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Committee on Industry, Research and Energy

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OPINION

of the Committee on Industry, Research and Energy

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

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

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AMENDMENTS

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

Amendment 1

Proposal for a regulation
Recital 1

Text proposed by the Commission	*Amendment*
(1) Pursuant to Articles 9 and 168 of the ***Treaty on the Functioning of the European Union (‘***TFEU***’)*** and Article 35 of the Charter of Fundamental Rights of the European Union the Union is to ensure a high level of human health protection in the definition and implementation of all Union policies and activities.	(1) ***According to Article 4(2) of the Treaty on the Functioning of the European Union (‘TFEU’), common safety concerns in public health matters are amongst the areas in which shared competence between the Union and the Member States applies.*** Pursuant to Articles 9 and 168 of the TFEU and Article 35 of the Charter of Fundamental Rights of the European Union the Union is to ensure a high level of human health protection in the definition and implementation of all Union policies and activities***, and within the strict limits defined by these two Articles of the TFEU***.

Amendment 2

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	(2) The unprecedented experience of the COVID-19 pandemic has demonstrated that the Union should be more effective ***and transparent*** in managing the availability of medicinal products and medical devices and in developing medical countermeasures to address the threats posed to public health ***in a harmonised way between authorities, industry and other stakeholders of the pharmaceuticals supply chain. Europe needs to give a higher priority to health notwithstanding the competences of the Member States in***

emergency impacting a majority of Member States.	***the area of healthcare, to have health systems ready to provide state of the art care, and to be prepared to cope with epidemics and other unforeseeable health threats in line with the International Health Regulations***. The Union's ability to do so has been severely impeded ***by austerity measures affecting public health services, insufficient control on production, and*** by the absence of a clearly defined legal framework for managing its response to the pandemic, and also by the limited degree of Union preparedness in case of a public health emergency impacting a majority of Member States. ***The pandemic has also shown the necessity of having an innovative and research based pharmaceutical industry that works closely with the European Medicines Agency ('the Agency') in order to be better prepared for future health crisis and disruptions in the supply chain. COVID-19 also underlined the need for more transparency on EU marketing authorisation.***

Amendment 3

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) Industry played a role during the COVID-19 crisis and demonstrated resilience, through continued manufacturing.

Amendment 4

Proposal for a regulation
Recital 2 b (new)

Text proposed by the Commission	*Amendment*
	(2b) Shortages consist of different and

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

Amendment 5

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) The often complex supply chains 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.	***deleted***

Amendment 6

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	(5) The COVID-19 pandemic has exacerbated the ***already-existing*** problem of shortages for certain medicinal products

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.	considered as critical in addressing the pandemic, and has highlighted the structural limitations in the Union's ***and the Member States'*** ability to rapidly and effectively react to such challenges during public health crises***, also due to the lack of implementation of industrial policy reforms which were needed***.

Amendment 7

Proposal for a regulation
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) The COVID-19 crisis has revealed the complexity of the supply of raw materials and highlighted a highly fragmented production chain and complex distribution networks, which are factors that the manufacturers and their management controllers are struggling to deal with and which require real collaboration between states, as well as a clear stance to be taken by the Agency.

Amendment 8

Proposal for a regulation
Recital 5 b (new)

Text proposed by the Commission	*Amendment*
	(5b) The essential free movement of goods should be guaranteed also in times of health crisis, potentially through adaptation of border control measures.

Amendment 9

Proposal for a regulation
Recital 5 c (new)

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

Amendment 10

Proposal for a regulation
Recital 6

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

Amendment 11

Proposal for a regulation
Recital 6 a (new)

Text proposed by the Commission	*Amendment*
	(6a) This Regulation aims to establish a framework to address the problem of shortages during public health emergencies and major events. However, shortages of medicinal products and medical devices is a persistent problem that affects health and lives of EU citizens between emergencies as well. Therefore, the Commission should carry out an implementation assessment of this Regulation and examine the expansion of this framework to ensure that the problem of shortages is tackled on a permanent basis.

Amendment 12

Proposal for a regulation
Recital 6 b (new)

Text proposed by the Commission	*Amendment*
	(6b) The outbreak of COVID-19 and the subsequent health crisis revealed the need for a more coordinated European approach in crisis management. Although the emergency of the situation explains the lack of an impact assessment, sufficient allocation of resources in terms of staff and funding should be secured, taking into account the specificities of the health sector in the different Member States.

Amendment 13

Proposal for a regulation
Recital 6 c (new)

Text proposed by the Commission	*Amendment*
	(6c) The COVID-19 pandemic has shown the need for increased cooperation

of the Agency with Member States and the pharmaceutical industry in order to improve the capacity of the EU and Member States to combat future health emergencies or serious events.

Amendment 14

Proposal for a regulation
Recital 7

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

devices.

Amendment 15

Proposal for a regulation
Recital 8

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

Amendment 16

Proposal for a regulation
Recital 9

Text proposed by the Commission	*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***, other stakeholders in the industrial supply chain*** and Member States, had to be found to achieve the objective of making available safe and efficacious medicinal products to treat COVID-19 or prevent its spread, and to facilitate and speed up the development

and marketing authorisation of treatments and vaccines.

Amendment 17

Proposal for a regulation
Recital 10

Text proposed by the Commission	*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 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. ***In order to achieve this goal analytics to predict emerging risks should be developed including the use of alternative data sources.***

Amendment 18

Proposal for a regulation
Recital 10 a (new)

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

Amendment 19

Proposal for a regulation
Recital 11

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

Amendment 20

Proposal for a regulation
Recital 12

Text proposed by the Commission	*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 ***and on experience and examples in other***

countries.

Amendment 21

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.	***deleted***

Amendment 22

Proposal for a regulation
Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(14a) Given the Agency's long-standing and proven record of expertise in the field of medicinal products and considering the Agency's experience from working with a multitude of groups of experts, it is

appropriate to establish the appropriate structures within the Agency to monitor potential shortages of medical devices in the context of a public health emergency and to provide the Agency with a mandate to host the expert panels on medical devices. In this regard, all national and, eventually, Union entities that are engaged in stockpiling of medical devices, should report their stocks to the Agency. This should 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 should in no way change the regulatory system or the decision-making procedures in the area of medical devices already in place in the Union, which should remain clearly distinct from the one for medicinal products.

Amendment 23

Proposal for a regulation
Recital 14 b (new)

Text proposed by the Commission	*Amendment*
	(14b) During the COVID-19 emergency, the regulatory flexibility allowed by the Commission has proven to be a tool for industry to prevent shortages. However, a temporary exemption from the conformity assessment procedure for medical devices should only be considered in exceptional circumstances. Before allowing for such a derogation, the considerations should take into account both the safety of citizens using the device and the safety of the product. Only if both can be ensured even without a conformity assessment procedure, and the benefits for safeguarding supply outweigh the risks, a temporary exemption might be offered.

Amendment 24

Proposal for a regulation
Recital 14 c (new)

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

Amendment 25

Proposal for a regulation
Recital 14 d (new)

Text proposed by the Commission	*Amendment*
	(14d) Robust transparency measures and standards regarding the Agency's regulatory activities on treatments, vaccines and medical devices falling under the scope of this Regulation should be put in place.

Amendment 26

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	(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.	relating to the supply of medicinal products. The Steering Group should establish ***a general*** lists of critical medicinal products ***applicable to any major event or public health emergency, in close cooperation with industry, all stakeholders and, where relevant, healthcare professionals,*** to ensure monitoring of those products and it should be able to provide advice on the necessary action to take to safeguard the quality, safety, and efficacy of ***these*** medicinal products and ensure a high level of human health protection ***during public health emergencies and major events***.

Amendment 27

Proposal for a regulation
Recital 16 a (new)

Text proposed by the Commission	*Amendment*
	(16a) With respect to medical devices, an executive steering group on medical devices should be established to coordinate urgent actions within the Union in relation to the management of supply and demand issues of medical devices, and to establish a list of critical devices for the most probable cases of public health emergencies.

Amendment 28

Proposal for a regulation
Recital 16 b (new)

Text proposed by the Commission	*Amendment*
	(16b) The Agency should make public the recommendations, opinions and decisions of the steering groups. The membership of the steering groups and working parties should be made public. Members of the steering groups and

experts should not have financial or other interests in the pharmaceutical industry which could affect their impartiality.

Amendment 29

Proposal for a regulation
Recital 17

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

Amendment 30

Proposal for a regulation
Recital 18

Text proposed by the Commission	*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	(18) ***While guaranteeing the independence of any subsequent evaluations,*** the work of the Emergency Task Force should be separate from the work of the scientific committees of the

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.

Agency and should be carried out without prejudice to the scientific assessments of those committees. The Emergency Task Force should provide recommendations ***driven only by science and public-health needs and not by other interests,*** with regard to the use of medicinal products in the fight ***to overcome*** the public health crisis. The Committee for Medicinal Products for Human Use should be able to use those recommendations when preparing scientific opinions on compassionate or other early use of a medicinal product prior to marketing authorisation.

Amendment 31

Proposal for a regulation
Recital 19

Text proposed by the Commission	*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 is committed to overcome the divergences among the individual regulatory frameworks, placing itself as guarantee and protection for EU citizens. The*** task force should build on the support provided by the Agency during the COVID-19 pandemic, notably as regards scientific advice on clinical trials design and product development***, the transparency of related activities, including the rapid publishing of clinical data for the products in question,*** as well as the 'rolling' review i.e. on an on-going basis, of emerging evidence to allow a more efficient assessment of medicinal products including vaccines during public health emergencies.

Amendment 32

Proposal for a regulation
Recital 20

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

Amendment 33

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(21) With respect to medical devices, an executive steering group on medical devices should be established to coordinate urgent actions within the	***deleted***

Union in relation to the management of supply and demand issues of medical devices, and to establish a list of critical devices in the case of a public health emergency.

Amendment 34

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 EU 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	[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 35

Proposal for a regulation
Recital 22 a (new)

Text proposed by the Commission	*Amendment*
	(22a) Experts should not have financial or other interests in the pharmaceutical

industry which could affect their impartiality.

Amendment 36

Proposal for a regulation
Recital 23 a (new)

Text proposed by the Commission	*Amendment*
	(23a) Experience with clinical trials during the COVID-19 pandemic revealed a tremendous amount of duplication, plethora of small trials, underrepresentation of important population groups and the lack of collaboration that increased the risk of research waste. To improve the clinical research agenda, there is a need for robust evidence on quality, efficacy and safety of medicinal products through well-designed, well-supported, large, randomised and controlled trials. All relevant information on approved products, clinical results and clinical data of trials need to be made public, having taken due regard to protection of personal data protection and commercially confidential information.

Amendment 37

Proposal for a regulation
Recital 23 b (new)

Text proposed by the Commission	*Amendment*
	(23b) Individual research entities may agree together, or with another party, to act as a sponsor in order to prepare one harmonised Union-wide clinical trial protocol, yet experience during the COVID-19 pandemic has shown that initiatives to set up large multinational trials struggle to materialise due to the lack of a single entity that can undertake

all the responsibilities and activities of a sponsor within the Union, while interacting with multiple Member States. It is therefore appropriate for the Agency to identify and facilitate such initiatives by giving advice on the possibilities to act as a sponsor or, where applicable, to define respective responsibilities as co-sponsors in accordance with Article 72 of Regulation (EU) 536/2014 and coordinate the development of clinical trial protocols. Such an approach would strengthen the research environment in the Union, while encouraging collaboration with external experts, including academia, and target recruitment of data scientists, omics specialists, biostatisticians, epidemiologists, and experts in advanced analytics and AI, as well as promote harmonisation and avoid subsequent delays in integrating the results of research to a marketing authorisation. A Union sponsor could benefit from Union research funding available at the time of the public health emergency as well as existing clinical trial networks to facilitate the development, application, submission, and running of the trial. This may be particularly valuable for trials established by Union or international public health or research organisations.

Amendment 38

Proposal for a regulation
Recital 23 c (new)

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

health interventions.

Amendment 39

Proposal for a regulation
Recital 23 d (new)

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

Amendment 40

Proposal for a regulation
Recital 23 e (new)

Text proposed by the Commission	*Amendment*
	(23e) Standardized reporting requirements for information on clearly defined shortages should be agreed, giving priority to critical products with high potential impact. That system should take into account already existing systems, such as SPOR, EMA systems, the European Medicines Verification System

	(set up in the context of the Falsified Medicines FMD), iSPOC, and the Data Analysis and Real World Interrogation Network - DARWIN, and be complemented with improved telematic structures to ensure appropriate management of public health crises and coordinate and provide advice on the research and development of medicinal products which may have the potential to address public health emergencies. In order to facilitate the monitoring and reporting on potential or actual shortages of medicinal products and medical devices, as well as to avoid duplications of the information submitted, the Agency should be able to ask and obtain information and data from the concerned marketing authorisation holders, manufacturers, wholesalers and Member States who all have the obligation to provide complete information and data through designated points of contact.

Amendment 41

Proposal for a regulation
Recital 23 f (new)

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

Amendment 42

Proposal for a regulation
Recital 24

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

Amendment 43

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	(25) That work should also be facilitated by, where appropriate, emerging digital technologies such as computational models and simulations for clinical trials, as well as data from the EU Space Programme such as the Galileo geolocation services, and Copernicus earth observation data. ***Underlines the potential of Big Data to complement the evidence from clinical trials and fill knowledge gaps on medicines, as well as to help to better characterise diseases, treatments and the performance of medicines in individual healthcare systems. The global pandemic has also shown how High Performance***

Copernicus earth observation data.	***Computing, in combination with Big Data and AI, can be of critical importance in the global fight against COVID-19.***

Amendment 44

Proposal for a regulation
Recital 26

Text proposed by the Commission	*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***, when generated with appropriate quality criteria,*** real world data i.e. health data generated outside of clinical studies, is essential to ensure effective management of public health emergencies and other major events. This Regulation should allow the Agency to use and facilitate such exchange and be part of the establishment and operation of the European Health Data Space infrastructure, ***while ensuring the applicability of Regulation (EU) 2016/679 of the European Parliament and of the Council[1a] (GDPR) and Regulation (EU) 2018/1725 of the European Parliament and of the Council [1b] (EUDPR), and compliance with principles relating to the processing of personal data, such as electronic health records, insurance claims data and data from patient registries, in accordance with Article 4 of the EUDPR; health data should be used in full respect of the provisions of the GDPR on personal data protection. This Regulation should also allow the definition of programs and data collection systems relating to outcomes, results and adverse and undesirable events to be usable by all developers.***
	[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).

Amendment 45

Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission	*Amendment*
	(26a) The handling of sensitive health data requires a high level of protection against cyber-attacks. The Agency was the target of a cyber-attack that resulted in the unlawful accessing of some documents related to COVID-19 medicines and vaccines belonging to third parties. Binding rules on security information and cybersecurity and the main 5G toolbox measures should be swiftly implemented, so as to achieve a high level of security against cyber-attacks, and particularly cyber-espionage, at all times and especially during public health emergencies.

Amendment 46

Proposal for a regulation
Recital 27

Text proposed by the Commission	*Amendment*
(27) During a public health emergency	(27) During a ***temporary*** public health

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

Amendment 47

Proposal for a regulation
Recital 27 a (new)

Text proposed by the Commission	*Amendment*
	(27a) In order to ensure that democratic oversight of the Agency is maintained, especially in times of crisis, the Commission should commit to answer priority written questions asked by Members of the European Parliament before the deadline expires.

Amendment 48

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

Text proposed by the Commission	*Amendment*
(b) monitor and report on shortages of medicinal products for human use and medical devices;	(b) monitor and report on shortages of medicinal products for human use and medical devices ***with the aim of preventing such shortages in the future***;

Amendment 49

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

Text proposed by the Commission	*Amendment*
	(ca) 'veterinary medicinal product' means any veterinary medicinal product as defined in point 2 of Article 1 of Directive 2001/82/EC of the European Parliament and the Council[1a];
	[1a] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

Amendment 50

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

Amendment 51

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

Text proposed by the Commission	*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 ***one or*** more Member ***States***. Such an event concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin or incident that can affect the supply or quality, safety, and efficacy of medicinal products. Such an event may lead to shortages of ***critical*** medicinal products ***and/or medical devices*** in one ***or more*** Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection.

Amendment 52

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

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

Amendment 53

Proposal for a regulation
Article 3 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Executive Steering Group on Shortages and Safety of Medicinal Products ('the Medicines Steering Group') is hereby established as part of the Agency. It shall meet either in person or remotely**,** in preparation for or during a public health emergency or following a request for assistance referred to in Article 4(3). The Agency shall provide its secretariat.	1. The Executive Steering Group on Shortages and Safety of Medicinal Products ('the Medicines Steering Group') is hereby established as part of the Agency. It shall meet either in person or remotely**.** ***Meetings may be scheduled*** in preparation for or during a public health emergency or following a request for assistance referred to in Article 4(3) ***or to deal with a shortage that has been declared by at least one Member State***. The Agency shall provide its secretariat.

Amendment 54

Proposal for a regulation
Article 3 – paragraph 3

Text proposed by the Commission	*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 ***supported in its work by a working party comprised of single points of contact related to shortages from national competent authorities for*** medicinal ***products established in accordance with Article 9(1). A two-way communication line shall be established between the Medicines Steering Group and the single points of contacts from national competent authorities, who shall in turn inform the actors of the industrial sector without delay***.

Amendment 55

Proposal for a regulation
Article 3 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Medicines Steering Group shall establish its rules of procedure	4. The Medicines Steering Group shall establish its rules of procedure

including procedures relating to the working party referred to the paragraph 5 and on the adoption of lists, sets of information, and recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.	including ***its clearly defined competencies in full compliance with the principles of proportionality and subsidiarity, the*** procedures relating to the working party referred to the paragraph 5 and on the adoption of lists, sets of information, and recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency ***and shall be made publicly available.***

Amendment 56

Proposal for a regulation
Article 3 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Medicines Steering Group shall be ***supported in its work by a working party comprised of single points of contact related to shortages from national competent authorities for*** medicinal ***products established in accordance with Article 9(1)***.	5. The Medicines Steering Group shall be ***chaired by the Agency. In order to ensure that a broad spectrum of opinions is taken into account, the Chair shall invite relevant third parties, including representatives of*** medicinal ***products interest groups and marketing authorisation holders and other stakeholders in the medicines and industrial supply chain as well as interest groups representing patients, consumers and healthcare professionals, clinical trial experts, public-health advocacy groups and sectoral trade unions, to attend its meetings, thus allowing stakeholders to give an opinion about the situation in different Member States concerned. To avoid market distortions, the Medicines Steering Group shall ensure that data is evenly shared within or withheld from all marketing authorisation holders.*** ***On the basis of these exchanges, the Medicines Steering Group shall draw up strategic recommendations addressed to the Member States during the public health emergency period.***

Amendment 57

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

Text proposed by the Commission	*Amendment*
	5a. The Medicine Steering Group shall consult the Committee for Medicinal Products for Veterinary Use whenever it deems it necessary to deal with public health emergencies related to zoonoses or diseases affecting only animals that have, or may have, a major impact on human health.

Amendment 58

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

Text proposed by the Commission	*Amendment*
	5b. The membership of the Medicines Steering Group shall be made public. In accordance with Article 107 of Regulation (EU) 2017/745 of the European Parliament and of the Council, all members of the Medicines Steering Group shall comply with the usual rules in force in the Union on conflicts of interest. For the sake of transparency, the declarations of interests of the Members and experts shall be made public. Members of the Medicines Steering Group and experts shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests. All indirect interests which could relate to the industry shall be entered in a register held by the Agency and shall be accessible to the public, on request. Should a conflict of interest occur, all necessary restrictions shall

apply.

Amendment 59

Proposal for a regulation
Article 4 – title

Text proposed by the Commission	*Amendment*
Monitoring of events and preparedness for major events and public health emergencies	Monitoring of events and preparedness for ***temporary*** major events and public health emergencies

Amendment 60

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

Amendment 61

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission	*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,***	2. To facilitate the monitoring task referred to in paragraph 1, the national competent authorities, through the single points of contact referred to in Article 3(5), shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b) ***pro-actively and with the shortest***

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).

delay, report to the Agency on any ***potential*** shortage of a ***critical*** medicinal product in a given Member State, that ***has the potential*** to lead to a major event or a public health emergency ***in other Member States and could compromise a quick and adequate reaction to said major event or 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***, as well as any relevant additional information provided by stakeholders and actors in the pharmaceutical industry, in full respect of confidentiality and privacy, as provided for in Regulation (EU) 2016/769 of the European Parliament and of the Council (the General Data Protection Regulation - GDPR)***. Based on a report of an event from a national competent authority and in order to understand ***and, in particular, anticipate*** the impact of the event in other Member States, the Agency may request information from the national competent authorities, through the working party referred to in Article 3(5).

Amendment 62

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

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

Amendment 63

Proposal for a regulation
Article 5 – paragraph 1

Text proposed by the Commission	*Amendment*
Following the recognition of a public health emergency or a request for assistance referred to in Article 4(3), the Medicines Steering Group shall evaluate the information related to the major event or the public health emergency and consider the need for urgent and coordinated action with regard to the safety, quality, and efficacy of the medicinal products concerned.	Following the recognition of a public health emergency or a request for assistance referred to in Article 4(3), the Medicines Steering Group shall evaluate the information related to the major event or the public health emergency and consider the need for urgent and coordinated action with regard to the ***manufacturing,*** safety, quality, and efficacy of the medicinal products concerned. ***The information evaluated shall be published in due time.***

Amendment 64

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 to the Commission and Member States on any appropriate action it believes should be taken at Union level on the medicinal products concerned in accordance with the provisions of Directive 2001/83/EC or Regulation (EC) No 726/2004.[18] ***This advice shall be made public, together with all the relevant information based on which the advice was compiled. If certain information cannot be made available to the public, due to respect for confidentiality, public health, commercial interests, grounds derived from Article 30 of this Regulation, or public order, this shall be indicated. The Medicines Steering Group shall strive for the greatest transparency possible.***
[18] Regulation (EC) No 726/2004	[18] Regulation (EC) No 726/2004**.**

Amendment 65

Proposal for a regulation
Article 6 – paragraph 1

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

Amendment 66

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission	*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***, and shall cease to apply at the end of the public health***

	emergency.

Amendment 67

Proposal for a regulation
Article 6 – paragraph 3

Text proposed by the Commission	*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 necessary to monitor the supply and demand of medicinal products included on the lists referred to in paragraphs 1 and 2 (‘the critical medicines lists’) and inform its working party ***and the pharmaceutical operators concerned*** thereof. ***Union or national entities that are engaged in stockpiling of medicinal products should be informed accordingly.***

Amendment 68

Proposal for a regulation
Article 6 – paragraph 4

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

Amendment 69

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

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

Amendment 70

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

	throughout the major event or emergency. ***Monitoring shall be conducted during health crises as well as before, after and outside these crises in order to identify potential shortages before they can affect health and lives of EU citizens***. As part of that monitoring, the Medicines Steering Group shall liaise, where relevant, with the Health Security Committee established in Article 4 of Regulation (EU) 2020/[…][19] and, in the case of a public health emergency, the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation.
[19] [insert reference to adopted text referred to in footnote 4]	[19] [insert reference to adopted text referred to in footnote 4].

Amendment 71

Proposal for a regulation
Article 8 – paragraph 2

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

Amendment 72

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

Amendment 73

Proposal for a regulation
Article 8 – paragraph 4

Text proposed by the Commission	*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 ***or Member States***, provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities to ensure preparedness to deal with potential or actual shortages of medicinal products caused by public health emergencies or major events.

Amendment 74

Proposal for a regulation
Article 8 – paragraph 5

Text proposed by the Commission	*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 healthcare professionals,*** to prevent or mitigate potential or actual shortages in the context of a major event or public health emergency.

Amendment 75

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

Text proposed by the Commission	*Amendment*
	5a. Measures recommended by the Medicines Steering Group to the Commission, Member States, marketing authorisation holders and other entities, shall not add any regulatory administrate burden and shall facilitate flexible supply chains.

Amendment 76

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

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

Amendment 77

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

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

Amendment 78

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

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

Amendment 79

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

Text proposed by the Commission	*Amendment*
(e) ***establish and maintain a list of single points of contact from marketing authorisation holders for all medicinal products for human use authorised in the Union, through the database provided for in*** Article 57(1)(l) of Regulation 726/2004;	(e) ***update the database provided for in*** Article 57(1)(l) of Regulation 726/2004 ***by including the industry single points of contact (iSPOC), as well as the contact details of healthcare professionals and patients organisations***; ***this database shall be digital, regularly updated, and compliant with the standards of the International Organization for Standardization (ISO) for the identification of medicinal products (IDMP);***

Amendment 80

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

Text proposed by the Commission	*Amendment*
(a) establish and maintain for the duration of the public health emergency or major event, a sub-network of single points of contact from marketing authorisation holders based on the medicinal products included on the critical medicines lists;	(a) establish and maintain for the duration of the public health emergency or major event, a sub-network of single points of contact***, selected within the competent national public health authorities and*** from marketing authorisation holders ***wholesalers, from the contacts established under Article 9(1) point (e), and of representatives of other relevant supply chain stakeholders involved in the distribution and supply of medicinal products to the public,*** based on the medicinal products included on the critical medicines lists;

Amendment 81

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

Text proposed by the Commission	*Amendment*
The information referred to in point (b) of paragraph 2 shall include at least:	The information referred to in point (b) of paragraph 2***, as determined in Article 9(1)(c) and Article 11, shall not include any duplication of information available to the Agency by the means of the collection of information submitted by industry by the national competent authorities (provided by the Industry Single Points of Contact (iSPOC)). The system referred to in Article 9(1)(c) shall be interoperable with the national shortages reporting systems. The information*** shall include at least:

Amendment 82

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

Text proposed by the Commission	*Amendment*
(d) details of the potential or actual shortage such as actual or estimated start and end dates and suspected or known cause;	(d) details of the potential or actual shortage such as actual or estimated start and end dates and suspected or known cause ***at each stage of the supply chain, as well as information on potential bottlenecks in the supply chain***;

Amendment 83

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

Text proposed by the Commission	*Amendment*
	(da) information on active substance manufacturing sites, where relevant;

Amendment 84

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

Text proposed by the Commission	*Amendment*
(e) ***sales and market share*** data***;***	(e) ***production*** data;

Amendment 85

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

Text proposed by the Commission	*Amendment*
(g) mitigation plans including production ***and*** supply capacity;	(g) mitigation plans including ***location-specific manufacturing, enhanced*** production***,*** supply capacity ***sourcing diversification and, where applicable, outsourcing plans***;

Amendment 86

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

Text proposed by the Commission	*Amendment*
(h) ***information from the wholesale distributors and legal person entitled to supply the*** medicinal ***product to the public.***	(h) ***available alternative*** medicinal ***products;***

Amendment 87

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

Text proposed by the Commission	*Amendment*
	(ha) information from the wholesale distributors and legal person entitled to supply the medicinal product to the public.

Amendment 88

Proposal for a regulation
Article 10 – paragraph 1

Text proposed by the Commission	*Amendment*
1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, marketing authorisation holders for medicinal products included on the critical medicines lists shall submit the information referred to in Article 9(3) by the deadline set by the Agency. They shall submit the information through the points of contact designated in accordance with Article 9(2) ***and using the*** reporting ***methods and system*** established ***pursuant to*** Article ***9(1)***. They shall provide updates ***where*** necessary.	1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, marketing authorisation holders for medicinal products included on the critical medicines lists ***and all distributors legally authorised to supply medicines to the public*** shall submit the information referred to in Article 9(3) by the deadline set by the Agency. They shall submit the information through the points of contact designated in accordance with Article 9(2) ***by the deadline set by the Agency, if the information is not already available via the interoperable system connected with the national shortages*** reporting ***systems*** established pursuant to Article ***9(1)(c)***. They shall provide updates ***whenever*** necessary ***or upon request***.

Amendment 89

Proposal for a regulation
Article 10 – paragraph 2

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

Amendment 90

Proposal for a regulation
Article 10 – paragraph 4

Text proposed by the Commission	*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 ***might contain*** information of a commercially confidential nature, they shall identify the relevant parts and clarify the reasons for such an indication ***and offer sufficient, actual and specific evidence of harm stemming from disclosure***.. The Agency shall ***determine upfront what information is commercially confidential, in accordance with Article 30, and on this basis*** assess the merits of each request***, considering the benefits for public health and interest of*** disclosure ***and act accordingly***. ***Marketing authorisation holders failing to comply with their reporting obligations shall be subject to sanctions to be determined by the Commission***.

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

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

Amendment 92

Proposal for a regulation
Article 11 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, Member States	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:	shall, by the deadline set by the Agency ***where relevant, following the creation of a European interoperable and digital National Competent Authorities (NCAs) shortages reporting system based on common data fields***:

Amendment 93

Proposal for a regulation
Article 11 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) submit the set of information requested by the Agency including available and estimated data on volume of demand, through its designated point of contact and using the reporting methods and system established pursuant to Article 9(1);	(a) submit the set of information requested by the Agency pursuant to ***Article 9(3)*** including available and estimated data on volume of demand, through its designated point of contact and using the reporting methods and system established pursuant to Article 9(1);

Amendment 94

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

Text proposed by the Commission	*Amendment*
(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities;	(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities ***including healthcare professionals, where this is proportionate, justified and necessary***;

Amendment 95

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

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

Amendment 96

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

Text proposed by the Commission	*Amendment*
	(fa) provide answers to priority written questions from Members of the European Parliament within the deadline.

Amendment 97

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

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

Amendment 98

Proposal for a regulation
Article 13 – paragraph 1

Text proposed by the Commission	*Amendment*
The Agency shall, via its web-portal and other appropriate means, in conjunction with national competent authorities, inform the public and interest groups with regard to the work of the Medicines Steering Group.	The Agency shall, via its web-portal and other appropriate means, in conjunction with national competent authorities, inform the public and interest groups ***in a timely manner*** with regard to the work***, advice, recommendations, opinions, decisions and findings*** of the Medicines Steering Group***, including dissenting views***. ***Agendas and minutes of the Group's meetings, as well as the data and sources on which the work is based, shall also be published.***

Amendment 99

Proposal for a regulation
Article 14 – paragraph 1

Text proposed by the Commission	*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 ***a permanent*** part of the Agency. It shall be ***only*** convened ***in preparation for or*** during ***recognised*** public health emergencies, either in person or remotely. The Agency shall provide its secretariat. ***The Emergency Task Force cooperates with EU bodies and agencies, the World Health Organisation, third countries and international scientific organisations in preparing timely and appropriate responses to health emergencies. The Emergency Task Force, in collaboration with Member States and their relevant actors, is committed to exchanging information and best practices, to developing protocols and expertise necessary for the timely and appropriate response to health crises, including for sectors other than health, in order to improve crisis response capacity and generate new synergies.***

Amendment 100

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

Text proposed by the Commission	*Amendment*
	(aa) defining the most clinically relevant performance targets for vaccines and treatments to be measured in clinical trials in order to guide the trials towards meeting the criteria for effective public health interventions;

Amendment 101

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

Text proposed by the Commission	*Amendment*
(b) reviewing clinical trial protocols and providing advice to developers on clinical trials to be conducted in the Union for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency, in accordance with Article 15;	(b) reviewing clinical trial protocols and providing advice ***and guidance*** to developers on clinical trials to be conducted in the Union for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency, in accordance with Article 15;

Amendment 102

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

Text proposed by the Commission	*Amendment*
(c) providing scientific support to facilitate clinical trials to be conducted in the Union for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency. Such support shall include advice to sponsors of similar or linked planned clinical trials on the establishment, in their place, of joint clinical trials and may include advice on establishing agreements to act as a sponsor or as co-sponsor in accordance with	(c) providing scientific support to facilitate clinical trials to be conducted in the Union for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency. Such support shall include advice to sponsors of similar or linked planned clinical trials on the establishment, in their place, of joint clinical trials and may include advice on establishing agreements to act as a sponsor or as co-sponsor in accordance with

Articles 2(14) and 72 of Regulation (EU) 536/2014;	Articles 2(14) and 72 of Regulation (EU) 536/2014 ***and on developing suitable protocols***;

Amendment 103

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

Text proposed by the Commission	*Amendment*
(e) providing scientific recommendations with regard to the use of any medicinal product, which may have the potential to address public health emergencies, in accordance with Article 16;	(e) providing***, by making publicly available,*** scientific recommendations with regard to the use of any medicinal product, which may have the potential to address public health emergencies, in accordance with Article 16;

Amendment 104

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

Text proposed by the Commission	*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 105
Proposal for a regulation
Article 14 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The composition of the Emergency Task Force shall be approved by the Management Board of the Agency. The Executive Director of the Agency or their	4. The composition of the Emergency Task Force shall be approved by the Management Board of the Agency ***and made publicly available***. The Executive

representative and representatives of the Commission shall be entitled to attend all meetings.

Director of the Agency or their representative and representatives of the Commission shall be entitled to attend all meetings.

Amendment 106

Proposal for a regulation
Article 14 – paragraph 5

Text proposed by the Commission	*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 ***shall*** invite***, during Task Force meetings and throughout the public health emergency,*** representatives of Member States, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial ***experts, public health advocacy groups***, representatives of clinical trial networks, ***researchers, sectoral trade unions***, and interest groups representing patients and ***consumer organisations, and the*** healthcare ***sector in order to provide the Task Force with the broadest and most detailed view of the situation at all times throughout the public health emergency***. ***Declarations of interest shall be made publicly available for all stakeholders and experts consulted. Stakeholders and experts with conflicts of interest shall not participate in the process.***

Amendment 107

Proposal for a regulation
Article 14 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Emergency Task Force shall establish its rules of procedure including rules on the adoption of recommendations.	6. The Emergency Task Force shall establish its rules of procedure***, which shall include all the rules relating to its***

The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.	***formation, structure and confidentiality,*** including ***potential conflicts of interest. These rules of procedure also include*** rules on the adoption of recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.

Amendment 108

Proposal for a regulation
Article 14 – paragraph 8

Text proposed by the Commission	*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 undertake to act in public interest and in an independent manner, and shall make an annual declaration of their financial interests which shall be published. Members of the Emergency Task Force shall declare, at each meeting, any potential conflict of interest with respect to the items on the agenda. In the event of such a conflict of interest, the concerned member shall withdraw from the meeting.***

Amendment 109

Proposal for a regulation
Article 14 – paragraph 9

Text proposed by the Commission	*Amendment*
9. The Agency shall publish information about the medicinal products that the Emergency Task Force considers may have the potential to address public health emergencies and any updates on its web-portal.	9. The Agency shall ***rapidly*** publish information about the medicinal products that the Emergency Task Force considers may have the potential to address public health emergencies and any updates on its web-portal. ***The Agency shall also publish clinical trials data on medicines and vaccines reviewed by the Emergency Task***

	Force and clinical trials protocols on which the Emergency Task Force provided advice to developers, in line with the provisions of Regulation (EU) No 536/2014.

Amendment 110

Proposal for a regulation
Article 15 – title

Text proposed by the Commission	*Amendment*
Advice on clinical trials	Advice ***and guidance*** on clinical trials

Amendment 111

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

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

Amendment 112

Proposal for a regulation
Article 15 – paragraph 1

Text proposed by the Commission	*Amendment*
1. During a public health emergency, the Emergency Task Force shall review clinical trial protocols submitted or intended to be submitted in a clinical trial application by developers of medicinal	1. During a public health emergency, the Emergency Task Force shall review clinical trial protocols submitted or intended to be submitted in a clinical trial application by developers of medicinal

products as part of an accelerated scientific advice process.	products as part of an accelerated scientific advice process ***based on targets referred to in paragraph -1. When providing scientific advice, a balance shall always be maintained between necessary facilitation in a crisis situation and patient safety.***

Amendment 113

Proposal for a regulation
Article 15 – paragraph 2

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

Amendment 114

Proposal for a regulation
Article 15 – paragraph 3

Text proposed by the Commission	*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 ***and update*** procedures for the request and submission of the set of information and data required, ***in cooperation with*** the Member States where an application for authorisation of a clinical trial is submitted or is intended to be submitted ***in accordance with Article 4 of Regulation (EU) 536/2014. These procedures shall become public.***

Amendment 115

Proposal for a regulation
Article 15 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Where a developer is the recipient of scientific advice, the developer shall subsequently submit the data resulting from clinical trials to the Agency following a request made pursuant to Article 16.	6. Where a developer is the recipient of scientific advice, the developer shall subsequently ***and continuously*** submit ***all*** the data resulting from clinical trials to the Agency following a request made pursuant to Article 16. ***In order to ensure the protection of sensitive data and in wait of the launch of the Clinical Trials Information System (CTIS) in accordance with Art. 80 and 81 of Regulation (EU) No 536/2014, a state-of-the-art pseudonymisation shall apply, including encryption, in line with the requirements of Article 89 of GDPR.***

Amendment 116

Proposal for a regulation
Article 16 – paragraph 1

Text proposed by the Commission	*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 ***and published*** during the public health emergency.

Amendment 117

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***	2. In preparation of ***their view***, the Emergency Task Force ***shall engage***

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.	marketing authorisation holders and developers in preliminary discussions ***and may subsequently request all relevant information and data from them***. The Emergency Task Force ***shall use the results of comparative randomized controlled trials when*** available***, but, if not, may also, when necessary***, make use of ***real world data including pragmatic trials as in "close to everyday practice",*** taking into account their reliability ***as supportive evidence or signal-eliciting evidence, while applying state-of-the-art pseudonymisation, including encryption***. ***The Emergency Task Force should liaise with agencies of third countries that authorise medicinal products for additional information and data.***

Amendment 118

Proposal for a regulation
Article 16 – paragraph 3 – introductory part

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

Amendment 119

Proposal for a regulation
Article 16 – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
(a) the compassionate use of medicinal products falling under the scope of Directive 2001/83/EC or Regulation (EC)	(a) the compassionate use of medicinal products falling under the scope of Directive 2001/83/EC or Regulation (EC)

No 726/2004;	No 726/2004 ***and the whole production and distribution chain, as well as the adapted prescription by carers in accordance with Article 83(8) of Regulation (EC) No 726/2004***;

Amendment 120

Proposal for a regulation
Article 16 – paragraph 6

Text proposed by the Commission	*Amendment*
6. In the preparation of its recommendations provided pursuant to paragraphs 3, the Emergency Task Force may consult the concerned Member State and request it to provide any information and data, which ***informed*** the Member State's decision to make the medicinal product available for compassionate use. Following such a request, the Member State shall provide all of the requested information.	6. In the preparation of its recommendations provided pursuant to paragraphs 3, the Emergency Task Force may consult the concerned Member State and request it to provide any information and data, which ***influenced*** the Member State's decision to make the medicinal product available for compassionate use. Following such a request, the Member State shall provide all of the requested information.

Amendment 121

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

Text proposed by the Commission	*Amendment*
	7a. Where relevant, marketing authorisation holders, healthcare professionals or developers may suggest medicinal products which may have the potential to be used to address the public health emergency. The Emergency Task Force shall take these suggestions into account and, given that the suggestion is accompanied with sufficient scientific data that the medicinal products have the potential to halt the public health emergency, give an appropriate science-based reaction to the suggestion. The reaction shall be public.

Amendment 122

Proposal for a regulation
Article 17 – paragraph 1

Text proposed by the Commission	*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 its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work ***and the data and sources used in the decision-making process*** of the Emergency Task Force.

Amendment 123

Proposal for a regulation
Article 18 – introductory part

Text proposed by the Commission	*Amendment*
To prepare for and support the work of the Emergency Task Force during public health emergencies, the Agency shall:	***1.*** To prepare for and support the work of the Emergency Task Force during public health emergencies, the Agency shall***:***

Amendment 124

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

Text proposed by the Commission	*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) ***use*** and maintain ***preferably European-designed, highly secure and resilient*** electronic tools for the submission of information and data, including electronic health data generated outside the scope of clinical studies;

Amendment 125

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

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

Amendment 126

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

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

Amendment 127

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

Text proposed by the Commission	*Amendment*
	1a. The Agency shall ensure that the processing of patients' personal data is in strict compliance with the European data

protection framework.

Amendment 128

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

Text proposed by the Commission	*Amendment*
	1b. The Agency shall adopt measures so as to be fully equipped with a high level of security against cyber-attacks, cyber-espionage and human leaks at all times, especially during major events and public health emergencies at Union level.
	The Agency shall be subject to binding rules on security information and cybersecurity, in line with the Security Union Strategy. These rules shall be built on a combination of regular penetration testing, decentralised solutions and security by design principles. The deployment of a secure quantum communication infrastructure (QCI), which would allow the transmission of sensitive information, using an ultra-secure form of encryption, shall be accelerated.

Amendment 129

Proposal for a regulation
Article 19 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Executive Steering Group on Medical Devices (‘the Medical Devices Steering Group’) is hereby established as part of the Agency. It shall meet either in person or remotely, in preparation for or during a public health emergency. The Agency shall provide its secretariat.	1. The Executive Steering Group on Medical Devices (‘the Medical Devices Steering Group’) is hereby established as part of the Agency. It shall meet either in person or remotely, in preparation for or during a public health emergency***, or upon request of a Member State affected by a shortage***. The Agency shall provide its secretariat.

Amendment 130

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

Text proposed by the Commission	*Amendment*
	2a. The membership of the Medical Devices Steering Group shall be made public. Members of the Medical Devices Steering Group and experts shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality. They shall vow to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests. All indirect interests which could relate to the industry shall be entered in a register held by the Agency and shall be accessible to the public, on request. The declarations of interests of all experts shall be made public and all necessary restrictions shall apply where conflicts of interest occur.

Amendment 131

Proposal for a regulation
Article 19 – paragraph 3

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

recommendations addressed to the Member States during the public health emergency period.

Amendment 132

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

Text proposed by the Commission	*Amendment*
	5a. The Medical Devices Steering Group shall establish the basis for strengthened cooperation with national health authorities and the pharmaceutical industry.

Amendment 133

Proposal for a regulation
Article 20 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medical Devices Steering Group shall adopt a list of medical devices which it considers as critical during the public health emergency (‘the public health emergency critical devices list’). The list shall be updated whenever necessary until the termination of the recognition of the public health emergency.	1. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medical Devices Steering Group shall adopt a list of medical devices which it considers as critical during the public health emergency (‘the public health emergency critical devices list’). The list shall be updated whenever necessary until the termination of the recognition of the public health emergency ***and shall cease to apply at the end of the public health emergency***.

Amendment 134

Proposal for a regulation
Article 20 – paragraph 3

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

Amendment 135

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

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

Amendment 136

Proposal for a regulation
Article 21 – paragraph 1

Text proposed by the Commission	*Amendment*
1. On the basis of the public health emergency critical devices list and the information and data provided in accordance with Articles 24 and 25, the Medical Devices Steering Group shall monitor supply and demand of medical devices included on that list with a view to identifying any potential or actual	1. On the basis of the public health emergency critical devices list and the information and data provided in accordance with Articles 24 and 25 ***of this Regulation***, the Medical Devices Steering Group shall ***meet regularly throughout the duration of the major event or public health emergency with the working group***

shortages of those medical devices. As part of that monitoring, the Medical Devices Steering Group shall liaise, where relevant, with the Health Security Committee established in Article 4 of Regulation (EU) 2020/[…][22] and the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation.

of designated national contact points for shortages in the national medicines authorities, with representatives of the medicines production and distribution sectors and with representatives of the healthcare sector to monitor supply and demand of medical devices included on that list with a view to identifying any potential or actual shortages of those medical devices ***and to adapt the list as best as possible throughout the duration of the emergency***. As part of that monitoring, the Medical Devices Steering Group shall liaise, where relevant, with the Health Security Committee established in Article 4 of Regulation (EU) 2020/[…][22] and the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation ***as well as with Union and national entities engaged with stockpiling of medical devices***.

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

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

Amendment 137

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission	*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***, national public health authorities*** and the sub-network referred to in Article 23(1)(b), and, in particular, signal any potential or actual shortages of medical devices included on the public health emergency critical devices list.

Amendment 138

Proposal for a regulation
Article 22 – paragraph 2

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

Amendment 139

Proposal for a regulation
Article 22 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Medical Devices Steering Group may, on its own initiative or upon request from the Commission, provide recommendations on measures which may be taken by the Commission, Member States, medical device manufacturers, notified bodies and other entities to ensure preparedness to deal with potential or actual shortages of medical devices caused by public health emergencies.	4. The Medical Devices Steering Group may, on its own initiative or upon request from the Commission, provide recommendations on measures which may be taken by the Commission, Member States, medical device manufacturers, notified bodies and other entities***, including healthcare professionals,*** to ensure preparedness to deal with potential or actual shortages of medical devices caused by public health emergencies.

Amendment 140

Proposal for a regulation
Article 22 – paragraph 5

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

Amendment 141

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

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

Amendment 142

Proposal for a regulation
Article 23 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) specify the procedures for establishing the public health emergency critical devices list;	(a) ***after consulting with representatives from the national competent authorities and marketing authorisation holders, as well as other stakeholders,*** specify the procedures ***and criteria*** for establishing the public health emergency critical devices list;

Amendment 143

Proposal for a regulation
Article 23 – paragraph 1 – point b

Text proposed by the Commission	*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 144

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 145

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***, selected within the competent national public health authorities and*** from medical device manufacturers and notified bodies based on the medical devices included on the public health emergency critical devices list ***composed of single points of contact to be included for all medical device manufacturers in the database referred to in Article 33 of Regulation (EU) 2017/745 and Article 30 of Regulation (EU) 2017/746***;

Amendment 146

Proposal for a regulation
Article 23 – 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 the known or suspected cause;	(d) details of the potential or actual shortage such as actual or estimated start and end dates, and the known or suspected cause ***at each level of the supply chain***;

Amendment 147

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

Text proposed by the Commission	*Amendment*
(e) ***sales and market share*** data;	(e) ***production*** data;

Amendment 148

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

Amendment 149

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

Text proposed by the Commission	*Amendment*
(i) where conformity assessments are on-going, the status of the conformity assessment by the concerned notified bodies in relation to medical devices included in the public health emergency critical devices list and possible issues	(i) where conformity assessments are on-going, the status of the conformity assessment by the concerned notified bodies in relation to medical devices included in the public health emergency critical devices list and possible issues

which need to be resolved in order to complete the conformity assessment process.

which need to be resolved in order to ***speedily*** complete the conformity assessment process.

Amendment 150

Proposal for a regulation
Article 24 – paragraph 1

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

Amendment 151

Proposal for a regulation
Article 24 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where manufacturers of medical devices included on the public health emergency critical devices list and concerned notified bodies indicate that the submitted information contains information of a commercially confidential nature, they shall identify the relevant parts and clarify the reasons for such an indication. The Agency shall assess the merits of each request and protect such commercially	3. Where manufacturers of medical devices included on the public health emergency critical devices list and concerned notified bodies indicate that the submitted information contains information of a commercially confidential nature, they shall identify the relevant parts and clarify the reasons for such an indication. The Agency shall assess the merits of each request and protect such commercially

confidential information against unjustified disclosure.	confidential information against unjustified disclosure ***unless the information is in the public interest***.

Amendment 152

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

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

Amendment 153

Proposal for a regulation
Article 25 – paragraph 2

Text proposed by the Commission	*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***, health care professionals*** and notified bodies on medical devices included on the public health emergency critical devices list.

Amendment 154

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

Text proposed by the Commission	*Amendment*
(b) consider the need to provide for temporary exemptions at Member State level pursuant to Article 59(1) of Regulation (EU) 2017/745 or Article 54(1) of Regulation (EU) 2017/746 with a view to mitigating potential or actual shortages	(b) consider the need to provide for temporary exemptions at Member State level pursuant to Article 59(1) of Regulation (EU) 2017/745 or Article 54(1) of Regulation (EU) 2017/746 with a view to mitigating potential or actual shortages

of medical devices included on the public health emergency critical devices list;	of medical devices included on the public health emergency critical devices list ***while at the same time ensuring both patient and product safety***;

Amendment 155

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

Text proposed by the Commission	*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 156

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

Text proposed by the Commission	*Amendment*
	(aa) provide answers to priority written questions from Members of the European Parliament within the deadline;

Amendment 157

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

Text proposed by the Commission	*Amendment*
(b) consider the need for guidelines	(b) consider the need for guidelines

addressed to Member States, medical device manufacturers, notified bodies and other entities;	addressed to Member States, medical device manufacturers, notified bodies, ***health care professionals*** and other entities ***where this is proportionate, justified and necessary***;

Amendment 158

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

Text proposed by the Commission	*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 ***or exported from*** the Union, and where such potential or actual shortages have international implications***, including the potential introduction of temporary export transparency and export authorisation mechanisms***.

Amendment 159

Proposal for a regulation
Article 27 – paragraph 1

Text proposed by the Commission	*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 its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Medical Devices Steering Group***, including the recommendations, opinions and decisions made by the Medical Devices Steering Group as well as agendas and minutes of the Group's meetings***.

Amendment 160

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 161

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. ***Without*** prejudice to Regulation (EC) No 1049/2001[24] and ***all*** existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:
[24] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.05.2001, p. 43	[24] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.05.2001, p. 43.

Amendment 162

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

Text proposed by the Commission	*Amendment*
(a) personal data ***in accordance with***	(a) personal data, ***as defined in Article 4(1) of Regulation (EU) 2016/679***

Article ***32***;	***('GDPR') and Article 3(1) EUDPR***;

Amendment 163

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 and, where necessary to protect public health, personal data, with regulatory authorities of third countries with which they have concluded ***legally binding and enforceable*** bilateral or multilateral confidentiality arrangements. ***Transfers of personal data to third countries or international organisations shall comply with relevant provisions of the GDPR, the LED and the Charter of Fundamental Rights, and take into account the recommendations and guidelines of the European Data Protection Board.***

Amendment 164

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

Text proposed by the Commission	*Amendment*
	The Commission shall carry out an implementation assessment of this Regulation 18 months after its entry into force. It shall carry out an impact assessment before proposing any modification.

Amendment 165

Proposal for a regulation
Article 31 – paragraph 1

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

PROCEDURE – COMMITTEE ASKED FOR OPINION

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

FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

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

0	-

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

Key to symbols:
+ : in favour
- : against
0 : abstention