Thursday 8 July 2021

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European Medicines Agency ***I

Amendments adopted by the European Parliament on 8 July 2021 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)) ([1])

(Ordinary legislative procedure: first reading)

(2022/C 99/43)

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 Serviced (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.

([1]) The matter was referred back for interinstitutional negotiations to the committee responsible, pursuant to Rule 59(4), fourth subparagraph (A9-0216/2021).

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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 107, 26.3.2021, p. 1.).

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

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Amendment 5

Proposal for a regulation

Recital 3

Text proposed by the Commission	*Amendment*
(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.	(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	*Amendment*
(4) ***Dealing with the issue of*** shortages of medicinal products has been a long-standing priority for the Member States and European Parliament as illustrated by several reports from the European Parliament ([11]) as well as discussions under recent Presidencies of the Council of the European Union.	(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 Parliament ([11]) as well as discussions under recent Presidencies of the Council of the European Union.
([11]) European Parliament resolution of 17 September 2020 on the shortage of medicines — how to address an emerging problem (2020/2071(INI))	([11]) European Parliament resolution of 17 September 2020 on the shortage of medicines — how to address an emerging problem (2020/2071(INI)).

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

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Amendment 9

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

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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 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.	(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 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***.

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Amendment 12

Proposal for a regulation

Recital 8

Text proposed by the Commission	*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.	(8) Safe and efficacious medicinal products that treat, prevent or diagnose diseases which cause public health 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	*Amendment*
(9) During the COVID-19 pandemic ad hoc solutions, including contingent arrangements between the Commission, the European Medicines Agency ('the Agency'), marketing authorisation holders, manufacturers and Member States, had to be found to achieve the objective of making available safe and efficacious medicinal products to treat COVID-19 or prevent its spread, and to facilitate and speed up the development and marketing authorisation of treatments and vaccines.	(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.

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Amendment 14

Proposal for a regulation

Recital 10

Text proposed by the Commission	*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.	(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 ***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.

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Amendment 17

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 ***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]) [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).

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Amendment 19

Proposal for a regulation

Recital 12

Text proposed by the Commission	*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.	(12) In order to improve crisis preparedness and management for medicinal products and medical devices and increase resilience and solidarity across the Union, the procedures and the respective roles and obligations of different concerned entities involved should be clarified. The framework should build on the ad hoc solutions identified so far in the response to the COVID-19 pandemic ***that have proven effective, and 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	*Amendment*
(13) A harmonised system of monitoring of shortages of medicinal products and medical devices should be established, which will facilitate appropriate access to critical medicinal products and medical devices during public health emergencies ***and*** major events, which may have a serious impact on public health. That system should be complemented with improved structures to ensure appropriate management of public health crises and coordinate and provide advice on the research and development of medicinal products which may have the potential to ***address*** public health emergencies. In order to facilitate the monitoring and reporting on potential or actual shortages of medicinal products and medical devices, the Agency should be able to ask and obtain information and data from the concerned marketing authorisation holders, manufacturers and Member States through designated points of contact.	(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***.

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Amendment 21

Proposal for a regulation

Recital 13 a (new)

Text proposed by the Commission	*Amendment*
	(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).

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Amendment 22

Proposal for a regulation

Recital 15

Text proposed by the Commission	*Amendment*
(15) With respect to medicinal products, an executive steering group should be established within the Agency to ensure a robust response to major events and to coordinate urgent actions within the Union in relation to the management of issues relating to the supply of medicinal products. The Steering Group should establish lists of critical medicinal products to ensure monitoring of those products and it should be able to provide advice on the necessary action to take to safeguard the quality, safety, and efficacy of medicinal products and ensure a high level of human health protection.	(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	*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.	(18) The work of the Emergency Task Force should be separate from the work of the scientific committees of the Agency and should be carried out without prejudice to the scientific assessments of those committees. The Emergency Task Force should provide recommendations with regard to the use of medicinal products in the fight ***to overcome*** the public health crisis. The Committee for Medicinal Products for Human Use should be able to use those recommendations when preparing scientific opinions on compassionate or other early use of a medicinal product prior to marketing authorisation. ***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.***

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Amendment 24

Proposal for a regulation

Recital 19

Text proposed by the Commission	*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.	(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.

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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).

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Amendment 27

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 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.	(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 17 February 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) ***No*** 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.

Thursday 8 July 2021

Amendment 28

Proposal for a regulation

Recital 22

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

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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	*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. 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.	(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.

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Amendment 32

Proposal for a regulation

Recital 26

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

Text proposed by the Commission	*Amendment*
	(26a) In order to facilitate the reliable exchange of medicinal product information in a robust and consistent manner, identification of human medicinal products will be based on International Organization for Standardization (ISO) for the identification of medicinal products for human use (IDMP) standards.

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Amendment 34

Proposal for a regulation

Recital 26 b (new)

Text proposed by the Commission	*Amendment*
	(26b) 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.

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Amendment 35

Proposal for a regulation

Recital 26 c (new)

Text proposed by the Commission	*Amendment*
	(26c) 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 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

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Amendment 36

Proposal for a regulation

Recital 26 d (new)

Text proposed by the Commission	*Amendment*
	(26d) 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 e (new)

Text proposed by the Commission	*Amendment*
	(26e) 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.

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Amendment 38

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 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.	(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.

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

Amendment 42

Proposal for a regulation

Article 1 — paragraph 1 — point a

Text proposed by the Commission	*Amendment*
(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;	(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	*Amendment*
(b) monitor and report on shortages of medicinal products for human use and medical devices;	(b) ***prevent,*** monitor and report on shortages of medicinal products for human use and ***critical*** medical devices;

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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 a (new)

Text proposed by the Commission	*Amendment*
	(ba) '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;

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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	*Amendment*
(d) 'shortage' means that supply of a medicinal product for human use or a medical device does not meet demand for that medicinal product or medical device;	(d) 'shortage' means that supply of a medicinal product for human 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	*Amendment*
(f) 'major event' means an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State. Such an event concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin or incident that can affect the supply or quality, safety, and efficacy of medicinal products. Such an event may lead to shortages of medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection.	(f) 'major event' means an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State. Such an event concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin or incident that can affect the ***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.***

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Amendment 50

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 ***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	*Amendment*
2. The Medicines Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields.	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	*Amendment*
3. The Medicines Steering Group shall be chaired by the Agency. The Chair ***may*** invite third parties, including representatives of medicinal product interest groups ***and*** marketing authorisation holders to attend its meetings.	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	*Amendment*
6. The Medicines Steering Group shall be responsible for fulfilling the tasks referred to in Article 4(4) and Articles 5 to 8.	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.

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

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Amendment 58

Proposal for a regulation

Article 4 — paragraph 2

Text proposed by the Commission	*Amendment*
2. To facilitate the monitoring task referred to in paragraph 1, the national competent authorities, through the single points of contact referred to in Article 3(5), shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report to the Agency on any event, including a shortage of a medicinal product in a given Member State, that is likely to lead to a major event or a public health emergency. Where a national competent authority informs the Agency of a shortage of a medicinal product in a given Member State, it shall provide the Agency with any information received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC. Based on a report of an event from a national competent authority and in order to understand the impact of the event in other Member States, the Agency may request information from the national competent authorities, through the working party referred to in Article 3(5).	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 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	*Amendment*
3. Where the Agency considers that an actual or imminent major event needs to be addressed, it shall inform the Commission and the Member States thereof. The Commission, on its own initiative or following a request from one or more Member States, or the Executive Director of the Agency ***may*** request the assistance of the Medicines Steering Group to ***address*** the major event.	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	*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]).	The Medicines Steering Group shall provide advice ***and recommendations*** to the Commission and Member States on any appropriate action it believes should be taken at Union level on the medicinal products concerned in accordance with the provisions of Directive 2001/83/EC or Regulation (EC) No 726/2004 ([18]).
([18]) Regulation (EC) No 726/2004	([18]) Regulation (EC) No 726/2004

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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 Products for Veterinary Use.

Amendment 63

Proposal for a regulation

Article 6 — paragraph 1

Text proposed by the Commission	*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.	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***.

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Amendment 64

Proposal for a regulation

Article 6 — paragraph 2

Text proposed by the Commission	*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.	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	*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.	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.***

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

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

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Amendment 68

Proposal for a regulation

Article 8 — paragraph 1

Text proposed by the Commission	*Amendment*
1. For the duration of a public health emergency or following a request for assistance referred to in Article 4(3) and until its closure, the Medicines Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article 9(2), and, in particular, signal any potential or actual shortages of medicinal products included on the critical medicines lists.	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	*Amendment*
2. Where requested by the Commission or the sub-network referred to in Article 9(2), the Medicines Steering Group shall provide aggregated data and forecasts of demand to substantiate its findings. In that regard, the Medicines Steering Group shall liaise with the European Centre for Disease Prevention and Control to obtain epidemiological data to help forecast medicinal product needs, and with the Executive Steering Group on Shortages of Medical Devices referred to in Article 19 where medicinal products included on the critical medicines lists are administered with a medical device.	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.***

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Amendment 70

Proposal for a regulation

Article 8 — paragraph 3

Text proposed by the Commission	*Amendment*
3. As part of that reporting, the Medicines Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, as relevant, with the Health Security Committee and, in the case of a public health emergency, the Advisory Committee on public health emergencies.	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	*Amendment*
4. The Medicines Steering Group may, on its own initiative or upon request from the Commission, provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities to ensure preparedness to deal with potential or actual shortages of medicinal products caused by public health emergencies or major events.	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	*Amendment*
5. The Medicines Steering Group may upon request from the Commission coordinate measures, where relevant, between the national competent authorities, the marketing authorisation holders and other entities to prevent or mitigate potential or actual shortages in the context of a major event or public health emergency.	5. The Medicines Steering Group may upon request from the Commission 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.

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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	*Amendment*
(a) specify the procedures for establishing the critical medicines lists;	(a) specify the procedures ***and criteria*** 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	*Amendment*
(b) specify the methods of and criteria for the monitoring, data collection and reporting provided for in Articles 4, 7 and 8;	(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	*Amendment*
(c) develop streamlined electronic monitoring and reporting systems;	(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***;

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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 this paragraph on its web-portal.

Amendment 78

Proposal for a regulation

Article 9 — paragraph 2 — point b

Text proposed by the Commission	*Amendment*
(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;	(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	*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.	(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	*Amendment*
(d) details of the potential or actual shortage such as actual or estimated start and end dates and suspected or known cause;	(d) details of the potential or actual shortage such as actual or estimated start and end dates and suspected or known cause ***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	*Amendment*
(h) information from the wholesale distributors and legal person entitled to supply the medicinal product to the public	***deleted***

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Amendment 86

Proposal for a regulation

Article 10 — paragraph 2

Text proposed by the Commission	*Amendment*
2. Marketing authorisation holders of medicinal products authorised in the Union shall, within 6 months from the date of application of this Regulation, provide the information required pursuant to Article 9(1)(e) in the form of an electronic submission in the database referred to in Article 57(1)(l) of Regulation (EC) No 726/2004. Those marketing authorisation holders shall update their submission wherever necessary.	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	*Amendment*
4. Where marketing authorisation holders for medicinal products included on the critical medicines lists indicate that the submitted information contains information of a commercially confidential nature, they shall identify the relevant parts and clarify the reasons for such an indication. The Agency shall assess the merits of each request and protect commercially confidential information against unjustified disclosure.	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 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	*Amendment*
5. Where marketing authorisation holders for medicinal products included on the critical medicines lists are in possession of any additional information, which provides evidence of a potential or actual shortage they shall immediately provide such information to the Agency.	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	*Amendment*
(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.	(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.

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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 reommendations on medicinal products shortage management.

Amendment 94

Proposal for a regulation

Article 12 — paragraph 1 — point a 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***;

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Amendment 96

Proposal for a regulation

Article 12 — paragraph 1 — point f

Text proposed by the Commission	*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.	(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.

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Text proposed by the Commission	*Amendment*
	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.

Text proposed by the Commission	*Amendment*
	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	*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 ***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.

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Amendment 100

Proposal for a regulation

Article 14 — paragraph 1

Text proposed by the Commission	*Amendment*
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.	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	*Amendment*
(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.	(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	*Amendment*
3. The Emergency Task Force shall be composed of representatives of the scientific committees, working parties, and staff members of the Agency, the coordination group established in accordance with Article 27 of Directive 2001/83/EC, and the Clinical Trials Coordination and Advisory Group established in accordance with Article 85 of Regulation (EU) 536/2014 ([21]). External experts may be appointed and representatives of other Union bodies and agencies be invited on an ad hoc basis, as necessary. It shall be chaired by the Agency.	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 of Regulation (EU) ***No*** 536/2014 ([21]). External experts may be appointed and representatives of other Union bodies and agencies be invited on an ad hoc basis, as necessary. It shall be chaired by the Agency.

([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

([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

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Amendment 103

Proposal for a regulation

Article 14 — paragraph 5

Text proposed by the Commission	*Amendment*
5. The Chair may invite representatives of Member States, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, and interest groups representing patients and healthcare professionals to attend its meetings.	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 104

Proposal for a regulation

Article 14 — paragraph 8

Text proposed by the Commission	*Amendment*
8. Article 63 of Regulation (EC) No 726/2004 shall apply to the Emergency Task Force as regards transparency and the independence of its members.	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 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	*Amendment*
3. The Emergency Task Force shall establish procedures for the request and submission of the set of information and data required, including information on the Member State or States where an application for authorisation of a clinical trial is submitted or is intended to be submitted.	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.

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Amendment 106

Proposal for a regulation

Article 15 — paragraph 5

Text proposed by the Commission	*Amendment*
5. When authorising a clinical trial application for which scientific advice has been given, Member States shall take that advice duly into account.	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)

Text proposed by the Commission	*Amendment*
	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.

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Amendment 108

Proposal for a regulation

Article 16 — paragraph 1

Text proposed by the Commission	*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.	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	*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.	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***

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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	*Amendment*
(a) develop and maintain electronic tools for the submission of information and data, including electronic health data generated outside the scope of clinical studies;	(a) develop and maintain electronic tools***, including an inter-operable and digitalised 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	*Amendment*
(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;	(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;

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Amendment 115

Proposal for a regulation

Article 18 — paragraph 1 — point c

Text proposed by the Commission	*Amendment*
(c) as part of its regulatory tasks, make use of digital infrastructures or tools, to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of clinical studies, and the exchange of such data between Member States, the Agency, and other Union bodies;	(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	*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 ***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	*Amendment*
2. The Medical Devices Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields.	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.***

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Amendment 118

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. ***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	*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.	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.***

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Amendment 121

Proposal for a regulation

Article 20 — paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency shall publish the public health emergency critical devices list and any updates to that list on its web-portal.	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 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.	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(2)(a)***, and, in particular, signal any potential or actual shortages of medical devices included on the public health emergency critical devices list.

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Amendment 124

Proposal for a regulation

Article 22 — paragraph 2

Text proposed by the Commission	*Amendment*
2. Where requested by the Commission or the sub-network referred to in Article ***23(2)(b)***, the Medical Devices Steering Group shall provide aggregated data and forecasts of demand to support its findings. In that regard, the Steering Group shall liaise with the European Centre for Disease Prevention and Control to obtain epidemiological data to help forecast medical device needs, and with the Medicines Steering Group referred to in Article 3 where medical devices included on the public health emergency critical devices list are used to jointly with a medicinal product.	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	*Amendment*
(a) specify the procedures for establishing the public health emergency critical devices list;	(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***;

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Amendment 127

Proposal for a regulation

Article 23 — paragraph 1 — point b

Text proposed by the Commission	*Amendment*
(b) develop streamlined electronic monitoring and reporting systems;	(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	*Amendment*
(d) establish and maintain a list of single points of contact from medical device manufacturers, authorised representatives and notified bodies;	***deleted***

Amendment 129

Proposal for a regulation

Article 23 — paragraph 2 — point a

Text proposed by the Commission	*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;	(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;

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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.

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Amendment 135

Proposal for a regulation

Article 25 — paragraph 4 — point a

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) 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;	(***a***) consider the need to provide for temporary exemptions at Member State level pursuant to Article 59(1) of Regulation (EU) 2017/745 or Article 54(1) of Regulation (EU) 2017/746 with a view to mitigating potential or actual shortages of medical devices included on the public health emergency critical devices list***, while at the same time ensuring a high level of patient and product safety***;

Amendment 136

Proposal for a regulation

Article 26 — paragraph 1 — point a

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

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Amendment 138

Proposal for a regulation

Article 26 — paragraph 1 — point e

Text proposed by the Commission	*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.	(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	*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 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.

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Amendment 141

Proposal for a regulation

Article 28 — paragraph 1 — introductory part

Text proposed by the Commission	*Amendment*
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:	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	*Amendment*
(a) provide administrative and technical support to the expert panels for the provision of scientific opinions, views and advice;	(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.

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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 this Regulation and without prejudice to Regulation (EC) No 1049/2001 ([24]) and existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:	1. Unless otherwise provided for in this Regulation and without prejudice to Regulation (EC) No 1049/2001 ([24]) ***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	*Amendment*
(a) personal data in accordance with Article 32;	***deleted***

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Amendment 147

Proposal for a regulation

Article 30 — paragraph 1 — point b

Text proposed by the Commission	*Amendment*
(b) ***commercially confidential information and*** trade secrets of a natural or legal person***, including*** intellectual property rights;	(b) trade secrets of a natural or legal person ***in accordance with Directive (EU) 2016/943 of the European Parliament and 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	*Amendment*
5. The Commission, the Agency, and Member States may exchange commercially confidential information ***and, where necessary to protect public health, personal data,*** with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.	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.

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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].