini, Antonio Tajani, Maria da Graça Carvalho

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 and healthcare actor’s needs at national level for a period of more than two weeks.

Or. en

Amendment 139
Carlo Calenda

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’ needs for that medicinal product or medical device at national level;
Amendment 140
Margarita de la Pisa Carrión
on behalf of the ECR Group

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 141
Aldo Patriciello, Ioan-Rareș Bogdan, Cristian-Silviu Bușoi, Massimiliano Salini, Antonio Tajani, Maria da Graça Carvalho

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 demand and/or 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. it
Amendment 142
Margarita de la Pisa Carrión
on behalf of the ECR Group

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 demand and/or 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.

Amendment 143
Jutta Paulus
on behalf of theVerts/ALE Group

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

*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 States. 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 144
Patrizia Toia

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 demand and/or 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.

Amendment 145
Ivo Hristov, Nicolás González Casares, Maria-Manuel Leitão-Marques, Lina Gálvez Muñoz, Romana Jerković, Carlos Zorrinho, Robert Hajšel, Tsvetelina Penkova, Josianne Cutajar, Alicia Homs Ginel

Proposal for a regulation
Article 2 – paragraph 1 – point f
(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 demand for, and/or 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 147
Jutta Paulus
on behalf of the Verts/ALE Group

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 either in person or remotely. Meetings may be scheduled in preparation for or during a public health emergency or following a request for assistance referred to in Article 4(3) or to deal with a shortage that has been declared by at least one Member State. The Agency shall provide its secretariat.

Or. en

Amendment 148
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a regulation
Article 3 – paragraph 1 a (new)

Text proposed by the Commission

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

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.

Or. en

Amendment 149
Marc Botenga, Marisa Matias, Manuel Bompard, Giorgos Georgiou, Sira Rego
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 declarations of interests of all experts shall be made public and all necessary restrictions shall apply where conflicts of interest occur.

Or. en

Amendment 150
Jutta Paulus
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 3 – paragraph 2 a (new)

*Text proposed by the Commission*

2 a. The membership of the Medicines Steering Group shall be made public. Members of the Medicines Steering Group and experts shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality. They shall undertake to act in the public interest and 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 and shall be accessible to the public, on request.

*Amendment*

2 a. The membership of the Medicines Steering Group shall be made public. Members of the Medicines Steering Group and experts shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality. They shall undertake to act in the public interest and 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 and shall be accessible to the public, on request.

Or. en
Amendment 151
Margarita de la Pisa Carrión
on behalf of the ECR Group

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 should 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 152
Jutta Paulus
on behalf of the Verts/ALE Group

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. To avoid market distortions, the Medicines Steering Group shall ensure that data is evenly shared within or withheld from all marketing authorisation holders.

Or. en
Amendment 153
Aldo Patriciello, Ioan-Răzvan Bogdan, Cristian-Silviu Bușoi, Massimiliano Salini, Antonio Tajani, Maria da Graça Carvalho

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, via the industry single point of contact (iSPOC), and other stakeholders in the medicines supply chain as well as interest groups representing patients and healthcare professionals, to attend its meetings.

Or. en

Amendment 154
Marc Botenga, Marisa Matias, Manuel Bompard, Giorgos Georgiou, Sira Rego

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 decide to hear third parties, including marketing authorisation holders, developers of medicinal products, clinical trial experts, public-health advocacy groups, sectoral trade unions, consumer and patient organisations, as well as healthcare professionals.

Or. en

Amendment 155
Marc Botenga, Marisa Matias, Manuel Bompard, Giorgos Georgiou, Sira Rego

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. After being established, these rules shall be made publicly available.

Or. en

Amendment 156
Margarita de la Pisa Carrión
on behalf of the ECR Group

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 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 rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.

Or. en

Amendment 157
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).

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

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 or other Union agencies, where relevant.

Amendment 160

Jutta Paulus
on behalf of the Verts/ALE Group

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 should be capable of establishing the necessary preventive mechanisms that are necessary.

Amendment 161

Margarita de la Pisa Carrión
on behalf of the ECR Group

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 should be capable of establishing the necessary preventive mechanisms that are necessary.
Amendment 162  
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 163  
Aldo Patriciello, Ioan-Rareş Bogdan, Cristian-Silviu Buşoi, Massimiliano Salini, Antonio Tajani, Maria da Graça Carvalho

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 authority.

*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) *pro-actively and with the shortest delay*, 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 authority.
authorities, through the working party referred to in Article 3(5).

information from the national competent authorities, through the working party referred to in Article 3(5).

Or. en

Amendment 164
Carlo Calenda

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).

Or. it

Amendment 165
Jutta Paulus
on behalf of the Verts/ALE Group
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 event, including a shortage of a medicinal product in a given Member State, that has the potential 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
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).

potential a shortage of a critical medicinal product in a given Member State, as in the case of 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 167
Ivo Hristov, Nicolás González Casares, Maria-Manuel Leitão-Marques, Lina Gálvez Muñoz, Romana Jerković, Carlos Zorrinho, Robert Hajšel, Tsvetelina Penkova, Josianne Cutajar, Alicia Homs Ginel

Proposal for a regulation
Article 4 – paragraph 5 – point a

Text proposed by the Commission

(a) where the major event or public health emergency may affect the safety, quality, and efficacy of medicinal products, Article 5 shall apply;

Amendment

(a) where the major event or public health emergency may affect the manufacturing, safety, quality, and efficacy of medicinal products, Article 5 shall apply;

Or. en

Amendment 168
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a regulation
Article 5 – paragraph 1
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.

Or. en

Amendment 169
Ivo Hristov, Nicolás González Casares, Maria-Manuel Leitão-Marques, Lina Gálvez Muñoz, Romana Jerković, Carlos Zorrinho, Robert Hajšel, Tsvetelina Penkova, Alicia Homs Ginel

Proposal for a regulation
Article 5 – paragraph 1

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 

manufacturing safety, quality, and efficacy of the medicinal products concerned.

Or. en

Amendment 170
Margarita de la Pisa Carrión
on behalf of the ECR Group

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}

Amendment

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} This advice shall be made public, together with all the relevant information based on which the advice was compiled. If certain information can't be made available to the public, in order to respect confidentiality, the public health, commercial interests, grounds derived from Article 30 of this regulation, or the public order, it is mentioned. The Medicines Steering Group shall strive for the greatest transparency possible.

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

Amendment 171
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, after consulting the marketing authorisation holders and representatives of 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 172**

Margarita de la Pisa Carrión
on behalf of the ECR Group

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 173**

Jutta Paulus
on behalf of the Verts/ALE Group

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

*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 should be informed accordingly.

Or. en

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 174
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a regulation
Article 6 – paragraph 3

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>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 and the pharmaceutical operators concerned thereof.</td>
</tr>
</tbody>
</table>

Or. en

Amendment 175
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a regulation
Article 6 – paragraph 4

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. The Agency shall immediately publish the critical medicines lists and any updates to those lists on its web-portal</td>
<td>4. Access to the critical medicines lists and any updates to those lists should be granted to Member State representatives</td>
</tr>
</tbody>
</table>

Or. en


Or. en

Amendment 176
Carlo Calenda

Proposal for a regulation
Article 6 – paragraph 4

Text proposed by the Commission


Amendment

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

Or. it

Amendment 177
Margarita de la Pisa Carrión
on behalf of the ECR Group
Pietro Fiocchi

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

Text proposed by the Commission

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

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.

Or. en

Amendment 178
Jutta Paulus
on behalf of the Verts/ALE Group

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.

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

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. 

Monitoring shall be conducted during health crises as well as before, after and outside these crises in order to identify potential shortages before they can affect health and lives of EU citizens. 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]

Or. en

Amendment 179
Patrizia Toia

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

Amendment

On the basis of the critical medicines lists, the establishment of two way communication line with industry and the information and data provided in
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.

\(\text{__________________________}\)

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

\(\text{__________________________}\)

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

**Amendment 180**

**Margarita de la Pisa Carrión**
on behalf of the ECR Group

**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, the Medicines Steering Group shall monitor supply and demand, based on actual patient’s needs at national level, 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 181
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]
Carlo Calenda

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 […] 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

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, based on the actual and potential needs of patients, 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]

Or. it

Amendment 183

Margarita de la Pisa Carrión
on behalf of the ECR Group

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

Text proposed by the Commission

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

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 184
Aldo Patriciello, Ioan-Rareș Bogdan, Cristian-Silviu Bușoi, Massimiliano Salini, Antonio Tajani, Maria da Graça Carvalho

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, relevant other stake-holders of the pharmaceutical supply chain 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 185
Margarita de la Pisa Carrión
on behalf of the ECR Group
Pietro Fiocchi, Jessica Stegrud

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, Member States and 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.
Amendment 186
Jutta Paulus
on behalf of the Verts/ALE Group

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 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.

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 187
Jutta Paulus
on behalf of the Verts/ALE Group

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.

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 or Member states, 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 188
Margarita de la Pisa Carrión
on behalf of the ECR Group
Jessica Stegrud

Amendment 189
Margarita de la Pisa Carrión
on behalf of the ECR Group
Proposal for a regulation
Article 8 – paragraph 4 a (new)

Text proposed by the Commission

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 190
Jutta Paulus
on behalf of the Verts/ALE Group

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.

Or. en

Amendment 191
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

Text proposed by the Commission

5 a. Measures recommended by the Medicines Steering Group to the
Commission, Member States, marketing authorisation holders and other entities, should cover regulatory solutions for addressing potential shortages, e.g., measured aiming at minimizing regulatory administrative burden and facilitating flexible supply chains.

Or. en

Amendment 192
Joëlle Mélin

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

Text proposed by the Commission

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

Or. fr

Amendment 193
Joëlle Mélin

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 194
Patrizia Toia

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 also consulting representatives from national competent authorities and from industries representatives, as well as other stakeholders in the medicines supply chain, the Agency shall:

Or. en

Amendment 195
Ivo Hristov, Nicolás González Casares, Maria-Manuel Leitão-Marques, Lina Gálvez Muñoz, Romana Jerković, Carlos Zorrinho, Robert Hajšel, Tsvetelina Penkova, Alicia Homs Ginell, Josianne Cutajar

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. en

Amendment 196
Ivars Ijabs, Mauri Pekkarinen, Christophe Grudler, Izaskun Bilbao Barandica

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 criteria and procedures for establishing the critical medicines lists;
Amendment 197
Aldo Patriciello, Ioan-Rareş Bogdan, Cristian-Silviu Buşoi, Massimiliano Salini, Antonio Tajani, Maria da Graça Carvalho

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 will 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 EMA from national competent authority shortages reporting systems in a harmonised and consolidated way, based on national 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 198
Margarita de la Pisa Carrión
on behalf of the ECR Group
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 EMA 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 199
Adam Jarubas

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

Text proposed by the Commission

Amendment
(c) develop streamlined electronic monitoring and reporting systems; (c) develop streamlined electronic monitoring and reporting systems, building upon EU telematics regulatory infrastructure, SPOR, into national shortage reporting interoperable system, 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;

Or. en

Amendment 200
Patrizia Toia

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 a streamlined and EU Harmonised electronic monitoring and reporting systems. The harmonised system prevent any duplication of the reporting process by industry;

Or. en

Amendment 201
Margarita de la Pisa Carrión
on behalf of the ECR Group
Jessica Stegrud

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 a streamlined electronic monitoring and reporting systems; accessible by Member State authorities and marketing authorization holders;

Or. en

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Amendment 202
Ivo Hristov, Nicolás González Casares, Maria-Manuel Leitão-Marques, Lina Gálvez Muñoz, Romana Jerković, Carlos Zorrinho, Robert Hajšel, Tsvetelina Penkova, Josianne Cutajar, Alicia Homs Ginel

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 in coordination with the national competent authorities;

Amendment 203
Margarita de la Pisa Carrión on behalf of the ECR Group 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)\(^a\);

Amendment 204
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 205
Aldo Patriciello, Ioan-Rareș Bogdan, Cristian-Silviu Bușoi, Massimiliano Salini, Antonio Tajani, Maria da Graça Carvalho

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

Text proposed by the Commission

(c) 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

(c) 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 with the International Organization for Standardization (ISO) for the identification of medicinal products (IDMP)\(^a\);

and consistent manner.

Or. en

Amendment 206
Margarita de la Pisa Carrión
on behalf of the ECR Group

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 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;

Or. en

Amendment 207
Patrizia Toia

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 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;
Amendment 208  
Jutta Paulus  
on behalf of the Verts/ALE Group

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 and wholesalers based on the medicinal products included on the critical medicines lists;

Amendment 209  
Margarita de la Pisa Carrión  
on behalf of the ECR Group  
Pietro Fiocchi

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 information referred to in point (b) of paragraph 2 (as determined in Article 9(1)(c) and Article 11) 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 will 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 210
Adam Jarubas

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 information referred to in point (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 211
Jutta Paulus  
on behalf of the Verts/ALE Group

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 212
Ivars Ijabs, Mauri Pekkarinen, Christophe Grudler, Izaskun Bilbao Barandica

Proposal for a regulation
Article 9 – paragraph 3 – point d

*Text proposed by the Commission*  
Amendment
(d) details of the potential or actual shortage such as actual or estimated start and end dates and suspected or known cause;  

(d) details of the potential or actual shortage such as actual or estimated start and end dates and suspected or known cause at each stage of the supply chain;

Amendment 213
Jutta Paulus
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 9 – paragraph 3 – point d a (new)

Text proposed by the Commission

Amendment

(d a) information on active substance manufacturing sites, where relevant;

Or. en

Amendment 214
Marc Botenga, Marisa Matias, Manuel Bompard, Giorgos Georgiou, Sira Rego

Proposal for a regulation
Article 9 – paragraph 3 – point e

Text proposed by the Commission

Amendment

(e) sales and market share data;

(e) production, sales and market share data;

Or. en

Amendment 215
Ivars Ijabs, Mauri Pekkarinen, Christophe Grudler, Izaskun Bilbao Barandica

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 including enhanced production, supply capacity
sourcing diversification and where applicable outsourcing plans;

Amendment 216
Marc Botenga, Marisa Matias, Manuel Bompard, Giorgos Georgiou, Sira Rego
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 location-specific manufacturing, production and supply capacity;

Amendment 217
Margarita de la Pisa Carrión on behalf of the ECR Group Pietro Fiocchi
Proposal for a regulation
Article 9 – paragraph 3 – point h a (new)

Text proposed by the Commission
(h a) 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)\(^1\);

Amendment 218
Margarita de la Pisa Carrión
on behalf of the ECR Group
Pietro Fiocchi

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

Or. en

Amendment 219
Ivars Ijabs, Mauri Pekkarinen, Christophe Grudler, Izaskun Bilbao Barandica

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

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.
necessary.

Amendment 220
Joëlle Mélin

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.

Amendment 221
Margarita de la Pisa Carrión
on behalf of the ECR Group
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

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. **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 whenever necessary.**

Amendment 222
Marc Botenga, Marisa Matias, Manuel Bompard, Giorgos Georgiou, Sira Rego

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. 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 **whenever** necessary or **upon request**.

Or. en

Amendment 223
Margarita de la Pisa Carrión
on behalf of the ECR Group
Pietro Fiocchi

Proposal for a regulation
Article 10 – paragraph 2

**Text proposed by the Commission**

**Amendment**
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.

Amendment 224
Margarita de la Pisa Carrión
on behalf of the ECR Group
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 225
Marc Botenga, Marisa Matias, Manuel Bompard, Giorgos Georgiou, Sira Rego

Proposal for a regulation
Article 10 – paragraph 4

Text proposed by the Commission

4. Where marketing authorisation

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.

Amendment 226
Jutta Paulus
on behalf of the Verts/ALE Group

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 might contain information of a commercially confidential nature, they shall identify the relevant parts, clarify the reasons for such an indication and offer sufficient, actual and specific evidence of harm stemming from disclosure. The Agency shall assess the merits of each request, considering the benefits for public health of disclosure and act accordingly.

Or. en

Amendment 227
Margarita de la Pisa Carrión
on behalf of the ECR Group

*Text proposed by the Commission*

Marketing authorisation holders failing to comply with their reporting obligations shall be subject to sanctions to be determined by the Commission.

*Amendment*

Marketing authorisation holders failing to comply with their reporting obligations shall be subject to sanctions to be determined 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 228**
Margarita de la Pisa Carrión on behalf of the ECR Group

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, 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;

**Amendment 229**
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 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 230
Jutta Paulus
on behalf of the Verts/ALE Group

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

Justification
For the monitoring and mitigation of shortages of medicinal products during a public health emergency or a major event guidelines should also be considered for healthcare professionals.

Amendment 231
Margarita de la Pisa Carrión
on behalf of the ECR Group
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 232
Ivars Ijabs, Mauri Pekkarinen, Christophe Grudler, Izaskun Bilbao Barandica

Proposal for a regulation
Article 12 – paragraph 1 – point f

Text proposed by the Commission
(f) liaise with third countries and relevant international organisations, as appropriate, to mitigate potential or actual shortages of medicinal products included on the critical medicines list or their active pharmaceutical ingredients, where those products or ingredients are imported into the Union and where such potential or actual shortages have international implications.

Amendment
(f) liaise with third countries and relevant international organisations, as appropriate, to mitigate potential or actual shortages of medicinal products included on the critical medicines list or their active pharmaceutical ingredients, where those products or ingredients are imported into or exported from the Union and where such potential or actual shortages have international implications, including potential introduction of temporary export transparency and export authorisation mechanisms.

Or. en

Amendment 233
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a regulation
Article 12 – paragraph 1 – point f a (new)

Text proposed by the Commission
(f a) The Commission shall provide
Amendment 234
Jutta Paulus
on behalf of the Verts/ALE Group

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 lists.

Or. en

Justification

Besides the measure proposed by the Commission in Article 13, a dedicated early warning system should be established to inform the relevant stakeholders, including doctors and community and hospital pharmacists of any problems related to the supply of medicines included by the Medicines Steering Group on the critical medicines lists.

Amendment 235
Marc Botenga, Marisa Matias, Manuel Bompard, Giorgos Georgiou, Sira Rego

Proposal for a regulation
Article 13 – paragraph 1

Text proposed by the Commission

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.

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 and the data used and its sources based on which the
recommendations of the Medicines Steering Group are taken. Proceedings and recommendations, including dissenting views, shall be documented and made publicly available.

Or. en

Amendment 236
Jutta Paulus
on behalf of the Verts/ALE Group

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 in a timely manner with regard to the work of the Medicines Steering Group, including the recommendations, opinions and decisions made by the Medicines Steering Group as well as agendas and minutes of the Group’s meetings.

Or. en

Amendment 237
Aldo Patriciello, Ioan-Rareș Bogdan, Cristian-Silviu Bușoi, Massimiliano Salini, Antonio Tajani, Maria da Graça Carvalho

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, advices and findings of the Medicines Steering Group.
Amendment 238
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 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 Organisation, third countries and international scientific organisations in preparing timely and appropriate responses to health emergencies. The Agency, working together with the Member States, shall apply itself to developing 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 239
Patrizia Toia

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.
Amendment 240
Jutta Paulus
on behalf of the Verts/ALE Group

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 or during public health emergencies, either in person or remotely. The Agency shall provide its secretariat.

Amendment 241
Margarita de la Pisa Carrión
on behalf of the ECR Group

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 during the declared public health emergencies, either in person or remotely. The Agency shall provide its secretariat.

Amendment 242
Jutta Paulus
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 14 – paragraph 2 – point a a (new)
The Emergency Task Force shall define the most clinically relevant performance targets for vaccines and treatments to be measured in clinical trials in order to guide the trials towards meeting the criteria for effective public health interventions.

Or. en

**Amendment 243**
Jutta Paulus
on behalf of the Verts/ALE Group

**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 and guidance 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;

Or. en

**Amendment 244**
Jutta Paulus
on behalf of the Verts/ALE Group

**Proposal for a regulation**
**Article 14 – paragraph 2 – point c**

*Text proposed by the Commission*

(c) providing scientific support to facilitate clinical trials to be conducted in the Union for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency. Such

*Amendment*

(c) providing scientific support to facilitate clinical trials to be conducted in the Union for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency. Such
support shall include advice to sponsors of similar or linked planned clinical trials on the establishment, in their place, of joint clinical trials and may include advice on establishing agreements to act as a sponsor or as co-sponsor in accordance with Articles 2(14) and 72 of Regulation (EU) 536/2014; support shall include advice to sponsors of similar or linked planned clinical trials on the establishment, in their place, of joint clinical trials and may include advice on establishing agreements to act as a sponsor or as co-sponsor in accordance with Articles 2(14) and 72 of Regulation (EU) 536/2014 and on developing suitable protocols;
Proposal for a regulation
Article 14 – paragraph 2 – point f

Text proposed by the Commission

(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.

Amendment

(f) cooperating with national competent authorities, 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. en

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, 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. Members of the Emergency Task Force, including external experts, shall
not have financial or other interests in the health industry which could affect their independence and impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests which shall be published. Members of the Emergency Task Force shall declare, at each meeting, any potential conflict of interest with respect to the items on the agenda. In the event of such a conflict of interest, the concerned member shall withdraw from the meeting.


Amendment 249
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a regulation
Article 14 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. The Emergency Task Force will 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.

Amendment 250
Marc Botenga, Marisa Matias, Manuel Bompard, Giorgos Georgiou, Sira Rego
Proposal for a regulation
Article 14 – paragraph 4

Text proposed by the Commission

4. The composition of the Emergency Task Force shall be approved by the Management Board of the Agency. The Executive Director of the Agency or their representative and representatives of the Commission shall be entitled to attend all meetings.

Amendment

4. The composition of the Emergency Task Force shall be approved by the Management Board of the Agency and made publicly available. The Executive Director of the Agency or their representative and representatives of the Commission shall be entitled to attend all meetings.

Or. en

Amendment 251
Marc Botenga, Marisa Matias, Manuel Bompard, Giorgos Georgiou, Sira Rego

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 to attend its meetings, and decide to hear third parties, including marketing authorisation holders, developers of medicinal products, clinical trial experts, public health advocacy groups, sectoral trade unions, consumer and patient organisations, as well as healthcare professionals.

Or. en

Amendment 252
Jutta Paulus
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 14 – paragraph 5
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 253
Marc Botenga, Marisa Matias, Manuel Bompard, Giorgos Georgiou, Sira Rego

Proposal for a regulation
Article 14 – paragraph 8

Text proposed by the Commission


Amendment

8. Article 63 of Regulation (EC) No 726/2004 shall apply to the Emergency Task Force as regards transparency and the independence of its members. Declarations of interest shall be made publicly available for all stakeholders and experts consulted. Stakeholders and experts with conflicts of interest shall not participate in the process.

Amendment 254
Jutta Paulus
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 14 – paragraph 9

Text proposed by the Commission

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9. The Agency shall publish information about the medicinal products that the Emergency Task Force considers may have the potential to address public health emergencies and any updates on its web-portal. The Agency shall also publish clinical trials data on medicines and vaccines reviewed by the Emergency Task Force and clinical trials protocols on which the Emergency Task Force provided advise to developers, in line with the provisions of the Regulation (EU) No 536/2014.

Amendment 255
Aldo Patriciello, Ioan-Rareș Bogdan, Cristian-Silviu Bușoi, Massimiliano Salini, Antonio Tajani, Maria da Graça Carvalho

Proposal for a regulation
Article 14 – paragraph 9

Text proposed by the Commission

9. The Agency shall publish information about the medicinal products that the Emergency Task Force considers may have the potential to address public health emergencies and any updates on its web-portal.

Amendment

9. The Agency shall publish all information about the medicinal products that the Emergency Task Force considers may have the potential to address public health emergencies and any updates on its web-portal.

Or. en

Amendment 256
Jutta Paulus
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 15 – title

Text proposed by the Commission

Advice on clinical trials

Amendment

Advice and guidance on clinical trials

Or. en
Amendment 257
Jutta Paulus
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 15 – paragraph -1 (new)

Text proposed by the Commission

Amendment

-1. The Emergency Task Force shall define the most clinically relevant performance targets for vaccines and treatments to be measured in clinical trials in order to ensure that these trials meet the criteria for effective public health interventions. These targets shall provide guidance for developers of medicinal products and underpin the scientific advice process outlined in this article.

Or. en

Amendment 258
Jutta Paulus
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 15 – paragraph 1

Text proposed by the Commission

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.

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 based on targets referred to in Article 15.(-1). When providing scientific advice, a balance shall always be maintained between necessary facilitation in a crisis situation and patients’ safety.

Or. en
Amendment 259
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a regulation
Article 15 – paragraph 2

Text proposed by the Commission

2. Where a developer engages in an accelerated scientific advice process, the Emergency Task force shall provide such advice free of charge at the latest 20 days following the submission to the Agency of a complete set of requested information and data by the developer. The advice shall be endorsed by the Committee for Medicinal Products for Human Use.

Amendment

2. Where a developer engages in an accelerated scientific advice process, the Emergency Task force shall provide such advice free of charge. The advice shall be endorsed by the Committee for Medicinal Products for Human Use at the latest 20 days following the submission to the Agency of a complete set of requested information and data by the developer.

Or. en

Amendment 260
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a regulation
Article 15 – paragraph 3

Text proposed by the Commission

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.

Amendment

3. The Emergency Task Force shall establish and update 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. These procedures shall become public.

Or. en
Amendment 261
Aldo Patriciello, Ioan-Rareș Bogdan, Cristian-Silviu Bușoi, Massimiliano Salini, Antonio Tajani, Maria da Graça Carvalho

Proposal for a regulation
Article 15 – paragraph 6

Amendment

6. Where a developer is the recipient of scientific advice, the developer shall subsequently submit the data resulting from clinical trials to the Agency following a request made pursuant to Article 16.

Text proposed by the Commission

6. Where a developer is the recipient of scientific advice, the developer shall subsequently submit the data resulting from clinical trials to the Agency following a request made pursuant to Article 16 and awaiting the launch of the Clinical Trials Information System (CTIS) in accordance with Art. 80 and 81 of Regulation (EU) No 536/2014.

Or. en

Amendment 262
Ivo Hristov, Nicolás González Casares, Maria-Manuel Leitão-Marques, Lina Gálvez Muñoz, Romana Jerković, Carlos Zorrinho, Robert Hajšel, Tsvetelina Penkova, Alicia Homs Ginel

Proposal for a regulation
Article 15 – paragraph 6

Amendment

6. Where a developer is the recipient of scientific advice, the developer shall subsequently submit the data resulting from clinical trials to the Agency following a request made pursuant to Article 16.

Text proposed by the Commission

6. Where a developer is the recipient of scientific advice, the developer shall subsequently submit the data resulting from clinical trials to the Agency following a request made pursuant to Article 16. In order to ensure the protection of sensitive data a state-of-the-art pseudonymisation shall apply, including encryption.

Or. en

Amendment 263
Jutta Paulus
on behalf of the Verts/ALE Group
Proposal for a regulation
Article 15 – paragraph 6

Text proposed by the Commission
6. Where a developer is the recipient of scientific advice, the developer shall subsequently submit the data resulting from clinical trials to the Agency following a request made pursuant to Article 16.

Amendment
6. Where a developer is the recipient of scientific advice, the developer shall subsequently submit the data resulting from clinical trials to the Agency following a request made pursuant to Article 16. Due to the sensitive nature of this data, it shall be pseudonymised in line with the requirements of Article 89 of GDPR.

Or. en

Amendment 264
Marc Botenga, Marisa Matias, Manuel Bompard, Giorgos Georgiou, Sira Rego

Proposal for a regulation
Article 15 – paragraph 6

Text proposed by the Commission
6. Where a developer is the recipient of scientific advice, the developer shall subsequently submit the data resulting from clinical trials to the Agency following a request made pursuant to Article 16.

Amendment
6. Where a developer is the recipient of scientific advice, the developer shall subsequently and continuously submit all the data resulting from clinical trials to the Agency following a request made pursuant to Article 16.

Or. en

Amendment 265
Aldo Patriciello, Ioan-Rareș Bogdan, Cristian-Silviu Bușoi, Massimiliano Salini, Antonio Tajani, Maria da Graça Carvalho

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

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 and
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.

veterinary medicinal products, which may have the potential to be used to address the public health emergency. The review shall be regularly updated and published during the public health emergency.

Amendment 266
Marc Botenga, Marisa Matias, Manuel Bomprad, Giorgos Georgiou, Síria Rego

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 all relevant information and data from marketing authorisation holders and from developers and engage with them in preliminary discussions. The Emergency Task Force shall use the results of comparative randomized controlled trials when available, but, if not, may also, when necessary, make use of real world data including pragmatic trials as in “close to everyday practice” taking into account their reliability as supportive evidence or signal-eliciting evidence.

Amendment 267
Jutta Paulus
on behalf of the Verts/ALE Group

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

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 should liaise with agencies of third countries that authorise medicinal products for additional information and data.

Justification

Data exchange with agencies like US FDA or Indian CDSCO can increase speed and improve knowledge and should be addressed as a possibility.

Amendment 268
Ivo Hristov, Nicolás González Casares, Maria-Manuel Leitão-Marques, Lina Gálvez Muñoz, Romana Jerković, Carlos Zorrinho, Robert Hajšel, Tsvetelina Penkova, Alicia Homs Ginel

Proposal for a regulation
Article 16 – paragraph 2

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 should liaise with agencies of third countries that authorise medicinal products for additional information and data.

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, while applying state-of-the-art pseudonymisation, including encryption.

Amendment 269
Margarita de la Pisa Carrión on behalf of the ECR Group
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 their view, the Emergency Task Force shall engage marketing authorisation holders and developers in preliminary discussions and may subsequently request information and data from marketing authorisation holders and from developers. 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. en

Amendment 270
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 271
Marc Botenga, Marisa Matias, Manuel Bompard, Giorgos Georgiou, Sira Rego

Proposal for a regulation  
Article 16 – paragraph 3 – introductory part
3. Based on a request from one or more Member States, or the Commission, the Emergency Task Force shall provide independent recommendations to the Committee for Medicinal Products for Human Use for an opinion in accordance with paragraph 4 on the following:

Amendment 272
Jutta Paulus
on behalf of the Verts/ALE Group

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 influenced 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 273
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a regulation
Article 16 – paragraph 7 a (new)
7 a. 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.

Amendment 274
Marc Botenga, Marisa Matias, Manuel Bompard, Giorgos Georgiou, Sira Rego

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 and the data and sources used in the decision-making process of the Emergency Task Force.

Amendment 275
Ivo Hristov, Nicolás González Casares, Maria-Manuel Leitão-Marques, Lina Gálvez Muñoz, Romana Jerković, Carlos Zorrinho, Robert Hajšel, Tsvetelina Penkova, Josianne Cutajar, Alicia Homs Ginel

Proposal for a regulation
Article 18 – paragraph 1 – point a
(a) develop and maintain electronic tools for the submission of information and data, including electronic health data generated outside the scope of clinical studies; while ensuring processing of patients' personal data is in compliance with the European data protection framework;

Amendment 276
Ivars Ijabs, Mauri Pekkarinen, Christophe Grudler, Izaskun Bilbao Barandica

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 highly secure and resilient electronic tools for the submission of information and data, including electronic health data generated outside the scope of clinical studies;

Amendment 277
Ivo Hristov, Nicolás González Casares, Maria-Manuel Leitão-Marques, Lina Gálvez Muñoz, Romana Jerković, Carlos Zorrinho, Robert Hajšel, Tsvetelina Penkova, Josianne Cutajar, Alicia Homs Ginel

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 Big Data Task Force.

Amendment
(b) coordinate independent vaccine effectiveness and safety monitoring studies using relevant data held by public authorities, while taking into consideration the priority recommendations of the HMA-EMA joint Big Data Task Force. Such coordination
platform; shall be conducted jointly with the European Centre for Disease Prevention and Control and notably through a new vaccine monitoring platform;

Or. en

**Amendment 278**

Ivo Hristov, Nicolás González Casares, Maria-Manuel Leitão-Marques, Lina Gálvez Muñoz, Romana Jerković, Carlos Zorrinho, Robert Hajšel, Tsvetelina Penkova, Alicia Homs Ginel, Josianne Cutajar

Proposal for a regulation

**Article 18 – paragraph 1 – point c**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tr>
<td>(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;</td>
<td>(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; <strong>underlines in this regard the need to speed up the deployment of a secure quantum communication infrastructure (QCI), which would allow the transmission of sensitive information, using an ultra-secure form of encryption to shield against cyberattacks</strong>;</td>
</tr>
</tbody>
</table>

Or. en

**Amendment 279**

Ivo Hristov, Nicolás González Casares, Maria-Manuel Leitão-Marques, Lina Gálvez Muñoz, Romana Jerković, Carlos Zorrinho, Robert Hajšel, Tsvetelina Penkova, Alicia Homs Ginel

Proposal for a regulation

**Article 18 – paragraph 1 – point c a (new)**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(c a) <strong>The Agency shall be equipped with a high level of security against cyber</strong>-</td>
<td></td>
</tr>
</tbody>
</table>
attacks and cyber-espionage at all times, especially during major events and public health emergencies at Union level. Binding rules on security information and cybersecurity shall apply in line with the Security Union Strategy.

Amendment 280
Adam Jarubas
Proposal for a regulation
Article 18 – paragraph 1 – point d a (new)

Text proposed by the Commission

(d a) 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 techniques to among others forecast crisis development, prepare responses and proactively initiate optimisation of resources management.

Or. en

Amendment 281
Jutta Paulus
on behalf of the Verts/ALE Group
Proposal for a regulation
Article 18 – paragraph 1 – point d a (new)

Text proposed by the Commission

(d a) take urgent and appropriate measures to ensure the protection of health data from cyber intrusions. These measures should be built on combination of regular penetration testing, decentralised solutions and security by design principles.
Amendment 282
Margarita de la Pisa Carrión
on behalf of the ECR Group
Pietro Fiocchi

Proposal for a regulation
Article 18 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment
(d a) 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 283
Jutta Paulus
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 19 – paragraph 1

Text proposed by the Commission

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 either in person or remotely, in preparation for or during a public health emergency, or upon request of a Member State affected by a shortage. The Agency shall provide its secretariat.

Amendment 284
Marc Botenga, Marisa Matias, Manuel Bompard, Giorgos Georgiou, Sira Rego
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. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields. The declarations of interests of all experts must be made public and all necessary restrictions shall apply where conflicts of interest occur.

Or. en

Amendment 285
Jutta Paulus
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 19 – paragraph 2 a (new)

Text proposed by the Commission

2 a. The membership of the Medical Devices Steering Group shall be made public. Members of the Medical Devices Steering Group and experts shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality. They shall vow to act in the public interest and 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 and shall be accessible to the public, on request.

Amendment

2 a. The membership of the Medical Devices Steering Group shall be made public. Members of the Medical Devices Steering Group and experts shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality. They shall vow to act in the public interest and 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 and shall be accessible to the public, on request.

Or. en
**Amendment 286**  
Marc Botenga, Marisa Matias, Manuel Bompard, Giorgos Georgiou, Sira Rego

**Proposal for a regulation**  
**Article 19 – paragraph 3**

<table>
<thead>
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<td>3. The Medical Devices Steering Group shall be chaired by the Agency. The Chair may <em>invite</em> third parties, including representatives of medical <em>device interest</em> groups to attend its meetings.</td>
<td>3. The Medical Devices Steering Group shall be chaired by the Agency. The Chair may <em>decide to hear</em> third parties, including <em>developers and producers</em> of medical <em>devices, public-health advocacy</em> groups, <em>sectoral trade unions, consumer and patient organisations, as well as healthcare professionals</em>.</td>
</tr>
</tbody>
</table>

| Or. en | |

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**Amendment 287**  
Jutta Paulus  
on behalf of the Verts/ALE Group

**Proposal for a regulation**  
**Article 19 – paragraph 3**

<table>
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<td>3. The Medical Devices Steering Group shall be chaired by the Agency. The Chair may <em>invite</em> third parties, including representatives of medical device interest groups to attend its meetings.</td>
<td>3. The Medical Devices Steering Group shall be chaired by the Agency. The Chair may <em>invite</em> third parties, including representatives of medical device interest groups, <em>healthcare professionals as well as representatives of patients and consumers</em> to attend its meetings.</td>
</tr>
</tbody>
</table>

| Or. en | |

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**Amendment 288**  
Margarita de la Pisa Carrión  
on behalf of the ECR Group

**Proposal for a regulation**  
**Article 19 – paragraph 5 a (new)**
5a. The Medical Devices Steering Group will establish the basis for strengthened cooperation with national health authorities and the pharmaceutical industry.

Or. en

Amendment 289
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 the 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.

Or. fr

Amendment 290
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a regulation
Article 20 – paragraph 3

Text proposed by the Commission

3. The Agency shall publish the public

Amendment

3. The Agency shall publish on an
health emergency critical devices list and any updates to that list on its web-portal.

Accessible way, the public health emergency critical devices list and any updates to that list on its web-portal.

Amendment 291
Jutta Paulus
on behalf of the Verts/ALE Group

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 in a timely manner on its web-portal.

Amendment 292
Jutta Paulus
on behalf of the Verts/ALE Group

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/[…])22 and the Advisory Committee on public health emergencies established

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, 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/[…])22 and the Advisory Committee on public health emergencies established
pursuant to Article 24 of that Regulation.

as well as with Union and national entities engaged with stockpiling of medical devices.

_________________

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

_________________

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

Or. en

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 293
Jutta Paulus
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 22 – paragraph 2

Text proposed by the Commission

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 to jointly with a medicinal product.

Or. en

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 to jointly with a medicinal product as well as with Union and national entities engaged with stockpiling of medical devices.
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 294
Jutta Paulus on behalf of the Verts/ALE Group

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.

Amendment

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, including healthcare professionals, to ensure preparedness to deal with potential or actual shortages of medical devices caused by public health emergencies.

Or. en

Amendment 295
Jutta Paulus on behalf of the Verts/ALE Group

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 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

Amendment

5. The Medical Devices Steering Group may, upon request from the Commission coordinate measures, where relevant, between the national competent authorities, manufacturers of medical devices, notified bodies, and other entities, including healthcare professionals, to prevent or mitigate potential or actual shortages in the context of a public health
Amendment 296  
Joëlle Mélin

Proposal for a regulation  
Article 22 – paragraph 5 a (new)

Text proposed by the Commission  
Amendment

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

Or. fr

Amendment 297  
Marc Botenga, Manuel Bompard, Giorgos Georgiou, Marisa Matias, Sira Rego

Proposal for a regulation  
Article 22 – paragraph 5 a (new)

Text proposed by the Commission  
Amendment

5a. All the recommendations made by the Medical Devices Steering Group shall be made publicly available.

Or. en

Amendment 298  
Joëlle Mélin

Proposal for a regulation  
Article 23 – paragraph 1 – introductory part

Text proposed by the Commission  
Amendment
1. In order to prepare for fulfilling the tasks referred to in Articles 20, 21, and 22, and after consulting the representatives of national authorities and marketing authorisation holders, as well as other stakeholders in the pharmaceutical sector, the Agency shall:

Amendment 299
Margarita de la Pisa Carrión
on behalf of the ECR Group
Jessica Stegrud

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) after consultation with all relevant stakeholders specify the procedures for establishing the public health emergency critical devices list;

Amendment 300
Ivo Hristov, Nicolás González Casares, Maria-Manuel Leitão-Marques, Lina Gálvez Muñoz, Romana Jerković, Carlos Zorrinho, Robert Hajšel, Tsvetelina Penkova, Alicia Homs Ginel, Josianne Cutajar

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;

Amendment 301
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 in coordination with the national competent authorities;

Amendment 302
Jutta Paulus
on behalf of the Verts/ALE Group

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
deleted

Justification
It will be difficult for the EMA 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). However, since there exists a database of medical device manufacturers ie EUDAMED, which is being established by the Commission pursuant to art 33 of the MD regulation and art 30 of the IVD MD regulation, it would be much more efficient to include such contact details in this 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 303
Jutta Paulus
on behalf of the Verts/ALE Group
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

Justification

It will be difficult for the EMA 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). However, since there exists a database of medical device manufacturers ie EUDAMED, which is being established by the Commission pursuant to art 33 of the MD regulation and art 30 of the IVD MD regulation, it would be much more efficient to include such contact details in this 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 304
Ivars Ijabs, Mauri Pekkarinen, Christophe Grudler, Izaskun Bilbao Barandica

Proposal for a regulation
Article 23 – 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 the known or suspected cause;

Amendment

(d) details of the potential or actual shortage such as actual or estimated start and end dates, and the known or suspected cause at each level of the supply chain;

Or. en

Amendment 305
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 enhanced production, supply capacity, sourcing diversification and where applicable outsourcing plans;

Or. en

Amendment 306
Jutta Paulus
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 23 – paragraph 3 – point i

Text proposed by the Commission

(i) where conformity assessments are on-going, the status of the conformity assessment by the concerned notified bodies in relation to medical devices included in the public health emergency critical devices list and possible issues which need to be resolved in order to complete the conformity assessment process.

Amendment

(i) where conformity assessments are on-going, the status of the conformity assessment by the concerned notified bodies in relation to medical devices included in the public health emergency critical devices list and possible issues which need to be resolved in order to speedily complete the conformity assessment process.

Or. en

Amendment 307
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

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, 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 308
Jutta Paulus
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 24 – paragraph 3

Text proposed by the Commission

3. Where manufacturers of medical devices included on the public health emergency critical devices list and concerned notified bodies 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 such commercially confidential information against unjustified disclosure.

Amendment

3. Where manufacturers of medical devices included on the public health emergency critical devices list and concerned notified bodies 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 such commercially confidential information against unjustified disclosure unless the information is in the public interest.

Amendment 309
Jutta Paulus
on behalf of the Verts/ALE Group
Proposal for a regulation
Article 25 – paragraph 2

Text proposed by the Commission

2. Where necessary to fulfil their reporting obligations set out in paragraph 1, Member States shall gather information from manufacturers, importers, distributors and notified bodies on medical devices included on the public health emergency critical devices list.

Amendment

2. Where necessary to fulfil their reporting obligations set out in paragraph 1, Member States shall gather information from manufacturers, importers, distributors, health care professionals and notified bodies on medical devices included on the public health emergency critical devices list.

Or. en

Amendment 310
Jutta Paulus
on behalf of the Verts/ALE Group

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 311
Jutta Paulus
on behalf of the Verts/ALE Group

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;

Or. en

Amendment 312
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a regulation
Article 26 – paragraph 1 – point a a (new)

Text proposed by the Commission

(a a) The Commission shall provide answers to (priority) written questions from Members of the European Parliament within the deadline.

Or. en

Amendment 313
Jutta Paulus
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 26 – paragraph 1 – point b

Text proposed by the Commission

(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, health care professionals and other
entities;

Amendment 314
Ivars Ijabs, Mauri Pekkarinen, Christophe Grudler, Izaskun Bilbao Barandica

Proposal for a regulation
Article 26 – paragraph 1 – point e

Text proposed by the Commission

(e) liaise with third countries and relevant international organisations, as appropriate, to mitigate potential or actual shortages of medical devices included on the critical devices list or their component parts, where those devices or parts are imported into the Union, and where such potential or actual shortages have international implications.

Amendment

(e) liaise with third countries and relevant international organisations, as appropriate, to mitigate potential or actual shortages of medical devices included on the critical devices list or their component parts, where those devices or parts are imported into or exported from the Union, and where such potential or actual shortages have international implications, including potential introduction of temporary export transparency and export authorisation mechanisms.

Amendment 315
Jutta Paulus
on behalf of the Verts/ALE Group

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, including the recommendations, opinions and decisions made by the Medical Devices Steering Group as well as agendas and minutes of the Group’s
Amendment 316
Jutta Paulus
on behalf of the Verts/ALE Group

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

Amendment 317
Margarita de la Pisa Carrión
on behalf of the ECR Group
Jessica Stegrud

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

Amendment 318
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a regulation
Article 30 – paragraph 1 – introductory part
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:


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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 Article 32 and Article 4(1) of Regulation (EU) 2016/679 (‘GDPR’) and Article 3(1) EUDPR;

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Amendment 320
Aldo Patriciello, Ioan-Rareș Bogdan, Cristian-Silviu Buzoii, Massimiliano Salini, Antonio Tajani, Maria da Graça Carvalho

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 definition contained in the Article 4 of GDPR and Article 3(1) EUDPR;

Or. en

Amendment 321

Ivo Hristov, Nicolás González Casares, Maria-Manuel Leitão-Marques, Lina Gálvez Muñoz, Romana Jerković, Carlos Zorrinho, Robert Hajšel, Tsvetelina Penkova, Alicia Homs Ginel

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, personal data, with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements. Recalls that transfers of personal data to third countries or international organisations must comply with Chapter V of the EUDPR, relevant provisions of the GDPR, the LED and the Charter of Fundamental Rights and take into account the recommendations and guidelines of the EDPB.

Or. en

Amendment 322

Jutta Paulus

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 30 – paragraph 5
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.

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 *legally binding and enforceable* bilateral or multilateral confidentiality arrangements.

Or. en