



Plenary sitting

A9-0216/2021

25.6.2021

*****I**
REPORT

on the proposal for a regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (COM(2020)0725) – C9-0365/2020 – 2020/0321(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Nicolás González Casares

Symbols for procedures

- * Consultation procedure
- *** Consent procedure
- ***I Ordinary legislative procedure (first reading)
- ***II Ordinary legislative procedure (second reading)
- ***III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▬ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.

By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

**on the proposal for a regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices
(COM(2020)0725 – C9-0365/2020 – 2020/0321(COD))**

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2020)0725),
 - having regard to Article 294(2) and Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0365/2020),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the reasoned opinion submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the French Senate, asserting that the draft legislative act does not comply with the principle of subsidiarity,
 - having regard to the opinion of the European Economic and Social Committee of 27 April 2021¹,
 - having regard to the opinion of the Committee of the Regions of 7 May 2021²,
 - having regard to Rules 59 of its Rules of Procedure,
 - having regard to the opinion of the Committee on Industry, Research and Energy,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety (A9-0216/2021),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

¹ Not yet published in the Official Journal.

² Not yet published in the Official Journal.

Amendment 1

Proposal for a regulation Recital 1 a (new)

Text proposed by the Commission

Amendment

(1a) The COVID-19 pandemic has highlighted the risks to human health posed by the over-exploitation of wildlife and other natural resources and the accelerated loss of biodiversity on earth. Approximately 70 % of emerging diseases and almost all known pandemics (influenza, HIV/AIDS and COVID-19) are zoonoses. Those diseases have increased globally over the past 60 years and there are more and more zoonotic pathogens as a result of human activity and its ecological footprint. Changes in land use, deforestation, urbanisation, agricultural expansion and intensification, wildlife trafficking and consumption patterns are contributing dramatically to that increase. Zoonotic pathogens can be bacterial, viral or parasitic, or can involve unconventional agents, with the possibility of spreading to humans through direct contact or through food, water or the environment. Some diseases, such as HIV/AIDS, begin as a zoonosis but later mutate into human-only strains. Other zoonoses can cause recurring disease outbreaks, such as the Ebola virus disease and salmonellosis. Still others, such as the coronavirus that causes COVID-19, have the potential to cause global pandemics. According to the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES), an estimated 1, 7 million currently undiscovered viruses are thought to exist in mammal and avian hosts. Of those viruses, between 631,000 and 827,000 could have the ability to infect humans.

Amendment 2

Proposal for a regulation Recital 1 b (new)

Text proposed by the Commission

Amendment

(1b) As recognised by the World Health Organization, many of the same microbes infect animals and humans, so efforts by just one sector cannot prevent or eliminate the problem. Diseases may be transmitted from humans to animals or vice versa and must therefore be tackled in both, taking advantage of potential synergies in research and treatments. The COVID-19 pandemic is a clear example of the need to reinforce the application of the One Health approach in the Union to achieve better public health outcomes, since, as stated in the EU4Health Programme established by Regulation (EU) 2021/522 of the European Parliament and of the Council^{1a}, human health is connected to animal health and the environment and actions to tackle threats to health must take into account those three dimensions.

^{1a} Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (OJ L 197, 26.3.2021, p. 1.).

Amendment 3

Proposal for a regulation Recital 2

Text proposed by the Commission

Amendment

(2) The unprecedented experience of the COVID-19 pandemic has demonstrated

(2) The unprecedented experience of the COVID-19 pandemic has ***also***

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.

highlighted the difficulties of the Union and the Member States to cope with such a public health emergency and has demonstrated the need to strengthen the Union's role in order to be more effective in managing the availability of medicinal products and medical devices and in developing medical countermeasures to address the threats posed to public health *from an early stage in a harmonised way ensuring cooperation and coordination between Union, national and regional competent authorities, industry and other actors of the pharmaceutical and medical devices supply chains, including healthcare professionals. The Union needs to give a higher priority to health, to ensure the continued provision of high quality healthcare services, and to be prepared to cope with epidemics and other health threats.* 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, *inadequate mandates and resources of its health agencies,* and also by the limited degree of Union *and Member States* preparedness in case of a public health emergency impacting a majority of Member States.

Amendment 4

Proposal for a regulation Recital 2 a (new)

Text proposed by the Commission

Amendment

(2a) Shortages consist of different and complex root causes which need to be further mapped, understood and analysed together with all different stakeholders in order to be comprehensively addressed. A better understanding of the shortages should include identification of bottlenecks in the supply chain. In the specific case of the COVID-19 pandemic, the shortage of adjuvant treatments for

the disease had a variety of causes, ranging from production difficulties in third countries, to logistical or production difficulties within the Union, where the shortage of vaccines was due to a rarer cause, namely an unexpectedly high and rising demand.

Amendment 5

Proposal for a regulation

Recital 3

Text proposed by the Commission

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

Amendment

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

Amendment 6

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 Parliament¹¹ as well as discussions under recent Presidencies of the Council of the

Amendment

(4) ***Addressing the*** shortages of medicinal products has been a long-standing priority, ***but unresolved,*** for the Member States and European Parliament as illustrated by several reports from the European Parliament¹¹ as well as discussions under recent Presidencies of

European Union.

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))

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

Amendment 7

Proposal for a regulation

Recital 4 a (new)

Text proposed by the Commission

Amendment

(4a) Shortages of medicinal products represent a growing threat to public health, with a serious impact on health care systems and on patients' right to access adequate medical treatment. Increased global demand exacerbated by the COVID-19 pandemic has led to further shortages of medicinal products, weakening the healthcare systems in Member States and posing significant risks to patients' health and care, particularly in terms of disease progression and worsening of symptoms, longer delays or interruptions in care or therapy, longer periods of hospitalisations, increased exposure to falsified medicinal products, medication errors, adverse effects as a result of substitution of unavailable medicinal products with alternative ones, significant psychological distress for patients and increased costs for the healthcare systems.

Amendment 8

Proposal for a regulation

Recital 5

Text proposed by the Commission

Amendment

(5) The COVID-19 pandemic has

(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.

exacerbated the *already existing* problem of shortages for certain medicinal products considered as critical in addressing the pandemic, and has highlighted the *Union's external dependence in terms of domestic production of medicinal products and medical devices, the lack of coordination and the* structural limitations in the Union's *and Member States'* ability to rapidly and effectively react to such challenges during public health crises, *the need to support and strengthen the industrial fabric through appropriate policies, as well as the need for a more active and extended involvement of the Union institutions, bodies, offices and agencies addressing the health of the Union citizens.*

Amendment 9

Proposal for a regulation

Recital 6

Text proposed by the Commission

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

Amendment

(6) The rapid evolution of COVID-19 and the spread of the virus led to a sharp increase in demand for medical devices such as ventilators, surgical masks, and COVID-19 test kits while disruption of production or limited capacity to rapidly increase production and the complexity and global nature of the supply chain for medical devices, led to *severe* supply *difficulties and, at certain times, serious stock-outs, and placed Member States in competition with each other to respond to the legitimate needs of their citizens, contributing to uncoordinated actions at national levels such as national hoarding and stockpiling.* Those issues *further* resulted in new entities being involved in the *rushed* production of those products, which subsequently resulted in bottlenecks in conformity assessment, as well as the prevalence of *over-priced*, non-compliant, unsafe, and in some cases counterfeit

products. It is therefore appropriate ***and urgent*** to establish long-term structures within an appropriate Union body to ensure ***a more solid and effective coordination and*** monitoring of shortages of medical devices ***that can occur during*** a public health emergency, ***as well as increased and early dialogue with the medical devices industry and healthcare professionals to prevent and mitigate those shortages.***

Amendment 10

Proposal for a regulation Recital 6 a (new)

Text proposed by the Commission

Amendment

(6a) The COVID-19 outbreak and the subsequent health crisis revealed the need for a more coordinated Union 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 should be secured, taking into account the specificities of the health sector in the different Member States.

Amendment 11

Proposal for a regulation Recital 7

Text proposed by the Commission

Amendment

(7) Uncertainty of supply and demand and the risk of shortages of essential medicinal products and medical devices during a public health emergency like the COVID-19 pandemic can trigger export restrictions amongst Member States and other national protective measures, which can seriously impact the functioning of the internal market. Furthermore, shortages of

(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 ***aggravating the***

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.

consequences for public health, as well as lead to the need for temporary export transparency and export authorisation mechanisms. 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, adverse reactions *and fatalities* 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 *or being protected when doing so, as evidenced during the COVID-19 pandemic, with serious consequences for the health of health professionals.* 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 have an appropriate framework at Union level to coordinate the response of Member States* to address the question of shortages and to reinforce and formalise monitoring of critical medicinal products and medical devices *in the most efficient way and so as to avoid creating unnecessary burdens for stakeholders which may strain resources and cause additional delays.*

Amendment 12

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

Amendment

(8) Safe and efficacious medicinal products that treat, prevent or diagnose diseases which cause public health

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

emergencies, should be *identified*, developed, *notably through joint efforts of public authorities, private sector and academia*, and made available *to* Union *citizens* as soon as possible during such emergencies. The COVID-19 pandemic has also highlighted sub-optimal coordination and decision-making as regards multinational clinical trials, and Union-level advice on the use of medicinal products in national compassionate use programmes or outside of their authorised indications in the Union, causing delays in the adoption of research outcomes and in the development and availability of new or repurposed medicines.

Amendment 13

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 *or other actors in 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.

Amendment 14

Proposal for a regulation Recital 10

Text proposed by the Commission

(10) In order to ensure a better

Amendment

(10) In order to ensure a better

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

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

Amendment 15

Proposal for a regulation Recital 10 a (new)

Text proposed by the Commission

Amendment

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

Amendment 16

Proposal for a regulation Recital 10 b (new)

Text proposed by the Commission

Amendment

(10b) In order to ensure a better functioning of the internal market of medicinal products and contribute to a high level of human health protection, it is appropriate to facilitate the research and development of medicinal products,

which may have the potential to treat, prevent, or diagnose diseases that cause public health crises.

Amendment 17

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 ***a high level of human health protection by ensuring*** the smooth functioning of the internal market as regards medicinal products and medical devices. 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 18

Proposal for a regulation

Recital 11 a (new)

Text proposed by the Commission

Amendment

(11a) This Regulation establishes a framework to address the problem of shortages during public health emergencies and major events. However, shortages of medicinal products and medical devices are a persistent problem that has been increasingly affecting

health and lives of Union citizens for decades. Therefore, this Regulation should be a first step towards improving the Union response to this long-lasting issue. The Commission should subsequently propose the expansion of this framework to ensure that the issue of shortages is broadly and permanently tackled in the upcoming revision of Regulation (EC) No 726/2004 of the European Parliament and of the Council^{1a} and Directive 2001/83/EC of the European Parliament and of the Council^{1b}.

^{1a} Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

^{1b} Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

Amendment 19

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

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.

response to the COVID-19 pandemic *that have proven effective, and on experience and examples in other countries, while remaining flexible enough to tackle any future health crisis in the most efficient way to the benefit of public health and patients.*

Amendment 20

Proposal for a regulation

Recital 13

Text proposed by the Commission

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

Amendment

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

Amendment 21

Proposal for a regulation

Recital 13 a (new)

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

Council^{1a}.

^{1a} Regulation (EU) 2021/241 of the European Parliament and of the Council of 12 February 2021 establishing the Recovery and Resilience Facility (OJ L 57, 18.2.2021, p. 17).

Amendment 22

Proposal for a regulation Recital 15

Text proposed by the Commission

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

Amendment

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

Amendment 23

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

Amendment

(18) The work of the Emergency Task Force should be separate from the work of the scientific committees of the Agency and should be carried out without prejudice to the scientific assessments of those committees. The Emergency Task Force

should provide recommendations with regard to the use of medicinal products in the fight ***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.

should provide recommendations with regard to the use of medicinal products in the fight ***to overcome*** the public health crisis. The Committee for Medicinal Products for Human Use should be able to use those recommendations when preparing scientific opinions on compassionate or other early use of a medicinal product prior to marketing authorisation. ***The Executive Steering Group on Shortages and Safety of Medicinal Products could also draw on the work of the Emergency Task Force when developing the critical medicines lists.***

Amendment 24

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 as well as the ‘rolling’ review i.e. on an on-going basis, of emerging evidence to allow a more efficient assessment of medicinal products including vaccines during public health emergencies, ***while guaranteeing a high level of human health protection.***

Amendment 25

Proposal for a regulation Recital 19 a (new)

Text proposed by the Commission

Amendment

(19a) Experience with clinical trials during the COVID-19 pandemic revealed a tremendous amount of duplication of

investigations on the same interventions, many small trials, under-representation of important population subgroups, based on gender, age, ethnicity or medical comorbidities, and a lack of collaboration, posing a risk of research waste. To improve the clinical research agenda, international regulators pointed out the need for robust evidence on quality, efficacy and safety of medicinal products. The main way to obtain reliable evidence is through coordinated, well-designed, adequately powered large randomised controlled trials. Clinical trial results and data should be made public.

Amendment 26

Proposal for a regulation Recital 19 b (new)

Text proposed by the Commission

Amendment

(19b) The clinical trials phase during which the safety, efficacy and quality of medicinal product candidates is studied in humans, is a key step in the development of medicinal products, including vaccines. It is therefore important that Regulation (EU) No 536/2014 of the European Parliament and of the Council^{1a} is fully applied, in particular as regards the launch of a functioning clinical trials information system.

^{1a} Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

Amendment 27

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.

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. ***In that regard, a new Union wide and Union funded vaccine trial network called VACCELERATE was launched in light of the Commission communication of 17February 2021 entitled ‘HERA Incubator: Anticipating together the threat of COVID-19 variants’ . The Emergency Task Force should build on that trial network and other established networks such as the Heads of Medicines Agencies , the Clinical Trials Facilitation and Coordination Group and the European Clinical Research Infrastructure Network to ensure that adequate data on new medicinal products in light of a possible public health emergency is expediently generated.*** It is therefore **imperative** 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 ***and coordinate the development of clinical trial protocols. 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.*** Such an approach would strengthen the research environment in the Union, and promote harmonisation and avoid subsequent delays in integrating

the results of research to a marketing authorisation. A Union sponsor could benefit from Union research funding available at the time of the public health emergency as well as existing clinical trial networks to facilitate the development, application, submission, and running of the trial. This may be particularly valuable for trials established by Union or international public health or research organisations.

Amendment 28

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) 2019/1396¹² to provide independent scientific and technical assistance to the Member States, the Commission, the Medical Device Coordination Group (MDCG), notified bodies and manufacturers.

¹² Commission Implementing Decision (EU) 2019/1396 of 10 September 2019 laying down the rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the designation of expert panels in the field of medical devices OJ L 234, 11.9.2019, p. 23

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) 2019/1396¹² 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 Union regulatory system.***

¹² Commission Implementing Decision (EU) 2019/1396 of 10 September 2019 laying down the rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the designation of expert panels in the field of medical devices OJ L 234, 11.9.2019, p. 23

Amendment 29

Proposal for a regulation

Recital 22 a (new)

Text proposed by the Commission

Amendment

(22a) The Emergency Task Force should review clinical trial protocols and advice developers on clinical trials that are conducted in the Union, providing guidance on clinically relevant endpoints and targets for vaccines and treatments in order to guide clinical trial design toward meeting the criteria for effective public health interventions.

Amendment 30

Proposal for a regulation

Recital 24

Text proposed by the Commission

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. This would allow for long-term sustainability for the functioning of the panels and provide clear synergies with related crisis preparedness work for medicinal products. Those structures would in no way change the regulatory system or the decision-making procedures in the area of medical devices already in place in the Union, which should remain clearly distinct from the one for medicinal products.

(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 light of this, all national and, eventually, Union entities engaged in stockpiling of medical devices, should report their stocks to the Agency.*** This would allow for long-term sustainability for the functioning of the panels and provide clear synergies with related crisis preparedness work for medicinal products. Those structures would in no way change the regulatory system or the decision-making procedures in the area of medical devices already in place in the Union, which should remain clearly distinct from the one for medicinal products.

Amendment 31

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 EUDAMED IT platform for medical devices, ***alongside enhanced protection of data infrastructure and deterrence from possible cyberattacks***. That work should also be facilitated by, where appropriate, emerging digital technologies such as computational models and simulations for clinical trials, as well as data from the EU Space Programme such as the Galileo geolocation services, and Copernicus earth observation data.

Amendment 32

Proposal for a regulation
Recital 26

Text proposed by the Commission

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

Amendment

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

Amendment 33

Proposal for a regulation Recital 26 b (new)

Text proposed by the Commission

Amendment

(26b) 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 International Organization for Standardization (ISO) for the identification of medicinal products for human use (IDMP) standards.

Amendment 34

Proposal for a regulation Recital 26 c (new)

Text proposed by the Commission

Amendment

(26c) The handling of sensitive data, crucial for dealing with potential public health emergencies, requires a high level of protection against cyber-attacks. Health care organisations have been also facing heightened cyber-security threats in the midst of the COVID-19 pandemic. The Agency itself has been 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 being leaked on the internet. There is therefore the need for the Agency to be equipped with a high level of security against cyber-attacks to ensure the normal functioning of the Agency at all times and especially during public health emergencies. To that end, the Agency should establish a plan to prevent, detect, mitigate and respond to cyber-attacks so that its operation is

secured at all times, while preventing any illegal access to documentation held by the Agency.

Amendment 35

Proposal for a regulation Recital 26 d (new)

Text proposed by the Commission

Amendment

(26d) Due to the sensitive nature of health data, the Agency should safeguard and guarantee its processing operations respect the data protection principles of lawfulness, fairness and transparency, purpose limitation, data minimisation, accuracy, storage limitation, integrity and confidentiality. Where it is necessary for the purposes of this Regulation to process personal data, this should be done in accordance with Union law on the protection of personal data. Any processing of personal data based on this Regulation should take place in accordance with Regulations (EU) 2016/679^{1a} and (EU) 2018/1725^{1b} of the European Parliament and of the Council

^{1a} Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

^{1b} Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No

Amendment 36

Proposal for a regulation Recital 26 e (new)

Text proposed by the Commission

Amendment

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

Amendment 37

Proposal for a regulation Recital 26 f (new)

Text proposed by the Commission

Amendment

(26f) Credibility of the Agency and public trust in its decisions relies on a high degree of transparency. Therefore, proactive engagement of adequate communication tools with the general public should be foreseen. In addition, strengthened and accelerated transparency standards and measures

regarding the Agency's working bodies and clinical data assessed for the evaluation and surveillance of medicinal products and medical devices are paramount to gain and upheld public trust. This Regulation establishes a framework for those strengthened transparency standards and measures, based on the Agency's efforts, standards and measures put in place during the COVID-19 pandemic.

Amendment 38

Proposal for a regulation Recital 27

Text proposed by the Commission

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

Amendment

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

Amendment 39

Proposal for a regulation
Recital 27 a (new)

Text proposed by the Commission

Amendment

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

Amendment 40

Proposal for a regulation
Recital 27 b (new)

Text proposed by the Commission

Amendment

(27b) Taking into account that the COVID-19 pandemic has not come to an end, and that the duration and evolution of health crises, such as pandemics, are uncertain, provision should be made for a review of the effectiveness of the functioning of the structures and mechanisms established in accordance with this Regulation. In light of that review, the structures and mechanisms should be amended, if appropriate.

Amendment 41

Proposal for a regulation
Recital 29

Text proposed by the Commission

Amendment

(29) In order to ensure that sufficient resources are available for the work

(29) In order to ensure that sufficient resources, ***including appropriate staffing***

provided for under this Regulation, expenditure of the Agency should be covered by the contribution from the Union to the Agency's revenue.

and adequate expertise, are available for the work provided for under this Regulation, expenditure of the Agency should be covered by the contribution from the Union to the Agency's revenue.

Amendment 42

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

Text proposed by the Commission

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

Amendment

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

Amendment 43

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

Text proposed by the Commission

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

Amendment

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

Amendment 44

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

Text proposed by the Commission

Amendment

(ba) set up an interoperable and digital database at Union level to monitor and report on shortages of medicinal products;

Amendment 45

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

Text proposed by the Commission

Amendment

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

^{1a} Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

Amendment 46

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

Text proposed by the Commission

Amendment

(ca) 'supply' refers to the total volume of stock of an individual medicinal product or medical device that is placed on the market by a marketing authorisation holder or a manufacturer;

Amendment 47

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

Text proposed by the Commission

Amendment

(cb) 'demand' relates to the request for a medicinal product or a medical device by a healthcare professional or patient in response to a clinical need. For demand to be satisfactorily met, the medicinal product or the medical device will need to be acquired in time and sufficient

quantity to allow continuity of best care of patients. Wholesalers are usually a key supply link between marketing authorisation holders or manufacturers and the users of medicinal products or medical devices, respectively, and in those cases, in order to estimate demand, the quantity requested in wholesale orders should be considered;

Amendment 48

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 **at a national level, whatever the cause;**

Amendment 49

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 **manufacturing, supply, demand** 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. **Recurrent problems of supply**

of medicinal products are excluded from the scope of this definition.

Amendment 50

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 **at regular intervals** either in person or remotely, **and whenever the situation requires**, 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 51

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 **authorised** senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields. **The Medicines Steering Group shall also include a representative of the Agency's Patients' and Consumers' Working Party (PCWP) and a representative of the Agency's Healthcare Professionals' Working Party (HCPWP) as observers. The list of the members of the Medicines Steering Group shall be transparent and**

made public on the Agency's web-portal.

Amendment 52

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. **Any member of the Medicines Steering Group may propose to** the Chair **to** invite third parties, including representatives of medicinal product interest groups, marketing authorisation holders, **wholesale distributors, or any other appropriate actor in the pharmaceutical supply chain, representatives of healthcare professionals, patients and consumers** to attend its meetings **when their contribution may inform the discussions of the Medicines Steering Group.**

Amendment 53

Proposal for a regulation

Article 3 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. The Medicines Steering Group shall guarantee an open communication and close cooperation with marketing authorisation holders, manufacturers, relevant actors of the pharmaceutical supply chain, and representatives of healthcare professionals, patients and consumers with a view to enabling early notification or identification of potential or actual shortages of medicinal products considered as critical during a major event or a public health emergency as provided for in Article 6.

Amendment 54

Proposal for a regulation Article 3 – paragraph 6

Text proposed by the Commission

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

Amendment

6. The Medicines Steering Group shall be responsible for fulfilling the tasks referred to in Article **4(3) and**(4) and Articles 5 to 8.

Amendment 55

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

Text proposed by the Commission

Amendment

6a. *The Medicines Steering Group may consult with the Committee for Medicinal Products for Veterinary Use whenever it deems it necessary to deal with public health emergencies and major events related to zoonoses or diseases affecting only animals that have or may have a major impact on human health.*

Amendment 56

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

Text proposed by the Commission

Amendment

6b. *Members of the Medicines Steering Group shall not have financial or other interests in the pharmaceutical industry that could affect their impartiality. They shall act in the public interest and in an independent manner and make an annual declaration of their financial interests and update it whenever a relevant change occurs. All indirect interests which could relate to the*

pharmaceutical industry shall be entered in a register held by the Agency and upon request shall be accessible to the public. The declaration of interests shall be made publicly available on the Agency's web-portal.

Amendment 57

Proposal for a regulation Article 4 – paragraph 1

Text proposed by the Commission

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

Amendment

1. The Agency shall continuously monitor any event that is likely to lead to a major event or a public health emergency ***in coordination with the national competent authorities. In that regard, the Agency shall cooperate closely with the European Centre for Disease Prevention and Control (ECDC) and other Union agencies, where relevant.***

Amendment 58

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

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) ***or the database referred to in Article 12a, once fully functional,*** shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report ***without delay*** to the Agency on any event, including a shortage of a medicinal product in a given Member State, that is likely to lead to a major event or a public health emergency. Where a national competent authority informs the Agency of a shortage of a medicinal product in a given Member

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).

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 59

Proposal for a regulation Article 4 – paragraph 3

Text proposed by the Commission

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

Amendment

3. Where the Agency considers that an actual or imminent major event needs to be addressed, it shall inform the Commission and the Member States thereof. The Commission, on its own initiative or following a request from one or more Member States, or the Executive Director of the Agency *shall then* request the assistance of the Medicines Steering Group to *analyse the available information. Based on the analysis of the information, the Medicines Steering Group may propose to the Commission to formally recognise* the major event *and, pursuant to Article 5, it shall provide recommendations to address such an event.*

Amendment 60

Proposal for a regulation Article 5 – paragraph 2

Text proposed by the Commission

The Medicines Steering Group shall provide advice to the Commission and

Amendment

The Medicines Steering Group shall provide advice *and recommendations* to

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 726/2004.¹⁸

¹⁸ Regulation (EC) No 726/2004

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 726/2004.¹⁸

¹⁸ Regulation (EC) No 726/2004

Amendment 61

Proposal for a regulation

Article 5 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

The Commission and Member States shall provide a substantiated justification in the event that the recommendations provided by the Medicines Steering Group are not taken into account. The recommendations provided by the Medicines Steering Group, as well as any substantiated justifications provided by the Commission and Member States, shall be made publicly available via the web-portal as referred to in Article 13.

Amendment 62

Proposal for a regulation

Article 5 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

Where a link is established with zoonoses or diseases affecting only animals that have or may have a major impact on human health or where the use of active ingredients of veterinary medicinal products may be useful to address the public health emergency or the major event, or otherwise whenever necessary, the Medicines Steering Group may liaise with the Committee for Medicinal

Amendment 63

Proposal for a regulation

Article 6 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Amendment 64

Proposal for a regulation

Article 6 – paragraph 2

Text proposed by the Commission

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

Amendment

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

updated in accordance with the outcomes of the review process under Article 16 of this Regulation, where appropriate, for which the Medicines Steering Group shall liaise with the Emergency Task Force.

Amendment 65

Proposal for a regulation Article 6 – paragraph 3

Text proposed by the Commission

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

Amendment

3. The Medicines Steering Group shall adopt a set of information **and actions** necessary to monitor the supply and demand of medicinal products included on the lists referred to in paragraphs 1 and 2 ('the critical medicines lists') and inform its working party thereof. ***Union or national entities that are engaged in stockpiling of medicinal products shall be informed accordingly. The Medicines Steering Group shall report to the Agency and to the Commission in due time on the monitoring and shall notify immediately on any major event or shortage in the supply.***

Amendment 66

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

Text proposed by the Commission

Amendment

4a. The Agency shall establish a publicly accessible webpage with information on actual shortages of critical medicinal products. Reference to national registries on medicinal products shortages shall also be included. The webpage shall contain information on, but not limited to:
(a) trade name and international non-proprietary name;

- (b) indication;*
- (c) reason for the shortage;*
- (d) start and end dates;*
- (e) Member States affected;*
- (f) information for healthcare professionals and patients, including information on alternative treatments.*

Amendment 67

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 68

Proposal for a regulation

Article 8 – paragraph 1

Amendment

On the basis of the critical medicines lists and the information and data provided in accordance with Articles 10 and 11, ***and the database established in accordance with Article 12a, once fully functional***, 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, ***as well as with the ECDC.***

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

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 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. ***Those reports may also be made available to other actors in the pharmaceutical supply chain, where relevant.***

Amendment 69

**Proposal for a regulation
Article 8 – paragraph 2**

Text proposed by the Commission

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

Amendment

2. Where requested by the Commission, ***one or more national competent authorities*** or the sub-network referred to in Article 9(2), the Medicines Steering Group shall provide aggregated data and forecasts of demand to substantiate its findings. In that regard, the Medicines Steering Group shall ***use data from the database established in accordance with Article 12a, once fully functional, and shall*** liaise with the European Centre for Disease Prevention and Control to obtain epidemiological data, ***models and development scenarios*** to help forecast medicinal product needs, and with the Executive Steering Group on Shortages of Medical Devices referred to in Article 19 where medicinal products included on the critical medicines lists are administered with a medical device. ***The aggregated data and forecasts of demand may also be made available to other actors in the pharmaceutical supply chain, where relevant, with a view to better prevent or***

mitigate potential or actual shortages. The Medicines Steering Group shall also share its findings and conclusions with Union and national actors engaged with stockpiling of medicinal products and medical devices.

Amendment 70

Proposal for a regulation Article 8 – paragraph 3

Text proposed by the Commission

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

Amendment

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

Amendment 71

Proposal for a regulation Article 8 – paragraph 4

Text proposed by the Commission

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

Amendment

4. The Medicines Steering Group may, on its own initiative or upon request from the Commission, provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders, ***representatives of healthcare professionals*** 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 72

Proposal for a regulation Article 8 – paragraph 5

Text proposed by the Commission

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

Amendment

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

Amendment 73

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

Text proposed by the Commission

Amendment

5a. Where the recommendations referred to in paragraphs 3 and 4 are not taken into account or are not implemented, the Commission, Member States and marketing authorisation holders shall provide, where appropriate, a substantiated justification.

Amendment 74

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

Text proposed by the Commission

(a) specify the procedures for

Amendment

(a) specify the procedures ***and criteria***

establishing the critical medicines lists;

for establishing ***and reviewing*** the critical medicines lists, ***ensuring adequate consultation with marketing authorisation holders and other relevant actors in the pharmaceutical supply chain as well as with healthcare professionals, consumers and patients;***

Amendment 75

Proposal for a regulation

Article 9 – paragraph 1 – point b

Text proposed by the Commission

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

Amendment

(b) specify the methods of and criteria for the monitoring, data collection and reporting provided for in Articles 4, 7 and 8 ***with a basic minimum data set;***

Amendment 76

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 until the database provided for in Article 12a is fully functional, based on harmonised data fields across Member States;***

Amendment 77

Proposal for a regulation

Article 9 – paragraph 1 – point f a (new)

Text proposed by the Commission

Amendment

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

Amendment 78

Proposal for a regulation

Article 9 – paragraph 2 – point b

Text proposed by the Commission

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

Amendment

(b) request information, ***including on the supply of the critical medicines lists,*** from the points of contact included in the sub-network referred to in point (a) and set a deadline for its submission ***if that information is not available in the database provided for in Article 12a;***

Amendment 79

Proposal for a regulation

Article 9 – paragraph 2 – point c

Text proposed by the Commission

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

Amendment

(c) request information from the single points of contact from Member States' national competent authorities based on the set of information agreed on by the Medicines Steering Group and set a deadline for its submission ***if that information is not available in the database provided for in Article 12a.***

Amendment 80

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;***

Amendment 81

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

Text proposed by the Commission

Amendment

(ea) available stocks;

Amendment 82

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

Text proposed by the Commission

Amendment

(eb) quantities already delivered;

Amendment 83

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

Text proposed by the Commission

Amendment

(ec) projected deliveries;

Amendment 84

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

Text proposed by the Commission

Amendment

(g) mitigation plans including production and supply capacity;

(g) **prevention and** mitigation plans including **information on** production and supply capacity, **production sites of the finished pharmaceutical product and of active pharmaceutical ingredients, potential alternative production sites or minimum stock levels, with a view to guarantee continued supply and prevent shortages of medicinal products included on the critical medicines lists;**

Amendment 85

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

Text proposed by the Commission

(h) information from the wholesale distributors and legal person entitled to supply the medicinal product to the public

Amendment

deleted

Amendment 86

Proposal for a regulation Article 10 – paragraph 2

Text proposed by the Commission

2. Marketing authorisation holders of medicinal products authorised in the Union shall, within 6 months from the date of application of this Regulation, provide the information required pursuant to Article 9(1)(e) in the form of an electronic submission in the database referred to in Article 57(1)(l) of Regulation (EC) No 726/2004. Those marketing authorisation holders shall update their submission wherever necessary.

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 ***and in compliance with the standards developed by the International Organization for Standardization (ISO) for the identification of medicinal products for human use (IDMP)***. Those marketing authorisation holders shall update their submission wherever necessary.

Amendment 87

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

Amendment

4. Where marketing authorisation holders for medicinal products included on the critical medicines lists indicate that the submitted information ***requested by the Agency or the national competent***

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.

authorities contains information of a commercially confidential nature, they shall identify the relevant parts and clarify the reasons for such an indication. The Agency shall assess the merits of each request and protect commercially confidential information against unjustified disclosure.

Amendment 88

Proposal for a regulation Article 10 – paragraph 5

Text proposed by the Commission

5. Where marketing authorisation holders for medicinal products included on the critical medicines lists are in possession of any additional information, which provides evidence of a potential or actual shortage they shall immediately provide such information to the Agency.

Amendment

5. Where marketing authorisation holders for medicinal products included on the critical medicines lists **and/or other relevant actors in the pharmaceutical supply chain** are in possession of any additional information, which provides evidence of a potential or actual shortage they shall immediately provide such information to the Agency.

Amendment 89

Proposal for a regulation Article 10 – paragraph 6 – point c

Text proposed by the Commission

(c) inform the Medicines Steering Group of any measures taken and report on the results of those measures, including information on the resolution of the potential or actual shortage.

Amendment

(c) inform the Medicines Steering Group of any measures taken and report on the **monitoring and** results of those measures, including information on the resolution of the potential or actual shortage.

Amendment 90

Proposal for a regulation Article 10 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6a. *In order to supplement the shortage prevention and mitigation plans of critical medicinal products, the Agency and national competent authorities may request additional information from wholesale distributors and other relevant actors regarding any logistical challenges incurred by the wholesale supply chain.*

Amendment 91

Proposal for a regulation

Article 11 – paragraph 1 – introductory part

Text proposed by the Commission

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:

1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, Member States shall, by the deadline set by the Agency, ***submit the following information provided that it is not available in the database established in Article 12a:***

Amendment 92

Proposal for a regulation

Article 11 – paragraph 2

Text proposed by the Commission

Amendment

2. Where necessary to fulfil their reporting obligations set out in paragraph 1, Member States, with the support of the Agency, shall gather information and data on stock levels from wholesale distributors and other legal entities entitled to supply the public with medicinal products included on the critical medicines lists.

2. Where necessary to fulfil their reporting obligations set out in paragraph 1, Member States, with the support of the Agency, shall gather ***relevant*** information and data, ***including*** on stock levels, from wholesale distributors and other legal entities ***and persons authorised or*** entitled to supply the public with medicinal products included on the critical medicines lists.

Amendment 93

Proposal for a regulation Article 11 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. National competent authorities for medicinal products shall facilitate online data collection on the impact of medicine shortages on patients and consumers. Relevant aggregated data from those surveys shall be shared by the sub-network of single points of contact from national competent authorities referred to in Article 3(5) with the Medicines Steering Group to inform recommendations on medicinal products shortage management.

Amendment 94

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

Text proposed by the Commission

Amendment

(aa) facilitate the coordination between manufacturers and other relevant stakeholders to address demand surges;

Amendment 95

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

Text proposed by the Commission

Amendment

(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities;

(b) consider the need for guidelines **and recommendations** addressed to Member States, marketing authorisation holders, and other entities, **including from the pharmaceutical supply chain as well as healthcare professionals, to support them in their work and in the communication with patients;**

Amendment 96

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 the Union and where such potential or actual shortages have international implications, ***and report those actions as well as the results obtained to the Medicines Steering Group.***

Amendment 97

Proposal for a regulation Article 12 a (new)

Text proposed by the Commission

Amendment

Article 12a

European Medicines Supply Database

1. The Agency shall, in collaboration with the Commission and Member States, set up, maintain and manage the European medicines supply database (EUMSD) for the following purposes:

(a) to enable the monitoring of supply and demand of medicinal products at Union and Member State level;

(b) to enable the monitoring and reporting of shortages of medicinal products at Union and Member State level;

(c) to enable marketing authorisation holders and wholesale distributors to comply with the information obligations

laid down in Article 10;

(d) to enable the Commission, the Agency and the national competent authorities to carry out their tasks in accordance with this Regulation on a well-informed basis and to enhance the cooperation between them.

The EUMSD, which shall be functional not only during public health emergencies and major events but also under normal circumstances, shall function as an interoperable and digital database at Union level, based on the data reported through the national electronic platforms established pursuant to paragraph 2. The database shall allow the Agency and the national competent authorities to simultaneously access and share the information provided in the database.

2. Each Member State shall develop an electronic platform with a view to establishing real-time monitoring of the supply of medicinal products, capable of determining the volume of supply of each medicinal product existing at any given moment, and detecting, predicting and preventing shortages of medicinal products. Those platforms, which shall be managed by the national competent authorities, shall be fully operational at Member State level by... [30 months after the date of entry into force of this Regulation].

Data on supply and demand shall be reported at Member State level by the following entities:

- (a) marketing authorisation holders*
- (b) wholesale distributors*
- (c) community and hospital pharmacies*

3. In addition to paragraph 2, the electronic platforms shall provide the national competent authorities with real-time access to information on unmet demands from wholesale distributors,

community pharmacies and hospital pharmacies at national level. Those platforms shall also allow marketing authorisation holders to report any medicinal products supply problems, including manufacturing problems.

4. Member State platforms shall be interoperable and shall replicate their information in the EUMSD managed by the Agency, thereby preventing any duplication of the reporting process by the single points of contact established in Article 9(2).

5. The data generated by the Member State platforms and consequently by the EUMSD shall make it possible to identify any supply problems along the supply chain and, through the application of big data techniques and, where appropriate, artificial intelligence, shall be able to forecast supply problems in advance.

6. The data submitted shall be compliant with the standards developed by the ISO for IDMP and be based on the four domains of master data in pharmaceutical regulatory processes: substance, product, organisation and referential data.

7. The Agency shall, in collaboration with the Commission and Member States, draw up the functional specifications for the database, together with a plan for the implementation of the EUMSD and the Member State platforms by... [6 months after the date of entry into force of this Regulation]. That plan shall seek to ensure that the EUMSD is fully functional by ... [48 months after the date of entry into force of this Regulation].

8. Where a national competent authority indicates that the submitted information contains information of a commercially confidential nature, it shall identify the relevant parts and clarify the reasons for such an indication. The Agency shall assess the merits of each request and protect commercially

confidential information against unjustified disclosure.

9. *In view of the commercially sensitive nature of the data provided to the EUMSD, access to the database shall be limited to the Commission, the Agency, national competent authorities reporting the data to the database and the Medicines Steering Group.*

Amendment 98

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 ***a dedicated space on*** 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, ***and respond to disinformation targeting the work of the Medicines Steering Group as appropriate.***

Amendment 99

Proposal for a regulation Article 13 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Proceedings undertaken by the Medicines Steering Group shall be transparent. The agenda and minutes of the Medicines Steering Group as well as the rules of procedure and recommendations and, where appropriate, votes shall be documented and made publicly available, including any dissensions.

Amendment 100

Proposal for a regulation
Article 14 – paragraph 1

Text proposed by the Commission

1. The Emergency Task Force is hereby established as part of the Agency. It shall be convened during public health emergencies, either in person or remotely. The Agency shall provide its secretariat.

Amendment

1. The Emergency Task Force is hereby established as part of the Agency. It shall be convened ***in preparation for and*** during public health emergencies, either in person or remotely. The Agency shall provide its secretariat.

Amendment 101

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.

Amendment 102

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) 536/2014.²¹ External

Amendment

3. The Emergency Task Force shall be composed of representatives of the scientific committees, working parties, ***including representatives of the PCWP and the HCPWP***, 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

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.

²¹ Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, OJ L 158, 27.5.2014, p. 1

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.

²¹ Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, OJ L 158, 27.5.2014, p. 1

Amendment 103

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 104

Proposal for a regulation Article 14 – paragraph 8

Text proposed by the Commission

8. Article 63 of Regulation (EC) No 726/2004 shall apply to the Emergency Task Force as regards transparency and the

Amendment

5. The Chair may invite representatives of Member States, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, ***independent clinical trial experts and researchers***, and interest groups representing patients and healthcare professionals to attend its meetings.

Amendment

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.

independence of its members. ***Members of the Emergency Task Force shall update the annual declaration of their financial interests provided for in Article 63 of Regulation (EC) No 726/2004 whenever a relevant change occurs.***

Amendment 105

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 procedures ***and guidance*** 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 106

Proposal for a regulation Article 15 – paragraph 5

Text proposed by the Commission

5. When authorising a clinical trial application for which scientific advice has been given, Member States shall take that advice duly into account.

Amendment

5. When authorising a clinical trial application for which scientific advice has been given, Member States shall take that advice duly into account. ***The scientific advice provided by the Emergency Task Force shall be without prejudice to the ethical review provided for in Regulation (EU) No 536/2014.***

Amendment 107

Proposal for a regulation Article 15 a (new)

Article 15a

***Public information about clinical trials
and marketing authorisation decisions***

1. For the duration of a public health emergency, the sponsors of clinical trials conducted in the Union shall:

(a) publish the study protocol at the start of the trial through the EU clinical trials register;

(b) publish the summary of the results through the EU clinical trials register within a timeline set by the Agency that is shorter than the timeline laid down in Article 37 of Regulation (EU) No 536/2014.

2. Where a medicinal product receives a marketing authorisation, the Agency shall publish:

(a) the product information with details of the conditions of use at the time of marketing authorisation;

(b) the European public assessment reports as soon as possible and, where possible, within seven days of marketing authorisation;

(c) the clinical data submitted to the Agency in support of the application where possible within two months of authorisation by the Commission, and after personal data have been anonymised and commercially confidential information redacted;

(d) the full body of the Risk Management Plan and any updated versions.

Amendment 108

**Proposal for a regulation
Article 16 – paragraph 1**

Text proposed by the Commission

1. Following the recognition of a public health emergency, the Emergency Task Force shall undertake a review of the available scientific data on medicinal products, which may have the potential to be used to address the public health emergency. The review shall be regularly updated during the public health emergency.

Amendment

1. Following the recognition of a public health emergency, the Emergency Task Force shall undertake a review of the available scientific data on medicinal products, which may have the potential to be used to address the public health emergency. The review shall be regularly updated during the public health emergency, ***including where agreed by the Emergency Task Force and the Committee for Medicinal Products for Human Use in preparation of the assessment of a marketing authorisation application.***

Amendment 109

**Proposal for a regulation
Article 16 – paragraph 2**

Text proposed by the Commission

2. In preparation of the review, the Emergency Task Force may request information and data from marketing authorisation holders and from developers and engage with them in preliminary discussions. The Emergency Task Force may also, where available, make use of observational studies of health data generated outside of clinical studies taking into account their reliability.

Amendment

2. In preparation of the review, the Emergency Task Force may request information and data from marketing authorisation holders and from developers and engage with them in preliminary discussions. The Emergency Task Force may also, where available, make use of observational studies of health data generated outside of clinical studies taking into account their reliability. ***The Emergency Task Force may liaise with medicine agencies of third countries for additional information and data exchange.***

Amendment 110

**Proposal for a regulation
Article 16 – paragraph 7**

Text proposed by the Commission

Amendment

7. The Agency shall publish the opinions adopted pursuant to paragraph 4 including any updates on its web-portal.

deleted

Amendment 111

Proposal for a regulation Article 17 – paragraph 1

Text proposed by the Commission

Amendment

The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Emergency Task Force.

The Agency shall, via ***a dedicated space on*** its web-portal and other appropriate means and, in conjunction with national competent authorities, inform ***without delay*** the public and relevant interest groups with regard to the work of the Emergency Task Force, ***and respond to disinformation targeting the work of the Emergency Task Force as appropriate.***

Amendment 112

Proposal for a regulation Article 17 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The list of the members of the Emergency Task Force, the rules of procedure, as well as the recommendations provided pursuant to Article 16 (3) and the opinions adopted pursuant to Article 16 (4) shall be published on the Agency's web-portal.

Amendment 113

Proposal for a regulation Article 18 – paragraph 1 – point a

Text proposed by the Commission

(a) develop and maintain electronic tools for the submission of information and data, including electronic health data generated outside the scope of clinical studies;

Amendment

(a) develop and maintain electronic tools, ***including an interoperable and digitalized platform***, for the submission of information and data, including electronic health data generated outside the scope of clinical studies;

Amendment 114

Proposal for a regulation

Article 18 – paragraph 1 – point b

Text proposed by the Commission

(b) coordinate independent ***vaccine*** effectiveness and safety monitoring studies using relevant data held by public authorities. Such coordination shall be conducted jointly with the European Centre for Disease Prevention and Control and notably through a new vaccine monitoring platform;

Amendment

(b) coordinate independent ***utilisation, effectiveness and safety monitoring studies of medicinal products intended to treat, prevent or diagnose a disease*** using relevant data held by public authorities; ***for vaccines***, such coordination shall be conducted jointly with the European Centre for Disease Prevention and Control and notably through a new vaccine monitoring platform;

Amendment 115

Proposal for a regulation

Article 18 – paragraph 1 – point c

Text proposed by the Commission

(c) as part of its regulatory tasks, make use of digital infrastructures or tools, to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of clinical studies, and the exchange of such data between Member States, the Agency, and other Union bodies;

Amendment

(c) as part of its regulatory tasks, make use of digital infrastructures or tools, to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of ***interventional*** clinical studies, and the exchange of such data between Member States, the Agency, and other Union bodies;

Amendment 116

Proposal for a regulation
Article 19 – paragraph 1

Text proposed by the Commission

1. The Executive Steering Group on Medical Devices (‘the Medical Devices Steering Group’) is hereby established as part of the Agency. It shall meet either in person or remotely, in preparation for or during a public health emergency. The Agency shall provide its secretariat.

Amendment

1. The Executive Steering Group on Medical Devices (‘the Medical Devices Steering Group’) is hereby established as part of the Agency. It shall meet ***at regular intervals*** either in person or remotely, ***and whenever the situation requires***, in preparation for or during a public health emergency. The Agency shall provide its secretariat.

Amendment 117

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 ***authorised*** senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields. ***The Medical Devices Steering Group shall also include a representative of the PCWP and a representative of the HCPWP as observers. The list of members of the Medical Devices Steering Group shall be transparent and made public on the Agency’s web-portal.***

Amendment 118

Proposal for a regulation
Article 19 – paragraph 3

Text proposed by the Commission

3. The Medical Devices Steering Group shall be chaired by the Agency. The Chair **may** invite third parties, including representatives of medical device interest groups to attend its meetings.

Amendment

3. The Medical Devices Steering Group shall be chaired by the Agency. ***Any member of the Medical Devices Steering Group may propose to the Chair to*** invite third parties, including representatives of medical device interest groups, ***such as representatives of manufacturers and notified bodies or any other actor in the medical devices supply chain, as well as representatives of healthcare professionals, patients and consumers*** to attend its meetings ***when their contribution may inform the discussions of the Medical Devices Steering Group.***

Amendment 119

Proposal for a regulation Article 19 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6a. Members of the Medical Devices Steering Group shall not have financial or other interests in the medical devices industry that could affect their impartiality. They shall act in the public interest and in an independent manner and make an annual declaration of their financial interests and update it whenever a relevant change occurs. All indirect interests which could relate to the medical devices industry shall be entered in a register held by the Agency and be accessible to the public, upon request. The declaration of interests shall be made publicly available on the Agency's web-portal.

Amendment 120

Proposal for a regulation Article 20 – paragraph 2

Text proposed by the Commission

2. The Medical Devices Steering Group shall adopt a set of information necessary to monitor the supply and demand of medical devices included on the public health emergency critical devices list and inform its working party thereof.

Amendment

2. The Medical Devices Steering Group shall adopt a set of information necessary to monitor the supply and demand of medical devices included on the public health emergency critical devices list and inform its working party thereof.
Union or national entities that are engaged in stockpiling of medical devices shall be informed accordingly.

Amendment 121

**Proposal for a regulation
Article 20 – paragraph 3**

Text proposed by the Commission

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

Amendment

3. The Agency shall publish the public health emergency critical devices list and any updates to that list on ***a dedicated space on*** its web-portal.

Amendment 122

**Proposal for a regulation
Article 20 – paragraph 3 a (new)**

Text proposed by the Commission

Amendment

3a. The Agency shall report about the shortage of critical medical devices included on the public health emergency critical devices list through the webpage referred to in Article 6(4a).

Amendment 123

**Proposal for a regulation
Article 22 – paragraph 1**

Text proposed by the Commission

Amendment

1. For the duration of the public health

1. For the duration of the public health

emergency, the Medical Devices Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article **23(1)(b)**, and, in particular, signal any potential or actual shortages of medical devices included on the public health emergency critical devices list.

emergency, the Medical Devices Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article **23(2)(a)**, and, in particular, signal any potential or actual shortages of medical devices included on the public health emergency critical devices list.

Amendment 124

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.

Amendment

2. Where requested by the Commission, ***one or more national competent authorities***, or the sub-network referred to in Article **23 (2)(a)**, 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. ***The Medical Devices Steering Group shall also share its findings and conclusions with Union and national actors engaged with stockpiling of medicinal products and medical devices.***

Amendment 125

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

Text proposed by the Commission

Amendment

5a. Where the recommendations

referred to in paragraphs 3 and 4 are not taken into account or are not implemented, the Commission, Member States, medical device manufacturers and notified bodies shall provide, where appropriate, a substantiated justification.

Amendment 126

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 ***and reviewing*** the public health emergency critical devices list, ***ensuring adequate consultation with manufacturers and other relevant actors in the medical devices supply chain as well as with healthcare professionals, consumers and patients;***

Amendment 127

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 128

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***

Amendment

deleted

representatives and notified bodies;

Amendment 129

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;***

Amendment 130

Proposal for a regulation

Article 23 – paragraph 3 – point e a (new)

Text proposed by the Commission

Amendment

(ea) available stocks;

Amendment 131

Proposal for a regulation

Article 23 – paragraph 3 – point e b (new)

Text proposed by the Commission

Amendment

(eb) quantities already delivered;

Amendment 132

Proposal for a regulation

Article 23 – paragraph 3 – point e c (new)

Text proposed by the Commission

Amendment

(ec) *projected deliveries;*

Amendment 133

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

Text proposed by the Commission

Amendment

(f) mitigation plans including production and supply capacity;

(f) ***prevention and*** mitigation plans including ***information on*** production and supply capacity ***with a view to guarantee continued supply and prevent shortages of medical devices included on the public health emergency critical devices list.***

Amendment 134

Proposal for a regulation Article 25 – paragraph 2

Text proposed by the Commission

Amendment

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.

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

Amendment 135

Proposal for a regulation Article 25 – paragraph 4 – point b

Text proposed by the Commission

Amendment

(b) 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)

(b) 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;

of Regulation (EU) 2017/746 with a view to mitigating potential or actual shortages of medical devices included on the public health emergency critical devices list, ***while at the same time ensuring a high level of patient and product safety;***

Amendment 136

Proposal for a regulation

Article 26 – paragraph 1 – point a

Text proposed by the Commission

(a) take all necessary action within the limits of the powers conferred on it, with a view to mitigating potential or actual shortages of medical devices included on the public health emergency critical devices list, including, where necessary, granting temporary exemptions at Union level pursuant to Article 59(3) of Regulation (EU) 2017/745 or Article 54(3) of Regulation (EU) 2017/746;

Amendment

(a) take all necessary action within the limits of the powers conferred on it, with a view to mitigating potential or actual shortages of medical devices included on the public health emergency critical devices list, including, where necessary, granting temporary exemptions at Union level pursuant to Article 59(3) of Regulation (EU) 2017/745 or Article 54(3) of Regulation (EU) 2017/746 ***while at the same time ensuring both patient and product safety;***

Amendment 137

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;

Amendment

(b) consider the need for guidelines addressed to Member States, medical device manufacturers, notified bodies, ***healthcare professionals*** and other entities ***where this is proportionate, justified and necessary;***

Amendment 138

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 the Union, and where such potential or actual shortages have international implications, **and report these actions as well as the results obtained to the Medical Devices Steering Group.**

Amendment 139

**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 **a dedicated space in** its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups **in a timely manner** with regard to the work of the Medical Devices Steering Group **and respond to disinformation targeting the work of the Medical Devices Steering Group as appropriate.**

Amendment 140

**Proposal for a regulation
Article 27 – paragraph 1 a (new)**

Text proposed by the Commission

Amendment

Proceedings undertaken by the Medical Devices Steering Group shall be transparent. The agenda and minutes of the Medical Devices Steering Group as well as the rules of procedure and recommendations and, where appropriate,

votes shall be documented and made publicly available, including any dissensions.

Amendment 141

Proposal for a regulation

Article 28 – paragraph 1 – introductory part

Text proposed by the Commission

The Agency shall, on behalf of the Commission, **from 1 March 2022 onwards**, provide the secretariat of the expert panels designated in accordance with Implementing Decision (EU) 2019/1396 and provide the support necessary to ensure that those panels can efficiently perform their tasks as set out in Article 106(9) and (10) of Regulation (EU) 2017/745. The Agency shall:

Amendment

The Agency shall, on behalf of the Commission, provide the secretariat of the expert panels designated in accordance with Implementing Decision (EU) 2019/1396 and provide the support necessary to ensure that those panels can efficiently perform their tasks as set out in Article 106(9) and (10) of Regulation (EU) 2017/745. The Agency shall:

Amendment 142

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;

Amendment 143

Proposal for a regulation

Article 29 a (new)

Text proposed by the Commission

Amendment

Article 29a

Protection against cyber-attacks

The Agency shall be equipped with a high level of security controls and processes

against cyber-attacks, cyber-espionage and other data breaches to ensure the protection of health data and the normal functioning of the Agency at all times, and especially during public health emergencies or major events at Union level. To that end, the Agency shall actively pursue and implement best cybersecurity practices within Union institutions, bodies, offices and agencies to prevent, detect, mitigate, and respond to cyber-attacks.

Amendment 144

Proposal for a regulation Article 29 b (new)

Text proposed by the Commission

Amendment

Article 29b

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the obligations established in Articles 10 and 24 and shall take all measures necessary to ensure that they are implemented. The penalties provided for, including financial, shall be effective, proportionate, and dissuasive. Member States shall by... [six months after the date of entry into force of this Regulation] notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.

Amendment 145

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

Text proposed by the Commission

Amendment

1. Unless otherwise provided for in

1. Unless otherwise provided for in

this Regulation and without prejudice to Regulation (EC) No 1049/2001²⁴ 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:

²⁴ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.05.2001, p. 43

this Regulation and without prejudice to Regulation (EC) No 1049/2001²⁴ **and Directive (EU) 2019/1937 of the European Parliament and of the Council^{24a}**, 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:

²⁴ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.05.2001, p. 43

^{24a} **Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of persons who report breaches of Union law (OJ L 305, 26.11.2019, p. 17).**

Amendment 146

Proposal for a regulation Article 30 – paragraph 1 – point a

Text proposed by the Commission

(a) personal data in accordance with Article 32;

Amendment

deleted

Amendment 147

Proposal for a regulation Article 30 – paragraph 1 – point b

Text proposed by the Commission

(b) commercially confidential information and trade secrets of a natural or legal person, including intellectual

Amendment

(b) trade secrets of a natural or legal person in accordance with Directive (EU) 2016/943 of the European Parliament and

property rights;

of the Council^{1a}, as well as other commercially confidential information and intellectual property rights;

^{1a} Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (OJ L 157, 15.6.2016, p. 1).

Amendment 148

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 with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

Amendment 149

Proposal for a regulation Article 30 a (new)

Text proposed by the Commission

Amendment

Article 30a

Personal data protection

1. Transfers of personal data under this Regulation shall be subject to Regulations (EU) 2016/679 and (EU) 2018/1725 as applicable.

2. For transfers of personal data to a third country, in the absence of an adequacy decision, or of appropriate safeguards, as referred to in Article 49(1)

of Regulation (EU) 2016/679 and Article 50(1) of Regulation (EU) 2018/1725, the Commission, the Agency, and Member States may exchange personal data with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements where it is necessary for important reasons of public interest, such as to protect public health.

Amendment 150

Proposal for a regulation Article 30 b (new)

Text proposed by the Commission

Amendment

Article 30b

Review

By 31 December 2026 the Commission shall submit to the European Parliament and to the Council an evaluation report on the functioning of this Regulation, accompanied, if appropriate, by a legislative proposal to amend it. This report shall specifically consider the possible extension of the scope to medicinal products for veterinary use.

Amendment 151

Proposal for a regulation Article 31 – title

Text proposed by the Commission

Amendment

Entry into Force

Entry into Force *and date of application*

Amendment 152

Proposal for a regulation Article 31 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Chapter IV shall apply from... [date of entry into force + 12 months].

EXPLANATORY STATEMENT

There are two unquestionable lessons to be learned from the COVID-19 pandemic.

The first relates to its origin, highlighting the risks to human health posed by overexploitation of fauna and other natural resources and the accelerated loss of biodiversity on the planet, caused in part as a result of climate change.

Approximately 70 % of emerging diseases and almost all known pandemics are zoonoses. These diseases have increased over the last 60 years and there are more and more zoonotic pathogens as a result of human activity and its ecological footprint. Changes in land use, deforestation, urbanisation, agricultural expansion and intensification, wildlife trafficking and consumption patterns are contributing dramatically to that increase.

As recognised by the World Health Organization, many of the same microbes infect animals and humans, so efforts by just one sector cannot prevent or eliminate the problem. The COVID-19 pandemic is a clear example of the need to reinforce the application of the One Health approach in the Union 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 must take into account those three dimensions.

The second lesson relates to its management and to the finding that Europe, both at Community and Member State level, was not ready to deal with public health emergencies of this magnitude. Despite having experienced previous threats, health structures were not geared towards this possibility, due, among other things, to the fact that the budget cuts made in the wake of the 2008 financial crisis diminished the adaptive capacities of our health systems.

Over the past months, we have seen how both the Commission and the Agency have had to act by setting up ad hoc structures to achieve a better and more coordinated response to the pandemic among the Member States.

Thus, the aim of this regulation is to apply the lessons learned to date, including the recognition that there is a need for the Union to equip itself with an appropriate institutional framework to deal with emergencies such as the one we are experiencing, without having to improvise, with a clear mandate, and by providing a legal framework for EU institutions to play a more active role. As such, this regulation is in line with the first three Health Union proposals: the mechanism for combating serious cross-border threats to health – regulating action at Union level in the areas of preparedness, surveillance, risk assessment, early warning and response – and the strengthened mandates of both the European Medicines Agency and the European Centre for Disease Prevention and Control as essential pillars thereof, boosting coordination and synergies between them.

Because, if a lesson has been learned from this pandemic it is that there is a need for more Europe also in the field of health, moving towards a Health Union: we all recall the multiplicity of initial national responses, border closures, refusals of assistance in response to the demand for medical equipment... and this must not happen again.

Europe must therefore develop an emergency prevention and response structure, which, in the case of the Agency, involves:

- An institutional framework defined together with the Steering Groups on Medicines and Medical Devices and the Task Force, identifying who does what at any given moment;
- A framework for monitoring and controlling the medicinal product supply chain, with obligations for the different actors;
- The drawing up of lists of critical medicinal products and medical devices;
- And, for the first time ever, a common definition of shortages of medicinal products, something which is both extremely necessary and much called for by the European Parliament.

As Parliament stressed in its resolution on the ‘shortage of medicines – how to address an emerging problem’, it is absolutely necessary for European health authorities to share a common definition of shortages, but also of supply and demand, since appropriate solutions can only be found on the basis of a common definition of the problem. Our proposal builds on those of the Agency and the HMA.

There is equally a need for Europe to have clear institutional structures such as steering groups, with a horizontal overview of the functioning of the production and supply chain of medicinal products and medical devices, and capable of coordinating responses to emergency situations that avoid unilateral and short-sighted reactions such as those witnessed during the COVID-19 pandemic. The key to such situations is to coordinate and share the knowledge of the Member States, Community institutions and industry in order to tackle them. In this connection, the role of health professionals in relation to these groups needs to be strengthened.

In order to respond to such emergencies, we must ready ourselves and take action to prevent shortages insofar as possible.

It is clear that this regulation alone cannot solve a problem such as that of shortages which can have many causes. The European Pharmaceutical Strategy is already pursuing a number of initiatives which will be implemented over the coming years and which should help to provide a comprehensive response in terms of affordability of medicines and of market functioning, competition, pricing, etc.

Nevertheless, this regulation constitutes a useful instrument, which can and should provide transparency in the functioning of the supply chain, and which can and should provide solutions for a better monitoring of the chain, in order to prevent shortages that may prove critical in health emergencies.

Hence the proposal to establish the European medicines supply database, a proposal which stems from the call made in the above-mentioned Parliament resolution to strengthen the supply chain and its transparency. The proposal draws on initiatives such as CISMED, a project funded by the EU through Horizon Europe, which provides useful lessons on how to implement a control and monitoring system for the drug supply chain.

If we wish to prevent shortages, we need to make progress in terms of transparency, using tools to keep track of what stocks we have, where they are and who manages them, and to cross-check these data at national and European level, in order to find solutions, make forecasts and anticipate potential problems by leveraging data.

Thus, a two-tiered system will be created: a national tier, with a database at Member State level managed by the competent national authority; and a European tier, managed by EMA, where data from national databases are reflected. This should allow us to keep track of supply and demand, product flows, volumes and unmet demand by distributors, pharmacies and

hospital pharmacies.

Of course, the time is ripe not least because we have the EU funds from the Recovery and Resilience Facility and the EU4Health instrument to promote the strengthening of our health systems, including our monitoring systems.

Given the magnitude of the proposal, sufficient time is foreseen for its implementation (4 years after the entry into force of the Regulation).

We have also considered it necessary to strengthen the emergency preparedness aspect, given that this forms part of the title but is not given sufficient consideration in the body of the proposal. We therefore propose that both the steering groups and the Task Force hold meetings in preparation for emergencies and not only once emergencies arise.

Similarly, the links between the Medicines Steering Group and the Task Force should be strengthened, with the former drawing on the latter's work when defining or updating the list of critical medicinal products.

In addition, attention should be paid to the veterinary aspect. As mentioned above, many of the same microbes infect animals and humans, so the efforts of a single sector cannot prevent or eliminate the problem. We therefore consider it necessary to strengthen the synergies of the Medicines Steering Group and the Committee for Medicinal Products for Veterinary Use so that the latter is consulted whenever an emergency is linked to a zoonosis.

As regards medical devices, we have sought to maintain a cautious approach as the Commission has not presented an impact assessment in light of the urgency of the proposals in the Health Union package. Therefore, and in view of the fact that the Agency's founding mandate does not give it a role as regards medical devices and that it therefore lacks an appropriate scientific body and sufficient experience beyond that gained during this pandemic, we have considered it reasonable not to go beyond what the Commission proposed in its work on emergency coordination.

Thus, with this proposal, and with the amendments introduced, we have sought to make it easier for the Agency to act with greater agility and assuredness in emergency situations, working in a more coordinated manner with Member States, but also with industry. Had a regulation of this nature been in force before the pandemic, some issues such as shortages or the approval of new treatments would probably have been dealt with more deftly during the pandemic.

**ANNEX: LIST OF ENTITIES OR PERSONS
FROM WHOM THE RAPPORTEUR HAS RECEIVED INPUT**

The following list is drawn up on a purely voluntary basis under the exclusive responsibility of the rapporteur. The rapporteur has received input from the following entities or persons in the preparation of the report, until the adoption thereof in committee:

Entity and/or person
Agencia Española de Medicamentos y Productos Sanitarios
European Economic and Social Committee - Ioannis Vardakastanis
DG SANTE
FEDIFAR, GIRP
Comité Permanent des Médecins Européens
TEVA
Affordable Medicines Europe
European Society of Intensive Care Medicine
EFPIA
European Medicines Agency
European Social Insurance Platform
PGEU
European Respiratory Society
Medicines for Europe
German Association of Pharmaceutical Parallel Distributors

27.5.2021

OPINION OF THE COMMITTEE ON INDUSTRY, RESEARCH AND ENERGY

for the Committee on the Environment, Public Health and Food Safety

on the proposal for a regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices
(COM(2020)0725 – C9-0365/2020 – 2020/0321(COD))

Rapporteur for opinion: Joëlle Mélin

AMENDMENTS

The Committee on Industry, Research and Energy calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to take into account the following amendments:

Amendment 1

Proposal for a regulation Recital 1

Text proposed by the Commission

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

Amendment

(1) ***According to Article 4(2) of the TFEU, common safety concerns in public health matters is amongst the shared competences of the EU.*** Pursuant to Articles 9 and 168 of the Treaty on the Functioning of the European Union ('TFEU') and Article 35 of the Charter of Fundamental Rights of the European Union the Union is to ensure a high level of human health protection in the definition and implementation of all Union policies and activities, ***and within the strict limits defined by these two Articles of the***

Amendment 2

Proposal for a regulation

Recital 2

Text proposed by the Commission

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

Amendment

(2) The unprecedented experience of the COVID-19 pandemic has demonstrated that the Union should be more effective ***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 ***in a harmonised way between authorities, industry and other stakeholders of the pharmaceuticals supply chain. Europe needs to give a higher priority to health notwithstanding 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 ***austerity measures affecting public health services, insufficient control on production, and*** 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 EU marketing authorisation.***

Amendment 3

Proposal for a regulation Recital 2 a (new)

Text proposed by the Commission

Amendment

(2 a) Acknowledges the role of the industry during the COVID-19 crisis and the fact that industry demonstrated resilience, through continued manufacturing.

Amendment 4

Proposal for a regulation Recital 2 b (new)

Text proposed by the Commission

Amendment

(2 b) Shortages consist of different and complex root causes which need to be further mapped, understood and analysed together with all different stakeholders in order to be comprehensively addressed. A better understanding of the shortages should include identification of bottlenecks in the supply chain. In the specific case of the COVID-19 epidemic, the shortage of adjuvant treatments for the disease had a variety of causes, ranging from production difficulties in third countries, to logistical or production difficulties within the EU, where the shortage of vaccines was due to a rarer cause, namely an unexpectedly high and rising demand.

Amendment 5

Proposal for a regulation Recital 3

Text proposed by the Commission

Amendment

(3) The often complex supply chains ***deleted***

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 6

Proposal for a regulation

Recital 5

Text proposed by the Commission

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

Amendment

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

Amendment 7

Proposal for a regulation

Recital 5 a (new)

Text proposed by the Commission

Amendment

(5 a) 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 Agency.

Amendment 8

Proposal for a regulation

Recital 5 b (new)

Text proposed by the Commission

Amendment

(5 b) The essential free movement of goods must be guaranteed also in times of health crisis, potentially through adaptation of border control measures.

Amendment 9

Proposal for a regulation

Recital 5 c (new)

Text proposed by the Commission

Amendment

(5 c) The COVID-19 pandemic is a clear example that human health is connected to animal health and the environment. Therefore, actions to tackle threats to health should take into account those three dimensions in order to achieve better public health outcomes.

Amendment 10

Proposal for a regulation

Recital 6

Text proposed by the Commission

Amendment

(6) The rapid evolution of COVID-19 and the spread of the virus led to a sharp increase in demand for medical devices such as ventilators, surgical masks, and COVID-19 test kits while disruption of production or limited capacity to rapidly increase production and the complexity and global nature of the supply chain for medical devices, led to a negative impact

(6) The rapid evolution of COVID-19 and the spread of the virus led to a sharp increase in demand for ***personal protective equipment 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

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.

devices, led to a negative impact on supply. Those issues resulted in new entities being involved in the production of those products, which subsequently resulted in bottlenecks in conformity assessment, as well as the prevalence of non-compliant, unsafe, and in some cases counterfeit products. It is therefore appropriate to establish long-term structures within an appropriate Union body to ensure monitoring of shortages of medical devices resulting from a public health emergency.

Amendment 11

Proposal for a regulation Recital 6 a (new)

Text proposed by the Commission

Amendment

(6 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 12

Proposal for a regulation Recital 6 b (new)

Text proposed by the Commission

Amendment

(6 b) 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 13

Proposal for a regulation Recital 6 c (new)

Text proposed by the Commission

Amendment

(6 c) The COVID-19 pandemic has shown the need for increased cooperation of the 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.

Amendment 14

Proposal for a regulation Recital 7

Text proposed by the Commission

Amendment

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

(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.*** 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, adverse reactions ***and fatalities*** caused by the administration 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.

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 *or being protected doing so*. 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 15

Proposal for a regulation Recital 8

Text proposed by the Commission

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

Amendment

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

Amendment 16

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 in the industrial 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.

Amendment 17

Proposal for a regulation
Recital 10

Text proposed by the Commission

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

Amendment

(10) In order to ensure a better functioning of the internal market of those products and contribute to a high level of human health protection, it is therefore appropriate to approximate the rules on monitoring of shortages of medicinal products and medical devices, and to facilitate the research and development of medicinal products, which may have the potential to treat, prevent, or diagnose diseases that cause public health crises. ***The development of analytics to predict emerging risks, including the use of alternative data sources, would be necessary to achieve this goal. Highlights in this respect the necessity of developing analytics to predict emerging risks, including the use of alternative data sources.***

Amendment 18

Proposal for a regulation Recital 10 a (new)

Text proposed by the Commission

Amendment

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

Amendment 19

Proposal for a regulation Recital 11

Text proposed by the Commission

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 ***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.

(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.

Amendment 20

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 21

Proposal for a regulation Recital 13

Text proposed by the Commission

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

Amendment

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authorisation holders, manufacturers and Member States through designated points of contact.

Amendment 22

Proposal for a regulation Recital 14 a (new)

Text proposed by the Commission

Amendment

(14 a) 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 medicinal products. Those structures would in no way change the regulatory system or the decision-making procedures in the area of medical devices already in place in the Union, which should remain clearly distinct from the one for medicinal products.

Amendment 23

Proposal for a regulation Recital 14 b (new)

Text proposed by the Commission

Amendment

(14 b) During the COVID-19 emergency,

the regulatory flexibility allowed by the Commission has proven to be a tool for industry to prevent shortages. However, 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.

Amendment 24

Proposal for a regulation Recital 14 c (new)

Text proposed by the Commission

Amendment

(14 c) The coordination structures set up to manage and react to public health threats established under this Regulation should pay due attention to the contribution of zoonoses on public health in the veterinary field, reinforcing coordination and drawing on the knowledge and expertise of veterinary services, acquired in this field by the Agency as the body in charge at Union level of the evaluation of medicinal products for veterinary use.

Amendment 25

Proposal for a regulation Recital 14 d (new)

Text proposed by the Commission

Amendment

(14 d) 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.

Amendment 26

Proposal for a regulation

Recital 15

Text proposed by the Commission

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

Amendment

(15) With respect to medicinal products, an executive steering group should be established within the Agency to ensure a robust response to major events and to coordinate urgent actions within the Union in relation to the management of issues relating to the supply of medicinal products. The Steering Group should establish ***a general*** lists of critical medicinal products ***applicable to any major event or public health emergency, in close cooperation with industry, all stakeholders and, where relevant, healthcare professionals,*** to ensure monitoring of those products and it should be able to provide advice on the necessary action to take to safeguard the quality, safety, and efficacy of ***these*** medicinal products and ensure a high level of human health protection ***during public health emergencies and major events.***

Amendment 27

Proposal for a regulation

Recital 16 a (new)

Text proposed by the Commission

Amendment

(16 a) 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 for the most probable cases of public health emergencies.

Amendment 28

Proposal for a regulation Recital 16 b (new)

Text proposed by the Commission

Amendment

(16 b) The Agency should make public the recommendations, opinions and decisions of 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 29

Proposal for a regulation Recital 17

Text proposed by the Commission

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

(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 ***driven by public health needs only*** should be established within the Agency to provide advice on such medicinal products. The Emergency Task Force should provide ***independent*** 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

academia, irrespective of their exact role in the development of such medicinal products.

trial sponsors, public health bodies, and academia, irrespective of their exact role in the development of such medicinal products.

Amendment 30

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 ***to overcome*** the public health crisis. The Committee for Medicinal Products for Human Use should be able to use those recommendations when preparing scientific opinions on compassionate or other early use of a medicinal product prior to marketing authorisation.

Amendment 31

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

Amendment

(19) The establishment of the Emergency ***Task Force is committed to overcome the divergences among the individual regulatory frameworks, placing itself as guarantee and protection for EU citizens.*** The task force should build on 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.

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 32

Proposal for a regulation Recital 20

Text proposed by the Commission

Amendment

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

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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 33

Proposal for a regulation Recital 21

Text proposed by the Commission

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

Amendment

deleted

Amendment 34

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) 2019/1396¹² 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) 2019/1396¹² 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.***

¹² Commission Implementing Decision

¹² Commission Implementing Decision

(EU) 2019/1396 of 10 September 2019 laying down the rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the designation of expert panels in the field of medical devices OJ L 234, 11.9.2019, p. 23

(EU) 2019/1396 of 10 September 2019 laying down the rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the designation of expert panels in the field of medical devices OJ L 234, 11.9.2019, p. 23

Amendment 35

Proposal for a regulation Recital 22 a (new)

Text proposed by the Commission

Amendment

(22 a) Experts should not have financial or other interests in the pharmaceutical industry which could affect their impartiality.

Amendment 36

Proposal for a regulation Recital 23 a (new)

Text proposed by the Commission

Amendment

(23 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. All relevant information on approved products, clinical results and clinical data of trials need to be made public, having taken due regard to protection of personal data protection and commercially confidential information.

Amendment 37

Proposal for a regulation Recital 23 b (new)

Text proposed by the Commission

Amendment

(23 b) 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 and coordinate the development of clinical trial protocols. Such an approach would strengthen the research environment in the Union, while encouraging 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 promote harmonisation and avoid subsequent delays in integrating the results of research to a marketing authorisation. A Union sponsor could benefit from Union research funding available at the time of the public health emergency as well as existing clinical trial networks to facilitate the development, application, submission, and running of the trial. This may be particularly valuable for trials established by Union or international public health or research organisations.

Amendment 38

Proposal for a regulation Recital 23 c (new)

Text proposed by the Commission

Amendment

(23 c) The Emergency Task Force should review clinical trial protocols and advice developers on clinical trials that are conducted in the Union, providing guidance on clinically relevant endpoints and targets for vaccines and treatments in order to guide clinical trial design toward meeting the criteria for effective public health interventions.

Amendment 39

Proposal for a regulation Recital 23 d (new)

Text proposed by the Commission

Amendment

(23 d) In order to facilitate the work and the exchange of information under this Regulation, the National Competent Authorities (NCAs) should establish a reliable and harmonised European interoperable (to avoid duplications of the information submitted) and digital system of monitoring of shortages of medicinal products, personal protective equipment and medical devices, based on common data fields, such as the standards of the International Organization for Standardization (ISO) for the identification of medicinal products (IDMP), which will facilitate appropriate access for relevant national and EU authorities to market situations for critical medicinal products and medical devices during public health emergencies and major events, which may have a serious impact on public health.

Amendment 40

Proposal for a regulation Recital 23 e (new)

Text proposed by the Commission

Amendment

(23 e) Standardized reporting requirements for information on clearly defined shortages should be agreed, giving priority to critical products with high potential impact. That system should take into account already existing systems, such as SPOR, EMA systems, the European Medicines Verification System (set up in the context of the Falsified Medicines FMD), iSPOC, and the Data Analysis and Real World Interrogation Network - DARWIN, and 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 information and data from the concerned marketing authorisation holders, manufacturers, wholesalers and Member States who all have the obligation to provide complete information and data through designated points of contact.

Amendment 41

Proposal for a regulation Recital 23 f (new)

Text proposed by the Commission

Amendment

(23 f) This system should have an effective alert system to discriminate between national and pan-European shortages and enable national regulators to assess the availability of products versus what has been consumed or parallel exported in their market.

Amendment 42

Proposal for a regulation

Recital 24

Text proposed by the Commission

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. This would allow for long-term sustainability for the functioning of the panels and provide clear synergies with related crisis preparedness work for medicinal products. Those structures would in no way change the regulatory system or the decision-making procedures in the area of medical devices already in place in the Union, which should remain clearly distinct from the one for medicinal products.

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Amendment 43

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) 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. ***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.***

Amendment 44

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, 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, such as electronic health records, insurance claims data and data from patient registries (as per 4 EUDPR); it is of utmost importance to ensure that health***

data is used in full respect of the provisions of the GDPR on personal data protection. 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.

Amendment 45

Proposal for a regulation Recital 26 a (new)

Text proposed by the Commission

Amendment

(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 swift implementation of binding rules on security information and cybersecurity and of the main 5G toolbox measures to achieve a high level of security against cyber-attacks, and particularly cyber-espionage, at all times and especially during public health emergencies.

Amendment 46

Proposal for a regulation Recital 27

Text proposed by the Commission

Amendment

(27) During a public health emergency or in relation to a major event, the Agency should ensure cooperation with the European Centre for Disease Prevention and Control and other Union Agencies as appropriate. Such cooperation should include data sharing, including data on

(27) During a ***temporary*** public health emergency or in relation to a major event, the Agency should ensure cooperation with the European Centre for Disease Prevention and Control – ***which should provide forecasts in a timely manner to relevant actor of the pharmaceutical***

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.

supply chain - 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 relevant 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 47

Proposal for a regulation Recital 27 a (new)

Text proposed by the Commission

Amendment

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

Amendment 48

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

Text proposed by the Commission

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

Amendment

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

Amendment 49

Proposal for a regulation

Article 2 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) ‘veterinary medicinal product’ means any veterinary medicinal product as defined in point 2 of Article 1 of Directive 2001/82/EC of the European Parliament and the Council;

Amendment 50

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, ***i.e. patient need plus appropriate buffer stocks***, for that medicinal product or medical device, ***at national level, no matter the cause***;

Amendment 51

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***.

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 than one Member

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.

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 *critical* medicinal products *and/or medical devices* in one *or more* Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection.

Amendment 52

Proposal for a regulation

Article 2 – paragraph 1 – point f a (new)

Text proposed by the Commission

Amendment

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

Amendment 53

Proposal for a regulation

Article 3 – paragraph 1

Text proposed by the Commission

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, in preparation for or during a public health emergency or following a request for assistance referred to in Article 4(3). The Agency shall provide its secretariat.

1. 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.

Amendment 54

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 ***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). A two-way communication line is established between the Medicines Steering Group and the single points of contacts from national competent authorities, who shall in turn inform the actors of the industrial sector without delay.***

Amendment 55

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 competencies in full compliance with the principles of proportionality and subsidiarity,*** the 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.***

Amendment 56

Proposal for a regulation Article 3 – paragraph 5

Text proposed by the Commission

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

Amendment

5. The Medicines Steering Group shall be *chaired by the Agency. In order to ensure that a broad spectrum of opinions is taken into account, the Chair shall invite relevant third parties, including representatives of medicinal product interest groups and marketing authorisation holders and other stakeholders in the medicines and industrial supply chain as well as interest groups representing patients, consumers and healthcare professionals, clinical trial experts, public-health advocacy groups and sectoral trade unions, to attend its meetings, thus allowing stakeholders to give an opinion about the situation in the various Member States concerned. To avoid market distortions, the Medicines Steering Group shall ensure that data is evenly shared within or withheld from all marketing authorisation holders.*

On the basis of these exchanges, the Medicines Steering Group shall draw up strategic recommendations which it addresses to the Member States during the public health emergency period.

Amendment 57

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

Text proposed by the Commission

Amendment

5 a. The Medicine Steering Group shall consult with the Committee for Medicinal Products for Veterinary Use whenever it deems it necessary to deal

with public health emergencies related to zoonoses or diseases affecting only animals that have, or may have, a major impact on human health.

Amendment 58

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

Text proposed by the Commission

Amendment

5 b. The membership of the Medicines Steering Group shall be made public. In accordance with Article 107 of Regulation (EU) 2017/745 of the European Parliament and of the Council, all members of the Medicines Steering Group shall comply with the usual rules in force in the Union on conflicts of interest. For the sake of transparency, the declarations of interests of the Members and experts 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. Should a conflict of interest occur, all necessary restrictions shall apply.

Amendment 59

Proposal for a regulation Article 4 – title

Text proposed by the Commission

Amendment

Monitoring of events and preparedness for

Monitoring of events and preparedness for

major events and public health emergencies

temporary major events and public health emergencies

Amendment 60

Proposal for a regulation Article 4 – paragraph 1

Text proposed by the Commission

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

Amendment

1. The Agency shall continuously monitor any event that **has the potential** to lead to a major event or a public health emergency **and should be capable of establishing the necessary preventive mechanisms. In this regard, the Agency shall cooperate closely with the European Centre for Disease Prevention and Control or other Union agencies, where relevant.**

Amendment 61

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

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 **potential** shortage of a **critical** medicinal product in a given Member State, that **has the potential** to lead to a major event or a public health emergency **in other Member States and could compromise a quick and adequate reaction to said major event of 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

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).

information received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC, **as well as any relevant additional information provided by stakeholders and actors in the pharmaceutical industry, in full respect of confidentiality and privacy, as provided for in Regulation (EU) 2016/769 of the European Parliament and of the Council (the General Data Protection Regulation - GDPR)**. Based on a report of an event from a national competent authority and in order to understand **and, in particular, anticipate** the impact of the event in other Member States, the Agency may request information from the national competent authorities, through the working party referred to in Article 3(5).

Amendment 62

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;

Amendment 63

Proposal for a regulation

Article 5 – paragraph 1

Text proposed by the Commission

Following the recognition of a public health emergency or a request for assistance referred to in Article 4(3), the Medicines Steering Group shall evaluate the information related to the major event or the public health emergency and consider the need for urgent and

Amendment

Following the recognition of a public health emergency or a request for assistance referred to in Article 4(3), the Medicines Steering Group shall evaluate the information related to the major event or the public health emergency and consider the need for urgent and

coordinated action with regard to the safety, quality, and efficacy of the medicinal products concerned.

coordinated action with regard to the **manufacturing**, safety, quality, and efficacy of the medicinal products concerned. ***The information evaluated shall become public in due time.***

Amendment 64

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 726/2004.¹⁸

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 726/2004.¹⁸ ***This advice shall be made public, together with all the relevant information based on which the advice was compiled. If certain information cannot be made available to the public, due to respect for confidentiality, public health, commercial interests, grounds derived from Article 30 of this Regulation, or public order, this shall be indicated. The Medicines Steering Group shall strive for the greatest transparency possible.***

¹⁸ Regulation (EC) No 726/2004

¹⁸ Regulation (EC) No 726/2004.

Amendment 65

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

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,***

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.

representatives from industry (via the industry single points of contacts - iSPOCs) and representatives of healthcare professionals, shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the major event ('the major event critical medicines list'). The list shall be updated whenever necessary until the major event has been sufficiently addressed, ***and shall cease to apply at the end of the major event.***

Amendment 66

Proposal for a regulation Article 6 – paragraph 2

Text proposed by the Commission

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

Amendment

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

Amendment 67

Proposal for a regulation Article 6 – paragraph 3

Text proposed by the Commission

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

Amendment

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

medicinal products included on the lists referred to in paragraphs 1 and 2 ('the critical medicines lists') and inform its working party thereof.

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. **Union or national entities that are engaged in stockpiling of medicinal products should be informed accordingly.**

Amendment 68

Proposal for a regulation Article 6 – paragraph 4

Text proposed by the Commission

4. The Agency shall immediately publish the critical medicines lists and any updates to those lists on its web-portal referred to in Article 26 of Regulation (EC) No 726/2004.

Amendment

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

Amendment 69

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

Text proposed by the Commission

Amendment

4a. The Agency, in cooperation with the Commission and the competent authorities of the Member States, shall work with representatives of the European pharmaceutical industry to ensure that medicinal products on the list of critical medicinal products made available in one Member State are equally available in all

Amendment 70

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 between the Medicines Steering Group and the single points of contact from national competent authorities***, and the information and data provided in accordance with Articles 10 and 11 ***of this Regulation***, the Medicines Steering Group shall ***meet regularly throughout the major event or public health emergency with the working group of designated national contact points for shortages and with representatives of the medicines production and distribution sectors and, where relevant, healthcare professionals in order to*** monitor supply and demand ***across the entire value-chain, based on actual and potential patient's needs at national level as per Article 2(f)***, of medicinal products included on those lists with a view to identifying any potential or actual shortages of those medicinal products ***and to adapt the list as best as possible throughout the major event or emergency. 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]

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

Amendment 71

Proposal for a regulation Article 8 – paragraph 2

Text proposed by the Commission

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

Amendment

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

Amendment 72

Proposal for a regulation Article 8 – paragraph 3

Text proposed by the Commission

3. As part of that reporting, the Medicines Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities to prevent or

Amendment

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

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.

healthcare professionals, to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, as relevant, with the Health Security Committee and, in the case of a public health emergency, the Advisory Committee on public health emergencies.

Amendment 73

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 74

Proposal for a regulation

Article 8 – paragraph 5

Text proposed by the Commission

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

Amendment

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

Amendment 75

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

Text proposed by the Commission

Amendment

5 a. Measures recommended by the Medicines Steering Group to the Commission, Member States, marketing authorisation holders and other entities, should not add any regulatory administrative burden and should facilitate flexible supply chains.

Amendment 76

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

Text proposed by the Commission

Amendment

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

1. In order to prepare for fulfilling the tasks referred to in Articles 4 to 8, **and after consulting representatives from national competent authorities and from industry and representatives of healthcare professionals, as well as other stakeholders in the medicines supply and distribution chain**, the Agency shall:

Amendment 77

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

Text proposed by the Commission

Amendment

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

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

Amendment 78

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 **European** electronic monitoring and reporting systems, **accessible by Member State authorities, by implementing and building on existing regulatory infrastructure (EU telematics). This system shall be developed in coordination with the national competent authorities and shall be interoperable with the national shortages reporting systems to prevent any duplication of the reporting process. The system should establish a two-way digital communication line between the Agency and the national competent authorities, as well as a two-way communication line between the Agency and, where necessary, marketing authorisation holders. In case of a 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 to the Member States;**

Amendment 79

**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 points of contact (iSPOC), as well as the contact details of healthcare professionals and patients organisations; 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);

Amendment 80

**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, ***selected within the competent national public health authorities and wholesalers, 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;

Amendment 81

**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 duplication of information available to the Agency via collection of information submitted by industry via the national competent authorities (provided by the Industry Single Points of Contact (iSPOC)). The system at the Agency shall be interoperable with the national shortages reporting systems. The information*** shall include at least:

Amendment 82

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 ***at each stage of the supply chain, as well as information on potential bottlenecks in the supply chain;***

Amendment 83

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;

Amendment 84

Proposal for a regulation

Article 9 – paragraph 3 – point e

Text proposed by the Commission

(e) ***sales and market share*** data;

Amendment

(e) ***production*** data;

Amendment 85

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, enhanced*** production, supply capacity ***sourcing diversification and, where applicable,***

outsourcing plans;

Amendment 86

Proposal for a regulation

Article 9 – paragraph 3 – point h

Text proposed by the Commission

(h) *information from the wholesale distributors and legal person entitled to supply the medicinal product to the public.*

Amendment

(h) *available alternative medicinal products;*

Amendment 87

Proposal for a regulation

Article 9 – paragraph 3 – point h a (new)

Text proposed by the Commission

Amendment

(h a) information from the wholesale distributors and legal person entitled to supply the medicinal product to the public.

Amendment 88

Proposal for a regulation

Article 10 – paragraph 1

Text proposed by the Commission

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 *where* necessary.

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) *by the deadline set by the Agency, if the*

information is not already available via the interoperable system connected with the national shortages reporting systems established pursuant to Article 9(1)(c). They shall provide updates whenever necessary or upon request.

Amendment 89

Proposal for a regulation Article 10 – paragraph 2

Text proposed by the Commission

2. Marketing authorisation holders of medicinal products authorised in the Union shall, within 6 months from the date of application of this Regulation, provide the information required pursuant to Article 9(1)(e) in the form of an electronic submission in the database referred to in Article 57(1)(l) of Regulation (EC) No 726/2004. Those marketing authorisation holders shall update their submission wherever necessary.

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 **and compliant with the standards of the International Organization for Standardization (ISO) for the identification of medicinal products (IDMP)**. Those marketing authorisation holders shall update their submission wherever necessary.

Amendment 90

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**

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 and clarify the reasons for such an indication **and offer sufficient, actual and specific evidence of harm stemming from**

commercially confidential information against unjustified disclosure.

disclosure.. The Agency shall determine upfront what information is commercially confidential, in accordance with Article 30 of this Regulation, and on this basis assess the merits of each request, considering the benefits for public health and interest of disclosure and act accordingly. Marketing authorisation holders failing to comply with their reporting obligations shall be subject to sanctions to be determined by the Commission.

Amendment 91
Proposal for a regulation
Article 10 – paragraph 6 – point a

Text proposed by the Commission

(a) provide any comments they have to the Agency;

Amendment

(a) provide any comments they have to the Agency, ***in accordance with Article 30 of this Regulation;***

Amendment 92

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 European interoperable and digital National Competent Authorities (NCAs) shortages reporting system based on common data fields:***

Amendment 93

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 pursuant to **Article 9(3)** including available and estimated data on volume of demand, through its designated point of contact and using the reporting methods and system established pursuant to Article 9(1);

Amendment 94

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, where this is proportionate, justified and necessary;***

Amendment 95

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;***

Amendment 96

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

Text proposed by the Commission

Amendment

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

Amendment 97

Proposal for a regulation Article 13 – paragraph -1 (new)

Text proposed by the Commission

Amendment

The Agency shall establish an early warning system to inform relevant stakeholders, including, where relevant, doctors and community and hospital pharmacists, via the relevant information chains or contact points, of any supply problems and potential or actual shortages of medicines included on the critical medicines lists.

Amendment 98

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 ***in a timely manner*** with regard to the work, ***advice, recommendations, opinions, decisions and findings*** of the Medicines Steering Group, ***including dissenting views. Agendas and minutes of the Group's meetings, as well as the data and sources on which the***

work is based, shall also be published.

Amendment 99

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*** part of the Agency. It shall be ***only*** convened ***in preparation for or*** during ***recognised*** public health emergencies, either in person or remotely. The Agency shall provide its secretariat. ***The Emergency Task Force cooperates 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 Emergency Task Force, in collaboration with Member States and their relevant actors, is committed to exchanging information and best practices, to developing protocols and expertise necessary for the timely and appropriate response to health crises, including for sectors other than health, in order to improve crisis response capacity and generate new synergies.***

Amendment 100

Proposal for a regulation Article 14 – paragraph 2 – point a (new)

Text proposed by the Commission

Amendment

(a a) defining 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;

Amendment 101

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;

Amendment 102

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 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;

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 **and on developing suitable protocols**;

Amendment 103

Proposal for a regulation Article 14 – paragraph 2 – point e

Text proposed by the Commission

(e) providing scientific

Amendment

(e) providing, **by making publicly**

recommendations with regard to the use of any medicinal product, which may have the potential to address public health emergencies, in accordance with Article 16;

available, scientific recommendations with regard to the use of any medicinal product, which may have the potential to address public health emergencies, in accordance with Article 16;

Amendment 104

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.

Amendment 105

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.

Amendment 106

Proposal for a regulation

Article 14 – paragraph 5

Text proposed by the Commission

5. The Chair *may* invite representatives of Member States, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, and interest groups representing patients and healthcare professionals *to attend its meetings*.

Amendment

5. The Chair *shall* invite, *during Task Force meetings and throughout the public health emergency*, representatives of Member States, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial *experts, public health advocacy groups*, representatives of clinical trial networks, *researchers, sectoral trade unions*, and interest groups representing patients and *consumer organisations, and the healthcare sector in order to provide the Task Force with the broadest and most detailed view of the situation at all times throughout the public health emergency. 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 107

Proposal for a regulation
Article 14 – paragraph 6

Text proposed by the Commission

6. The Emergency Task Force shall establish its rules of procedure including rules on the adoption of recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.

Amendment

6. The Emergency Task Force shall establish its rules of procedure, *which shall include all the rules relating to its formation, structure and confidentiality, including potential conflicts of interest. These rules of procedure also include* rules on the adoption of recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.

Amendment 108

Proposal for a regulation Article 14 – paragraph 8

Text proposed by the Commission

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.

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. ***Members of the Emergency Task Force 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 109

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 ***rapidly*** 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 advice to developers, in line with the provisions of Regulation (EU) No 536/2014.***

Amendment 110

Proposal for a regulation Article 15 – title

Text proposed by the Commission

Advice on clinical trials

Amendment

Advice **and guidance** on clinical trials

Amendment 111

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

Text proposed by the Commission

Amendment

The Emergency Task Force shall define the most clinically relevant performance targets for treatments, including vaccines, 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.

Amendment 112

Proposal for a regulation Article 15 – paragraph 1

Text proposed by the Commission

1. During a public health emergency, the Emergency Task Force shall review clinical trial protocols submitted or intended to be submitted in a clinical trial application by developers of medicinal products as part of an accelerated scientific advice process.

Amendment

1. During a public health emergency, the Emergency Task Force shall review clinical trial protocols submitted or intended to be submitted in a clinical trial application by developers of medicinal products as part of an accelerated scientific advice process ***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 patient safety.***

Amendment 113

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.

Amendment 114

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 Regulation (EU) 536/2014. These procedures shall become public.***

Amendment 115

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

Amendment

6. Where a developer is the recipient of scientific advice, the developer shall subsequently ***and continuously*** submit ***all***

from clinical trials to the Agency following a request made pursuant to Article 16.

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 and in wait of the launch of the Clinical Trials Information System (CTIS) in accordance with Art. 80 and 81 of Regulation (EU) No 536/2014, a state-of-the-art pseudonymisation shall apply, including encryption, in line with the requirements of Article 89 of GDPR.***

Amendment 116

Proposal for a regulation Article 16 – paragraph 1

Text proposed by the Commission

1. Following the recognition of a public health emergency, the Emergency Task Force shall undertake a review of the available scientific data on medicinal products, which may have the potential to be used to address the public health emergency. The review shall be regularly updated during the public health emergency.

Amendment

1. Following the recognition of a public health emergency, the Emergency Task Force shall undertake a review of the available scientific data on 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 117

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 all relevant information and data from them***. 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, while applying state-of-the-art pseudonymisation, including encryption. The Emergency Task Force should liaise with agencies of third countries that authorise medicinal products for additional information and data.

Amendment 118

Proposal for a regulation

Article 16 – paragraph 3 – introductory part

Text proposed by the Commission

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

Amendment

3. Based on a request from one or more Member States, or the Commission, the Emergency Task Force shall provide ***independent*** recommendations, ***driven only by public-health needs and not by other interests***, to the Committee for Medicinal Products for Human ***and Veterinary*** Use for an opinion in accordance with paragraph 4 on the following:

Amendment 119

Proposal for a regulation

Article 16 – paragraph 3 – point a

Text proposed by the Commission

(a) the compassionate use of medicinal products falling under the scope of Directive 2001/83/EC or Regulation (EC) No 726/2004;

Amendment

(a) the compassionate use of medicinal products falling under the scope of Directive 2001/83/EC or Regulation (EC) No 726/2004 ***and the whole production and distribution chain, as well as the adapted prescription by carers in accordance with Article 83(8) of Regulation (EC) No 726/2004;***

Amendment 120

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 121

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

Text proposed by the Commission

Amendment

7 a. Where relevant, marketing authorisation holders, healthcare professionals or developers may suggest medicinal products which may have the potential to be used to address the public health emergency. The Emergency Task Force 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 science-based reaction to the suggestion. The reaction shall be public.

Amendment 122

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 123

**Proposal for a regulation
Article 18 – introductory part**

Text proposed by the Commission

To prepare for and support the work of the Emergency Task Force during public health emergencies, the Agency shall:

Amendment

1. To prepare for and support the work of the Emergency Task Force during public health emergencies, the Agency shall:

Amendment 124

**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) ***use*** and maintain ***preferably European-designed, 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 125

**Proposal for a regulation
Article 18 – paragraph 1 – point b**

Text proposed by the Commission

(b) coordinate independent vaccine effectiveness and safety monitoring studies using relevant data held by public authorities. Such coordination shall be conducted jointly with the European Centre for Disease Prevention and Control and notably through a new vaccine monitoring platform;

Amendment

(b) coordinate independent 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 shall be conducted jointly with the European Centre for Disease Prevention and Control and notably through a new vaccine monitoring platform;

Amendment 126

**Proposal for a regulation
Article 18 – paragraph 1 – point c**

Text proposed by the Commission

(c) as part of its regulatory tasks, make use of digital infrastructures or tools, to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of clinical studies, and the exchange of such data between Member States, the Agency, and other Union bodies;

Amendment

(c) as part of its regulatory tasks, ***use IT tools interoperable with harmonized shortages reporting systems of National Competent Authorities (NCAs) by building on the existing digital regulatory infrastructure and ongoing projects on data management, and implement AI technics and*** make use of digital infrastructures or tools, to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of clinical studies, and the exchange of such data between Member States, the Agency, and other Union bodies;

Amendment 127

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

Text proposed by the Commission

Amendment

1a. The Agency shall ensure that the processing of patients' personal data is in strict compliance with the European data

protection framework.

Amendment 128

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

Text proposed by the Commission

Amendment

1b. The Agency shall adopt sufficient means to be fully equipped with a high level of security against cyber-attacks, cyber-espionage and human leaks 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 and these measures should be built on combination of regular penetration testing, decentralised solutions and security by design principles. 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.

Amendment 129

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. The Agency shall provide its secretariat.

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 130

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

Text proposed by the Commission

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. The declarations of interests of all experts must be made public and all necessary restrictions shall apply where conflicts of interest occur.

Amendment 131

Proposal for a regulation Article 19 – paragraph 3

Text proposed by the Commission

Amendment

3. The Medical Devices Steering Group shall be chaired by the Agency. The Chair *may* invite third parties, including representatives of medical device interest groups to attend its meetings.

3. The Medical Devices Steering Group shall be chaired by the Agency. The Chair **shall regularly** invite third parties, including representatives of medical device interest groups, **developers and producers of medical devices, public-health advocacy groups, sectoral trade unions, consumer and patient organisations, as well as healthcare professionals, marketing authorisation holders and other stakeholders in the pharmaceutical industry** to attend its meetings **to exchange on the situation of drug production in**

Europe and worldwide. On the basis of these exchanges, the Medical Devices Steering Group shall draw up strategic recommendations which it addresses to the Member States during the public health emergency period.

Amendment 132

Proposal for a regulation Article 19 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. The Medical Devices Steering Group will establish the basis for strengthened cooperation with national health authorities and the pharmaceutical industry.

Amendment 133

Proposal for a regulation Article 20 – paragraph 1

Text proposed by the Commission

Amendment

1. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medical Devices Steering Group shall adopt a list of medical devices which it considers as critical during the public health emergency ('the public health emergency critical devices list'). The list shall be updated whenever necessary until the termination of the recognition of the public health emergency.

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 **and shall cease to apply at the end of the public health emergency.**

Amendment 134

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, ***in a timely manner***, the public health emergency critical devices list and any updates to that list on its web-portal. ***This list shall be published in a clear and accessible way so that Member States, actors in the pharmaceutical supply chain and all stakeholders can easily access this information and, where appropriate, can easily report possible changes or publication problems.***

Amendment 135

**Proposal for a regulation
Article 20 – paragraph 3 a (new)**

Text proposed by the Commission

Amendment

3a. The Agency, in cooperation with the Commission and the national competent authorities of the Member States, shall work with representatives of the European medical device industry to ensure medical devices on the list of critical medical devices made available in one Member State are equally available in all Member States.

Amendment 136

**Proposal for a regulation
Article 21 – paragraph 1**

Text proposed by the Commission

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

1. On the basis of the public health emergency critical devices list and the information and data provided in accordance with Articles 24 and 25 ***of this Regulation***, the Medical Devices Steering Group shall ***meet regularly throughout the duration of the major event or public health emergency with the working group***

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.

*of designated national contact points for shortages in the national medicines authorities, with representatives of the medicines production and distribution sectors and with representatives of the healthcare sector to monitor supply and demand of medical devices included on that list with a view to identifying any potential or actual shortages of those medical devices **and to adapt the list as best as possible throughout the duration of the emergency.*** As part of that monitoring, the Medical Devices Steering Group shall liaise, where relevant, with the Health Security Committee established in Article 4 of Regulation (EU) 2020/[...] 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.*

²² [insert reference to adopted text referred to in footnote 4]

²² [insert reference to adopted text referred to in footnote 4].

Amendment 137

Proposal for a regulation Article 22 – paragraph 1

Text proposed by the Commission

1. For the duration of the public health emergency, the Medical Devices Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article 23(1)(b), and, in particular, signal any potential or actual shortages of medical devices included on the public health emergency critical devices list.

Amendment

1. For the duration of the public health emergency, the Medical Devices Steering Group shall regularly report the results of its monitoring to the Commission, ***national public health authorities*** and the sub-network referred to in Article 23(1)(b), and, in particular, signal any potential or actual shortages of medical devices included on the public health emergency critical devices list.

Amendment 138

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.

Amendment

2. Where requested by the Commission, ***one or more national public health authorities*** 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.***

Amendment 139

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.

Amendment 140

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 emergency.

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 emergency.

Amendment 141

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

Text proposed by the Commission

Amendment

5 a. Measures recommended by the Medical Devices Steering Group to the Commission, Member States, marketing authorisation holders and other entities, shall be made publicly available and should cover regulatory solutions for addressing potential shortages.

Amendment 142

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 consulting with representatives from the national competent authorities and marketing authorisation holders, as well as other stakeholders***, specify the procedures ***and criteria*** for establishing the public health

emergency critical devices list;

Amendment 143

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 144

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

Amendment 145

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, ***selected within the competent national public health authorities and*** from medical device manufacturers and notified bodies based on the medical devices included on the public health emergency critical devices list ***composed of single points of contact to be included for all medical device manufacturers in the database referred to in Article 33 of***

Amendment 146

**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;***

Amendment 147

**Proposal for a regulation
Article 23 – paragraph 3 – point e**

Text proposed by the Commission

(e) ***sales and market share*** data;

Amendment

(e) ***production*** data;

Amendment 148

**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;***

Amendment 149

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

Text proposed by the Commission

(i) where conformity assessments are

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 complete the conformity assessment process.

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.

Amendment 150

Proposal for a regulation Article 24 – paragraph 1

Text proposed by the Commission

1. In order to facilitate the monitoring referred to in Article 21 and following a request from the Agency, medical device manufacturers of the medical devices included on the public health emergency critical devices list and, where necessary, concerned notified bodies, shall submit the information requested by the deadline set by the Agency. They shall submit the information requested through the points of contact designated in accordance with Article 23(2) and using the reporting methods and system established pursuant to Article 23(1). They shall provide updates wherever necessary.

Amendment

1. In order to facilitate the monitoring referred to in Article 21 and following a request from the Agency, medical device manufacturers of the medical devices included on the public health emergency critical devices list, ***all distributors legally authorised to supply medical devices to the public*** and, where necessary, concerned notified bodies, shall submit the information requested by the deadline set by the Agency. They shall submit the information requested through the points of contact designated in accordance with Article 23(2) and using the reporting methods and system established pursuant to Article 23(1). They shall provide updates wherever necessary.

Amendment 151

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

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.

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 152

Proposal for a regulation Article 25 – paragraph 1 – point b

Text proposed by the Commission

(b) indicate the existence of any commercially confidential information, and, clarify the reasons for such an indication;

Amendment

(b) indicate the existence of any commercially confidential information, and, clarify the reasons for such an indication, ***in accordance with Article 30 of this Regulation;***

Amendment 153

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.

Amendment 154

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;***

Amendment 155

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

Text proposed by the Commission

(a) take all necessary action within the limits of the powers conferred on it, with a view to mitigating potential or actual shortages of medical devices included on the public health emergency critical devices list, including, where necessary, granting temporary exemptions at Union level pursuant to Article 59(3) of Regulation (EU) 2017/745 or Article 54(3) of Regulation (EU) 2017/746;

Amendment

(a) take all necessary action within the limits of the powers conferred on it, with a view to mitigating potential or actual shortages of medical devices included on the public health emergency critical devices list, including, where necessary, granting temporary exemptions at Union level pursuant to Article 59(3) of Regulation (EU) 2017/745 or Article 54(3) of Regulation (EU) 2017/746 ***while at the same time ensuring both patient and product safety;***

Amendment 156

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

Text proposed by the Commission

Amendment

(a a) provide answers to priority written questions from Members of the European Parliament within the deadline;

Amendment 157

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;

Amendment

(b) consider the need for guidelines addressed to Member States, medical device manufacturers, notified bodies, **health care professionals** and other entities **where this is proportionate, justified and necessary**;

Amendment 158

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 the potential introduction of temporary export transparency and export authorisation mechanisms**.

Amendment 159

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

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,

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 meetings.

Amendment 160

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;

Amendment 161

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

Text proposed by the Commission

1. ***Unless otherwise provided for in this Regulation and*** without prejudice to Regulation (EC) No 1049/2001²⁴ 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:

²⁴ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.05.2001, p. 43

Amendment

1. ***Without*** prejudice to Regulation (EC) No 1049/2001²⁴ and ***all*** 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:

²⁴ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.05.2001, p. 43.

Amendment 162

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, *as defined in Article 4(1) of Regulation (EU) 2016/679 ('GDPR') and Article 3(1) EUDPR;*

Amendment 163

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 ***legally binding and enforceable*** bilateral or multilateral confidentiality arrangements. ***Recalls that transfers of personal data to third countries or international organisations must comply with relevant provisions of the GDPR, the LED and the Charter of Fundamental Rights, and take into account the recommendations and guidelines of the EDPB.***

Amendment 164

Proposal for a regulation Article 31 – paragraph -1 (new)

Text proposed by the Commission

Amendment

The Commission shall carry out an implementation assessment of this Regulation 18 months after its entry into force. It shall carry out an impact assessment before proposing any

modification.

Amendment 165

Proposal for a regulation Article 31 – paragraph 1

Text proposed by the Commission

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

Amendment

This Regulation, *with the exception of its Chapter IV*, shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. *Chapter IV shall apply from [date of entry into force + 6 months].*

PROCEDURE – COMMITTEE ASKED FOR OPINION

Title	A reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices
References	COM(2020)0725 – C9-0365/2020 – 2020/0321(COD)
Committee responsible Date announced in plenary	ENVI 14.12.2020
Opinion by Date announced in plenary	ITRE 14.12.2020
Rapporteur for the opinion Date appointed	Joëlle Mélin 3.12.2020
Discussed in committee	18.3.2021
Date adopted	26.5.2021
Result of final vote	+: 68 –: 0 0: 3
Members present for the final vote	François-Xavier Bellamy, Hildegard Bentele, Tom Berendsen, Vasile Blaga, Michael Bloss, Paolo Borchia, Marc Botenga, Markus Buchheit, Cristian-Silviu Buşoi, Jerzy Buzek, Carlo Calenda, Maria da Graça Carvalho, Ignazio Corrao, Ciarán Cuffe, Josianne Cutajar, Nicola Danti, Pilar del Castillo Vera, Christian Ehler, Valter Flego, Niels Fuglsang, Lina Gálvez Muñoz, Claudia Gamon, Bart Groothuis, Christophe Grudler, Henrike Hahn, Robert Hajšel, Ivo Hristov, Ivars Ijabs, Romana Jerković, Eva Kaili, Seán Kelly, Izabela-Helena Kloc, Łukasz Kohut, Zdzisław Krasnodebski, Andrius Kubilius, Miapetra Kumpula-Natri, Thierry Mariani, Marisa Matias, Eva Maydell, Joëlle Mélin, Iskra Mihaylova, Dan Nica, Angelika Niebler, Ville Niinistö, Mauri Pekkarinen, Mikuláš Peksa, Tsvetelina Penkova, Morten Petersen, Markus Pieper, Clara Ponsatí Obiols, Manuela Ripa, Robert Roos, Massimiliano Salini, Sara Skytvedal, Maria Spyraiki, Jessica Stegrud, Beata Szydło, Grzegorz Tobiszowski, Patrizia Toia, Evžen Tošenovský, Isabella Tovaglieri, Viktor Uspaskich, Henna Virkkunen, Pernille Weiss, Carlos Zorrinho
Substitutes present for the final vote	Martin Hojsik, Alicia Homs Ginel, Elena Lizzi, Jutta Paulus, Susana Solís Pérez, Tomas Tobé

FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

68	+
ECR	Izabela-Helena Kloc, Zdzisław Krasnodębski, Robert Roos, Beata Szydło, Grzegorz Tobiszowski, Evžen Tošenovský
ID	Paolo Borchia, Markus Buchheit, Elena Lizzi, Thierry Mariani, Joëlle Mélin, Isabella Tovaglieri
NI	Clara Ponsatí Obiols, Viktor Uspaskich
PPE	François-Xavier Bellamy, Hildegard Bentele, Tom Berendsen, Vasile Blaga, Cristian-Silviu Buşoi, Jerzy Buzek, Maria da Graça Carvalho, Pilar del Castillo Vera, Christian Ehler, Seán Kelly, Andrius Kubilius, Eva Maydell, Angelika Niebler, Markus Pieper, Massimiliano Salini, Sara Skyttedal, Maria Spyraiki, Tomas Tobé, Henna Virkkunen, Pernille Weiss
Renew	Nicola Danti, Valter Flego, Claudia Gamon, Bart Groothuis, Martin Hojsík, Ivars Ijabs, Iskra Mihaylova, Mauri Pekkarinen, Morten Petersen, Susana Solís Pérez
S&D	Carlo Calenda, Josianne Cutajar, Niels Fuglsang, Lina Gálvez Muñoz, Robert Hajšel, Alicia Homs Ginell, Ivo Hristov, Romana Jerković, Eva Kaili, Miapetra Kumpula-Natri, Dan Nica, Tsvetelina Penkova, Patrizia Toia, Carlos Zorrinho
The Left	Marc Botenga, Marisa Matias
Verts/ALE	Michael Bloss, Ignazio Corrao, Ciarán Cuffe, Henrike Hahn, Ville Niinistö, Jutta Paulus, Mikuláš Peksa, Manuela Ripa

3	0
ECR	Jessica Stegrud
Renew	Christophe Grudler
S&D	Łukasz Kohut

Key to symbols:

+ : in favour

- : against

0 : abstention

PROCEDURE – COMMITTEE RESPONSIBLE

Title	A reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices		
References	COM(2020)0725 – C9-0365/2020 – 2020/0321(COD)		
Date submitted to Parliament	12.11.2020		
Committee responsible Date announced in plenary	ENVI 14.12.2020		
Committees asked for opinions Date announced in plenary	BUDG 14.12.2020	ITRE 14.12.2020	IMCO 14.12.2020
Not delivering opinions Date of decision	BUDG 2.12.2020	IMCO 2.12.2020	
Rapporteurs Date appointed	Nicolás González Casares 25.11.2020		
Discussed in committee	25.2.2021	15.4.2021	21.6.2021
Date adopted	22.6.2021		
Result of final vote	+: -: 0:	68 3 8	
Members present for the final vote	Nikos Androulakis, Bartosz Arłukowicz, Margrete Auken, Simona Baldassarre, Marek Paweł Balt, Traian Băsescu, Aurélie Beigneux, Monika Beňová, Sergio Berlato, Alexander Bernhuber, Malin Björk, Simona Bonafè, Delara Burkhardt, Pascal Canfin, Sara Cerdas, Mohammed Chahim, Tudor Ciuhodaru, Nathalie Colin-Oesterlé, Esther de Lange, Christian Doleschal, Marco Dreosto, Bas Eickhout, Cyrus Engerer, Eleonora Evi, Agnès Evren, Pietro Fiocchi, Catherine Griset, Jytte Guteland, Teuvo Hakkarainen, Anja Hazekamp, Martin Hojsík, Pär Holmgren, Jan Huitema, Yannick Jadot, Adam Jarubas, Petros Kokkalis, Athanasios Konstantinou, Ewa Kopacz, Joanna Kopcińska, Ryszard Antoni Legutko, Peter Liese, Sylvia Limmer, Javi López, Fulvio Martusciello, Liudas Mažylis, Joëlle Mélin, Tilly Metz, Silvia Modig, Dolors Montserrat, Alessandra Moretti, Dan-Ștefan Motreanu, Ville Niinistö, Ljudmila Novak, Grace O’Sullivan, Jutta Paulus, Stanislav Polčák, Jessica Polfjärd, Frédérique Ries, Sándor Rónai, Rob Rooker, Silvia Sardone, Christine Schneider, Günther Sidl, Linea Sjøgaard-Lidell, Maria Spyrali, Nicolae Ștefănuță, Nils Torvalds, Véronique Trillet-Lenoir, Petar Vitanov, Alexandr Vondra, Mick Wallace, Pernille Weiss, Emma Wiesner, Michal Wiezik, Tiemo Wölken, Anna Zalewska		
Substitutes present for the final vote	Nicolás González Casares, Sophia in ‘t Veld, Susana Solís Pérez		
Date tabled	25.6.2021		

FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

68	+
PPE	Bartosz Arłukowicz, Traian Băsescu, Alexander Bernhuber, Nathalie Colin-Oesterlé, Christian Doleschal, Agnès Evren, Adam Jarubas, Ewa Kopacz, Esther de Lange, Peter Liese, Fulvio Martusciello, Liudas Mažylis, Dolors Montserrat, Dan-Ștefan Motreanu, Ljudmila Novak, Stanislav Polčák, Jessica Polfjård, Christine Schneider, Maria Spyraki, Pernille Weiss, Michal Wiezik
S&D	Nikos Androulakis, Marek Paweł Balt, Monika Beňová, Simona Bonafè, Delara Burkhardt, Sara Cerdas, Mohammed Chahim, Tudor Ciuhodaru, Cyrus Engerer, Nicolás González Casares, Jytte Guteland, Javi López, Alessandra Moretti, Sándor Rónai, Günther Sidl, Petar Vitanov, Tiemo Wölken
Renew	Pascal Canfin, Martin Hojsík, Jan Huitema, Sophia in 't Veld, Frédérique Ries, Susana Solís Pérez, Linea Søgaard-Lidell, Nicolae Ștefănuță, Nils Torvalds, Véronique Trillet-Lenoir, Emma Wiesner
Verts/ALE	Margrete Auken, Bas Eickhout, Eleonora Evi, Pär Holmgren, Yannick Jadot, Tilly Metz, Ville Niinistö, Grace O'Sullivan, Jutta Paulus
ID	Aurelia Beigneux, Catherine Griset, Joëlle Mélin
ECR	Joanna Kopcińska
The Left	Malin Björk, Anja Hazekamp, Petros Kokkalis, Silvia Modig, Mick Wallace
NI	Athanasios Konstantinou

3	-
NI	Teuvo Hakkarainen, Sylvia Limmer
ECR	Rob Rooker

8	0
ECR	Sergio Berlato, Pietro Fiocchi, Ryszard Antoni Legutko, Alexandr Vondra, Anna Zalewska
ID	Simona Baldassare, Marco Dreosto, Silvia Sardone

Key to symbols:

+ : in favour

- : against

0 : abstention