Council of the
European Union

Brussels, 16 September 2021
(OR. en)

11544/21

Interinstitutional File:
2020/0321(COD)

LIMITE

SAN 535
PHARM 166
MI 674
COMPET 634
COVID-19 338
CODEC 1218

PUBLIC

NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	Proposal for a Regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

Delegations will please find enclosed a document for comparing positions on the above-mentioned subject that will be presented at the informal videoconference of the members of the Working Party on Pharmaceuticals and Medical Devices scheduled for 17 September 2021.

COUNCIL OF
THE EUROPEAN UNION
DG LIFE.4

Brussels, 9 July 2021

First informal trilogue
on 13 July 2021

Document for comparing positions

Proposal for a Regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

This is a document comparing the text of the Commission Proposal, amendments voted by the European Parliament on 7 July 2021 and changes to the Proposal approved by the Council on 15 June 2021 (document 9764/21).

This document contains

in Annex A	explanations of the tables used in this document;
in Annexes B and C	the changes to the draft Regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, together with tentative agreements and compromise proposals.

DRAFT

ANNEX A

Explanation of the table layout[1]

Item	Article/ Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
1 item is unchanged compared to the previous document		Plain text in this column is text from the Commission proposal. ***Text in bold italics in this column is text from the Commission proposal that the EP proposes to delete.***	Plain text in this column is text from the Commission proposal that the European Parliament proposes to maintain. ***Text in bold italics in this column is text that the EP proposes to add to the Commission proposal.***	Plain text in this column is text from the Commission proposal that Council wishes to maintain. ***Text in bold italics underlined*** in this column is text that Council has agreed to add. Text in ~~strikethrough~~ in this column is text that Council has agreed to delete.	**This column contains comments, compromise proposals and tentatively agreed text.** *Text in green is tentativelyagreed by the negotiators.* *Text in yellow is for discussion.* *Text in red is identified for the political trilogue.* ***Text in bold italics in this column is text that the EP proposes to add to the Commission proposal.*** ***Text in bold italics underlined*** in this column is text that Council proposes to add. Text in ~~strikethrough~~ in this column is text that Council proposes to delete. *Text in italics is a compromise.* **[…]** means text has been deleted from the Commission proposal.

[1] For the sake of readability this document does not contain footnotes. The footnotes will be reintroduced in the consolidated compromise text at the end of the negotiation process.

DRAFT

ANNEX B

Citations and Recitals

This Annex contains the Citations and Recitals in the Proposal for a Regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. For explanations of layout and fonts see Annex A.

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
1	Citations	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 168(4)(c) thereof, Having regard to the proposal from the European Commission, After transmission of the draft legislative act to the national parliaments, After consulting the European Economic and Social Committee, After consulting the Committee of the Regions, Acting in accordance with the ordinary legislative procedure, Whereas:		THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 168(4)(c) thereof, Having regard to the proposal from the European Commission, After transmission of the draft legislative act to the national parliaments, After consulting the European Economic and Social Committee, After consulting the Committee of the Regions, Acting in accordance with the ordinary legislative procedure, Whereas:	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
2	Recital 1	(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) 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.	
3	Recital 1 a (new)		**Amendment 1** ***(1a) The COVID-19 pandemic has highlighted the risks to human health posed by the over-exploitation of wildlife and other natural resources and the accelerated loss of biodiversity on earth. Approximately 70 % of emerging diseases and almost all known pandemics (influenza, HIV/AIDS and COVID-19) are zoonoses. Those diseases have increased globally over the past 60 years and there are more and more zoonotic pathogens as a result of human activity and its ecological footprint. Changes in land use, deforestation, urbanisation, agricultural expansion and intensification,***		

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
3 continued			***wildlife trafficking and consumption patterns are contributing dramatically to that increase. Zoonotic pathogens can be bacterial, viral or parasitic, or can involve unconventional agents, with the possibility of spreading to humans through direct contact or through food, water or the environment. Some diseases, such as HIV/AIDS, begin as a zoonosis but later mutate into human-only strains. Other zoonoses can cause recurring disease outbreaks, such as the Ebola virus disease and salmonellosis. Still others, such as the coronavirus that causes COVID-19, have the potential to cause global pandemics. According to the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Serviced (IPBES), an estimated 1, 7 million currently undiscovered viruses are thought to exist in mammal and avian hosts. Of those viruses, between 631,000 and 827,000 could have the ability to infect humans.***		

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
4	Recital 1 b (new)		**Amendment 2** ***(1b) As recognised by the World Health Organization, many of the same microbes infect animals and humans, so efforts by just one sector cannot prevent or eliminate the problem. Diseases may be transmitted from humans to animals or vice versa and must therefore be tackled in both, taking advantage of potential synergies in research and treatments. The COVID-19 pandemic is a clear example of the need to reinforce the application of the One Health approach in the Union to achieve better public health outcomes, since, as stated in the EU4Health Programme established by Regulation (EU) 2021/522 of the European Parliament and of the Council[1a], human health is connected to animal health and the environment and actions to***		

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
4 continued			***tackle threats to health must take into account those three dimensions.*** _____ ***[1a] Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (OJ L 197, 26.3.2021, p. 1.).***		
5	Recital 2	(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.	**Amendment 3** (2) The unprecedented experience of the COVID-19 pandemic has ***also highlighted the difficulties of the Union and the Member States to cope with such a public health emergency and has*** demonstrated ***the need to strengthen the Union's role in order to*** be more effective in managing the availability of medicinal products and medical devices and in developing medical countermeasures to address the threats posed to public health ***from an early stage in a***	(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.	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
5 continued		The Union's ability to do so has been severely impeded by the absence of a clearly defined legal framework for managing its response to the pandemic, and also by the limited degree of Union preparedness in case of a public health emergency impacting a majority of Member States.	***harmonised way ensuring cooperation and coordination between Union, national and regional competent authorities, industry and other actors of the pharmaceutical and medical devices supply chains, including healthcare professionals. The Union needs to give a higher priority to health, to ensure the continued provision of high quality healthcare services, and to be prepared to cope with epidemics and other health threats***. The Union's ability to do so has been severely impeded by the absence of a clearly defined legal framework for managing its response to the pandemic, ***inadequate mandates and resources of its health agencies,*** and also by the limited degree of Union ***and Member States*** preparedness in case of a public health emergency impacting a majority of Member States.	The Union's ability to do so has been severely impeded by the absence of a clearly defined legal framework for managing its response to the pandemic, and also by the limited degree of Union preparedness in case of a public health emergency impacting a majority of Member States.	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
6	Recital 2 a (new)		**Amendment 4** ***(2a) Shortages consist of different and complex root causes which need to be further mapped, understood and analysed together with all different stakeholders in order to be comprehensively addressed. A better understanding of the shortages should include identification of bottlenecks in the supply chain. In the specific case of the COVID-19 pandemic, the shortage of adjuvant treatments for the disease had a variety of causes, ranging from production difficulties in third countries, to logistical or production difficulties within the Union, where the shortage of vaccines was due to a rarer cause, namely an unexpectedly high and rising demand.***		

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
7	Recital 3	(3) The often complex supply chains of medicinal products and medical devices, national export restrictions and bans, border closures impeding the free movement of those goods, ***and*** uncertainty related to their supply and demand in the context of the COVID-19 pandemic have led to significant impediments to the smooth functioning of the single market and to addressing the serious threats to public health across the Union.	**Amendment 5** (3) ***Disruptions to*** the often complex supply chains of medicinal products and medical devices, national export restrictions and bans, border closures impeding the free movement of those goods, uncertainty related to their supply and demand in the context of the COVID-19 pandemic***, and the lack of production in the Union of certain essential medicinal products or chemical active ingredients*** have led to significant impediments to the smooth functioning of the single market and to addressing the serious threats to public health across the Union***, with dire consequences for its citizens***.	(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.	
8	Recital 4	(4) ***Dealing with the issue of*** shortages of medicinal products has been a long-standing priority for the Member States and European Parliament as illustrated by several reports from the European Parliament[11] as well as discussions under recent Presidencies of the Council of the European Union.	**Amendment 6** (4) ***Addressing the*** shortages of medicinal products has been a long-standing priority***, but unresolved,*** for the Member States and European Parliament as illustrated by several reports from the European Parliament[11] as well as discussions under recent Presidencies of the Council of the European Union.	(4) Dealing with the issue of shortages of medicinal products has been a long-standing priority for the Member States and European Parliament as illustrated by several reports from the European Parliament as well as discussions under recent Presidencies of the Council of the European Union.	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
9	Recital 4 a (new)		**Amendment 7** ***(4a) Shortages of medicinal products represent a growing threat to public health, with a serious impact on health care systems and on patients' right to access adequate medical treatment. Increased global demand exacerbated by the COVID-19 pandemic has led to further shortages of medicinal products, weakening the healthcare systems in Member States and posing significant risks to patients' health and care, particularly in terms of disease progression and worsening of symptoms, longer delays or interruptions in care or therapy, longer periods of hospitalisations, increased exposure to falsified medicinal products, medication errors, adverse effects as a result of substitution of unavailable medicinal products with alternative ones, significant psychological distress for patients and increased costs for the healthcare systems.***		

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
10	Recital 5	(5) The COVID-19 pandemic has exacerbated the problem of shortages for certain medicinal products considered as critical in addressing the pandemic, and has highlighted the structural limitations in the Union's ability to rapidly and effectively react to such challenges during public health crises.	**Amendment 8** (5) The COVID-19 pandemic has exacerbated the ***already existing*** problem of shortages for certain medicinal products considered as critical in addressing the pandemic, and has highlighted the ***Union's external dependence in terms of domestic production of medicinal products and medical devices, the lack of coordination and the*** structural limitations in the Union's ***and Member States'*** ability to rapidly and effectively react to such challenges during public health crises***, the need to support and strengthen the industrial fabric through appropriate policies, as well as the need for a more active and extended involvement of the Union institutions, bodies, offices and agencies addressing the health of the Union citizens***.	(5) The COVID-19 pandemic has exacerbated the problem of shortages for certain medicinal products considered as critical in addressing the pandemic, and has highlighted the structural limitations in the Union's ability to rapidly and effectively react to such challenges during public health crises.	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
11	Recital 6	(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	**Amendment 9** (6) The rapid evolution of COVID-19 and the spread of the virus led to a sharp increase in demand for medical devices such as ventilators, surgical masks, and COVID-19 test kits while disruption of production or limited capacity to rapidly increase production and the complexity and global nature of the supply chain for medical devices, led to ***severe*** supply ***difficulties and, at certain times, serious stock-outs, and placed Member States in competition with each other to respond to the legitimate needs of their citizens, contributing to uncoordinated actions at national levels such as national hoarding and stockpiling***. Those issues ***further*** resulted in new entities being involved in the ***rushed*** production of those products, which subsequently resulted in bottlenecks in conformity assessment, as well as the prevalence of ***over-priced,*** non-compliant, unsafe, and in some cases counterfeit products. It is	(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	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
11 continued		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.	therefore appropriate ***and urgent*** to establish long-term structures within an appropriate Union body to ensure ***a more solid and effective coordination and*** monitoring of shortages of medical devices ***that can occur during*** a public health emergency***, as well as increased and early dialogue with the medical devices industry and healthcare professionals to prevent and mitigate those shortages***.	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.	
12	Recital 6 a (new)		**Amendment 10** ***(6a) The COVID-19 outbreak and the subsequent health crisis revealed the need for a more coordinated Union approach in crisis management. Although the emergency of the situation explains the lack of an impact assessment, sufficient allocation of resources in terms of staff and fundisng should be secured, taking into account the specificities of the health sector in the different Member States.***		

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
13	Recital 7	(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	**Amendment 11** (7) Uncertainty of supply and demand and the risk of shortages of essential medicinal products and medical devices during a public health emergency like the COVID-19 pandemic can trigger export restrictions amongst Member States and other national protective measures, which can seriously impact the functioning of the internal market ***aggravating the consequences for public health, as well as lead to the need for temporary export transparency and export authorisation mechanisms***. Furthermore, shortages of medicinal products can result in serious risks to the health of patients in the Union due to their lack of availability, which can cause, medication errors, increased duration of hospital stays, adverse reactions ***and fatalities*** caused by the administration of unsuitable products used as a substitute for unavailable ones. With respect to medical devices, shortages can	(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	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
13 continued		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.	lead to a lack of diagnostic resources with negative consequences for public health measures, a lack of treatment or deterioration of the disease and may also prevent health professionals from adequately carrying out their tasks ***or being protected when doing so, as evidenced during the COVID-19 pandemic, with serious consequences for the health of health professionals.*** Those shortages can also have a significant impact on controlling the spread of a given pathogen caused by, for example, an insufficient supply of COVID-19 test kits. It is therefore important ***to have an appropriate framework at Union level to coordinate the response of Member States*** to address the question of shortages and to reinforce and formalise monitoring of critical medicinal products and medical devices ***in the most efficient way and so as to avoid creating unnecessary burdens for stakeholders which may strain resources and cause additional delays***.	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.	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
14	Recital 8	(8) Safe and efficacious medicinal products that treat, prevent or diagnose diseases which cause public health emergencies, should be developed and made available ***within the*** Union as soon as possible during such emergencies. The COVID-19 pandemic has also highlighted sub-optimal coordination and decision-making as regards multinational clinical trials, and Union-level advice on the use of medicinal products in national compassionate use programmes or outside of their authorised indications in the Union, causing delays in the adoption of research outcomes and in the development and availability of new or repurposed medicines.	**Amendment 12** (8) Safe and efficacious medicinal products that treat, prevent or diagnose diseases which cause public health emergencies, should be ***identified,*** developed***, notably through joint efforts of public authorities, private sector and academia,*** and made available ***to*** Union ***citizens*** as soon as possible during such emergencies. The COVID-19 pandemic has also highlighted sub-optimal coordination and decision-making as regards multinational clinical trials, and Union-level advice on the use of medicinal products in national compassionate use programmes or outside of their authorised indications in the Union, causing delays in the adoption of research outcomes and in the development and availability of new or repurposed medicines.	(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~~***the need to coordinate assessments*** and ~~decision-making as regards~~***conclusions on*** multinational clinical trials***, in line with what is currently done on a voluntary basis by clinical experts of Member States***, 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.	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
15	Recital 9	(9) During the COVID-19 pandemic ad hoc solutions, including contingent arrangements between the Commission, the European Medicines Agency ('the Agency'), marketing authorisation holders, manufacturers and Member States, had to be found to achieve the objective of making available safe and efficacious medicinal products to treat COVID-19 or prevent its spread, and to facilitate and speed up the development and marketing authorisation of treatments and vaccines.	**Amendment 13** (9) During the COVID-19 pandemic ad hoc solutions, including contingent arrangements between the Commission, the European Medicines Agency ('the Agency'), marketing authorisation holders, manufacturers ***or other actors in the pharmaceutical supply chain*** and Member States, had to be found to achieve the objective of making available safe and efficacious medicinal products to treat COVID-19 or prevent its spread, and to facilitate and speed up the development and marketing authorisation of treatments and vaccines.	(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.	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
16	Recital 10	(10) In order to ensure a better functioning of the internal market of those products and contribute to a high level of human health protection, it is therefore appropriate to approximate the rules on monitoring of shortages of medicinal products and medical devices, and to facilitate the research and development of medicinal products, which may have the potential to treat, prevent, or diagnose diseases that cause public health crises.	**Amendment 14** (10) In order to ensure a better functioning of the internal market of those products and contribute to a high level of human health protection, it is therefore appropriate to approximate ***and strengthen*** the rules on monitoring of shortages of medicinal products and medical devices, and to facilitate the research and development of medicinal products, which may have the potential to treat, prevent, or diagnose diseases that cause public health crises***, with a view to strategically complementing the efforts of the Commission and Union agencies to that end, as well as that of future key agencies such as the proposed European Health Emergency Preparedness and Response Authority (HERA)***.	(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.	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
17	Recital 10 a (new)		**Amendment 15** ***(10a) In order to ensure effective health systems, stress tests should be introduced to assess the resilience of health systems in emergencies with a view to providing an effective means of countering shortages in the event of pandemics and identifying structural risk factors that create shortages.***		
18	Recital 10 b (new)		**Amendment 16** ***(10b) In order to ensure a better functioning of the internal market of medicinal products and contribute to a high level of human health protection, it is appropriate to facilitate the research and development of medicinal products, which may have the potential to treat, prevent, or diagnose diseases that cause public health crises.***		

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
19	Recital 11	(11) This Regulation aims to ensure the smooth functioning of the internal market as regards medicinal products and medical devices***, with a high level of human health protection being fundamental in those aims***. Moreover, this Regulation aims to ensure the quality, safety and efficacy of medicinal products with the potential to address public health emergencies. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 TFEU, this Regulation establishes a framework for the monitoring and reporting on shortages of medicinal products and medical devices during public health crises. As regards Article 168(4)(c) TFEU, this Regulation provides for a strengthened Union framework ensuring the quality and safety of medicinal products and medical devices.	**Amendment 17** (11) This Regulation aims to ensure ***a high level of human health protection by ensuring*** the smooth functioning of the internal market as regards medicinal products and medical devices. Moreover, this Regulation aims to ensure the quality, safety and efficacy of medicinal products with the potential to address public health emergencies. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 TFEU, this Regulation establishes a framework for the monitoring and reporting on shortages of medicinal products and medical devices during public health crises. As regards Article 168(4)(c) TFEU, this Regulation provides for a strengthened Union framework ensuring the quality and safety of medicinal products and medical devices.	(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.	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
20	Recital 11 a (new)		**Amendment 18** ***(11a) This Regulation establishes a framework to address the problem of shortages during public health emergencies and major events. However, shortages of medicinal products and medical devices are a persistent problem that has been increasingly affecting health and lives of Union citizens for decades. Therefore, this Regulation should be a first step towards improving the Union response to this long-lasting issue. The Commission should subsequently propose the expansion of this framework to ensure that the issue of shortages is broadly and permanently tackled in the upcoming revision of Regulation (EC) No 726/2004 of the European Parliament and of the Council[1a] and Directive 2001/83/EC of the European Parliament and of the Council[1b].*** _____ ***[1a] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004***		

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
20 continued			***laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).*** ***[1b] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).***		

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
21	Recital 12	(12) In order to improve crisis preparedness and management for medicinal products and medical devices and increase resilience and solidarity across the Union, the procedures and the respective roles and obligations of different concerned entities involved should be clarified. The framework should build on the ad hoc solutions identified so far in the response to the COVID-19 pandemic.	**Amendment 19** (12) In order to improve crisis preparedness and management for medicinal products and medical devices and increase resilience and solidarity across the Union, the procedures and the respective roles and obligations of different concerned entities involved should be clarified. The framework should build on the ad hoc solutions identified so far in the response to the COVID-19 pandemic ***that have proven effective, and on experience and examples in other countries***, ***while remaining flexible enough to tackle any future health crisis in the most efficient way to the benefit of public health and patients***.	(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.	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
22	Recital 13	(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	**Amendment 20** (13) A harmonised system of monitoring of shortages of medicinal products and medical devices should be established, which will facilitate appropriate access to critical medicinal products and medical devices during public health emergencies**,** major events, which may have a serious impact on public health. That system should be complemented with improved structures to ensure appropriate management of public health crises and coordinate and provide advice on the research and development of medicinal	(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~~.~~ ***and cannot be sufficiently addressed by the Member States concerned.*** 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	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
22 continued		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.	products which may have the potential to ***mitigate*** public health emergencies. In order to facilitate the monitoring and reporting on potential or actual shortages of medicinal products and medical devices, the Agency should be able to ask and obtain information and data from the concerned marketing authorisation holders, manufacturers and Member States through designated points of contact***, while avoiding any duplication of the information requested and submitted***.	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. ***This should not interfere with the obligation of MAHs under article 23a of the Directive 2001/83/EC to notify Member States when the product ceases to be placed on the market of that Member State and the obligation under article 81 of the Directive 2001/83/EC for MAH and wholesale distributors within the limits of their responsibilities, to ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.***	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
23	**Recital 13 a (EP) (new)**		**Amendment 21** ***(13a) In order to facilitate the prevention, monitoring and reporting of shortages of medicinal products, it would be necessary for the Union and Member States to set up an electronic platform capable of determining the volume of stocks existing at any given moment, and detecting, predicting and preventing shortages of medicinal products. To facilitate the development of such a system, lessons could be learnt from projects such as CISMED, funded by the Union through Horizon Europe. The platform should provide the national competent authorities with real-time access to information on unmet demands from wholesale distributors, community pharmacies and hospital pharmacies, providing accurate data in order to understand the functioning of the supply chain and anticipate potential shortages of medicinal products. The platform should also act as the***		

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
23 continued			***sole portal for marketing authorisation holders and wholesale distributors to provide the information required during major events and public health emergencies once fully implemented, with a view to increasing efficiency, predictability during crises, and accelerate the decision-making process while avoiding duplication of efforts and an unjustified burden on all stakeholders. In order to facilitate the coordination role of the Agency, Member States' supply monitoring platforms should be interoperable and replicate their information in the Union database managed by the Agency. To accelerate the implementation of the system at Union and national level, its development and implementation should be supported by Union funding from, inter alia, the EU4Health Programme or the Recovery and Resilience Facility established by Regulation (EU) 2021/241 of the European***		

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
23 continued			***Parliament and of the Council[1a].*** _____ ***[1a] Regulation (EU) 2021/241 of the European Parliament and of the Council of 12 February 2021 establishing the Recovery and Resilience Facility (OJ L 57, 18.2.2021, p. 17).***		

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
23 bis	Recital 13 a (Council) (new)			***(13a) In the event that the actual future demand is unknown due to a major event or public health emergency, it is important to make pragmatic predictions of demand for certain medicines through the use of best available information. In this context, planned minimum stocks and available stocks should be collected and taken into account in identifying the demand to the extent possible. This information is essential for correct adjustments in the manufacturing of medicinal products to avoid or at least mitigate the impact of shortages. However, when data on stocks are not available or cannot be provided due to national security interests, Member States should provide the Agency with estimated data on volumes of demand.***	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
24	Recital 14	(14) The operational phase of the work of the Steering Groups and Emergency Task Force provided for in this Regulation should be triggered by the recognition of a public health emergency in accordance with Regulation (EU) 2020/[…] on Cross-Border Health Threats and, as regards the Medicines Steering Group, the existence of a major event. Continuous monitoring of the risk to public health from major events, including manufacturing issues, natural disasters and bioterrorism with the potential to affect the quality, safety, efficacy or supply of medicinal products should also be ensured.		(14) The operational phase of the work of the Steering Groups and Emergency Task Force provided for in this Regulation should be triggered by the recognition of a public health emergency in accordance with Regulation (EU) 2020/[…] on Cross-Border Health Threats and, as regards the Medicines ***Shortages*** Steering Group, the existence of a major event. Continuous monitoring of the risk to public health from major events, including manufacturing issues, natural disasters and bioterrorism with the potential to affect the quality, safety, efficacy or supply of medicinal products should also be ensured. ***In addition, such monitoring should take into consideration the One Health principles namely by recognising the importance of a multidisciplinary approach and the interconnection between people, animals and plants and their shared environment.***	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
25	Recital 15	(15) With respect to medicinal products, an executive steering group should be established within the Agency to ensure a robust response to major events and to coordinate urgent actions within the Union in relation to the management of issues relating to the supply of medicinal products. The Steering Group should establish lists of critical medicinal products to ensure monitoring of those products and it should be able to provide advice on the necessary action to take to safeguard the quality, safety, and efficacy of medicinal products and ensure a high level of human health protection.	**Amendment 22** (15) With respect to medicinal products, an executive steering group should be established within the Agency to ensure a robust response to major events and to coordinate urgent actions within the Union in relation to the management of issues relating to the supply of medicinal products. The Steering Group should establish lists of critical medicinal products to ensure monitoring of those products and it should be able to provide advice ***and recommendations*** on the necessary action to take to safeguard the quality, safety, and efficacy of medicinal products ***as well as their supply*** and ensure a high level of human health protection.	(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.	
26	Recital 16	(16) The Executive Steering Group on Shortages and Safety of Medicinal Products should benefit from the Agency's extensive scientific expertise as regards the evaluation and supervision of medicinal products and should further develop the Agency's leading role in coordinating and supporting the response to shortages during the COVID-19 pandemic.		(16) The Executive Steering Group on Shortages and Safety of Medicinal Products should benefit from the Agency's extensive scientific expertise as regards the evaluation and supervision of medicinal products and should further develop the Agency's leading role in coordinating and supporting the response to shortages during the COVID-19 pandemic.	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
27	Recital 17	(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 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. ***Decisions on clinical trial applications should remain within the responsabilities of the Member States, in accordance with Regulation (EU) No 536/2014.***	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
28	Recital 18	(18) The work of the Emergency Task Force should be separate from the work of the scientific committees of the Agency and should be carried out without prejudice to the scientific assessments of those committees. The Emergency Task Force should provide recommendations with regard to the use of medicinal products in the fight ***against the disease that is responsible for*** the public health crisis. The Committee for Medicinal Products for Human Use should be able to use those recommendations when preparing scientific opinions on compassionate or other early use of a medicinal product prior to marketing authorisation.	**Amendment 23** (18) The work of the Emergency Task Force should be separate from the work of the scientific committees of the Agency and should be carried out without prejudice to the scientific assessments of those committees. The Emergency Task Force should provide recommendations with regard to the use of medicinal products in the fight ***to overcome*** the public health crisis. The Committee for Medicinal Products for Human Use should be able to use those recommendations when preparing scientific opinions on compassionate or other early use of a medicinal product prior to marketing authorisation. ***The Executive Steering Group on Shortages and Safety of Medicinal Products could also draw on the work of the Emergency Task Force when developing the critical medicines lists.***	(18) The work of the Emergency Task Force should be separate from the work of the scientific committees of the Agency and should be carried out without prejudice to the scientific assessments of those committees. The Emergency Task Force should provide ***advice and*** 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.	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
29	Recital 19	(19) The establishment of the Emergency Task Force should build on the support provided by the Agency during the COVID-19 pandemic, notably as regards scientific advice on clinical trials design and product development as well as the 'rolling' review i.e. on an on-going basis, of emerging evidence to allow a more efficient assessment of medicinal products including vaccines during public health emergencies.	**Amendment 24** (19) The establishment of the Emergency Task Force should build on the support provided by the Agency during the COVID-19 pandemic, notably as regards scientific advice on clinical trials design and product development as well as the 'rolling' review i.e. on an on-going basis, of emerging evidence to allow a more efficient assessment of medicinal products including vaccines during public health emergencies***, while guaranteeing a high level of human health protection***.	(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.	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
30	Recital 19 a (EP) (new)		**Amendment 25** ***(19a) Experience with clinical trials during the COVID-19 pandemic revealed a tremendous amount of duplication of investigations on the same interventions, many small trials, under-representation of important population subgroups, based on gender, age, ethnicity or medical comorbidities, and a lack of collaboration, posing a risk of research waste. To improve the clinical research agenda, international regulators pointed out the need for robust evidence on quality, efficacy and safety of medicinal products. The main way to obtain reliable evidence is through coordinated, well-designed, adequately powered large randomised controlled trials. Clinical trial results and data should be made public.***		

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
30 bis	Recital 19 a (Council) (new)			***(19a) Whenever necessary and considering that human medicinal products may impact the veterinary sector, a close liaison with the national competent authorities for veterinary medicinal products should be foreseen.***	
31	Recital 19 b (EP) (new)		**Amendment 26** ***(19b) The clinical trials phase during which the safety, efficacy and quality of medicinal product candidates is studied in humans, is a key step in the development of medicinal products, including vaccines. It is therefore important that Regulation (EU) No 536/2014 of the European Parliament and of the Council[1a] is fully applied, in particular as regards the launch of a functioning clinical trials information system.*** _____ ***[1a] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).***		

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
32	Recital 20	(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	**Amendment 27** (20) Individual research entities may agree together, or with another party, to act as a sponsor in order to prepare one harmonised Union-wide clinical trial protocol, yet experience during the COVID-19 pandemic has shown that initiatives to set up large multinational trials struggle to materialise due to the lack of a single entity that can undertake all the responsibilities and activities of a sponsor within the Union, while interacting with multiple Member States. ***In that regard, a new Union wide and Union funded vaccine trial network called VACCELERATE was launched in light of the Commission communication of 17February 2021 entitled 'HERA Incubator: Anticipating together the threat of COVID-19 variants'. The Emergency Task Force should build on that trial network and other established networks such as the Heads of Medicines Agencies, the Clinical Trials Facilitation and***	(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.	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
32 continued		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	***Coordination Group and the European Clinical Research Infrastructure Network to ensure that adequate data on new medicinal products in light of a possible public health emergency is expediently generated.*** It is therefore ***imperative*** for the Agency to identify and facilitate such initiatives by giving advice on the possibilities to act as a sponsor or, where applicable, to define respective responsibilities as co-sponsors in accordance with Article 72 of Regulation (EU) 536/2014 ***and coordinate the development of clinical trial protocols. The Emergency Task Force should define the most clinically relevant performance targets for vaccines and treatments to be measured in clinical trials, so that they can meet the criteria for effective public health interventions***. Such an approach would strengthen the research environment in the Union, and promote harmonisation and avoid subsequent delays in integrating the results of research to a.	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	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
32 continued		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.	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	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.	
33	Recital 21	(21) With respect to medical devices, an executive steering group on medical devices should be established to coordinate urgent actions within the Union in relation to the management of supply and demand issues of medical devices, and to establish a list of critical devices in the case of a public health emergency.		(21) With respect to medical devices, an executive steering group on medical devices should be established to coordinate urgent actions within the Union in relation to the management of supply and demand issues of medical devices, and to establish a list of critical devices in the case of a public health emergency.	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
34	Recital 21a (new)			***(21a) In order to establish the list of critical devices and to facilitate the monitoring process, the manufacturers or their authorised representative and, where necessary, concerned notified bodies should provide the requested information. In specific situations, namely when a Member State considers the need to provide for temporary exemptions 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 and in vitro diagnostic medical devices, also the importer and distributor should play a relevant role in providing the requested information, if no authorised representative is designated by the non-EU manfacturer.***	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
35	Recital 21b (new)			***(21b) Considering that the Medical Device Coordination Group (MDCG), as established in Regulation (UE) 2017/745, is the formal forum to discuss regulatory aspects on medical devices sector, including Market Surveillance and in order to contribute with medical devices competence and experience necessary for the monitoring and mitigating of shortages of critical medical devices, the Executive Steering Group on Shortages of Medical Devices should closely liaise with the MDCG, as appropriate. Effective coordination with the MDCG could be useful for the definition of the list of critical medical devices and information to be provided as well for the adoption of recommendations by the Executive Steering Group on Shortages of medical devices.***	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
36	Recital 22	(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 to provide independent scientific and technical assistance to the Member States, the Commission, the Medical Device Coordination Group (MDCG), notified bodies and manufacturers.	**Amendment 28** (22) This Regulation also provides the Agency with a role to support the expert panels on medical devices designated under Commission Implementing Decision (EU) 2019/1396[12] to provide independent scientific and technical assistance to the Member States, the Commission, the Medical Device Coordination Group (MDCG), notified bodies and manufacturers***, while upholding maximum transparency as a condition for fostering trust and confidence in the Union regulatory system***. [12] Commission Implementing Decision (EU) 2019/1396 of 10 September 2019 laying down the rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the designation of expert panels in the field of medical devices OJ L 234, 11.9.2019, p. 23	(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 to provide independent scientific and technical assistance to the Member States, the Commission, the ~~Medical Device Coordination Group (MDCG),~~ ***MDCG,*** notified bodies and manufacturers.	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
37	Recital 22 a (new)		**Amendment 29** ***(22a) The Emergency Task Force should review clinical trial protocols and advice developers on clinical trials that are conducted in the Union, providing guidance on clinically relevant endpoints and targets for vaccines and treatments in order to guide clinical trial design toward meeting the criteria for effective public health interventions.***		

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
38	Recital 23	(23) In addition to their role in clinical evaluation assessments and performance evaluations of certain high risk medical devices and *in vitro* diagnostic medical devices in accordance with Regulation (EU) 2017/745 and Regulation (EU) 2017/746 respectively, as well as providing opinions in response to consultation by manufacturers and notified bodies, the expert panels should play an essential role in the preparedness for and management of public health crises for medical devices, including those devices which have the potential to address public health emergencies. The panels are to provide scientific, technical, and clinical assistance to the Member States, the Commission, and the Medical Device Coordination Group (MDCG). In particular the panels are to contribute to the development of guidance on a number of points including clinical and performance aspects for specific devices, categories, or groups of devices or specific hazards related to a category or		(23) In addition to their role in clinical evaluation assessments and performance evaluations of certain high risk medical devices and *in vitro* diagnostic medical devices in accordance with Regulation (EU) 2017/745 and Regulation (EU) 2017/746 respectively, as well as providing opinions in response to consultation by manufacturers and notified bodies~~, the expert panels should play an essential role in the preparedness for and management of public health crises for medical devices, including those devices which have the potential to address public health emergencies.~~. The panels are to provide scientific, technical, and clinical assistance to the Member States, the Commission, and the ~~Medical Device Coordination Group (MDCG).~~***MDCG.*** In particular the panels are to contribute to the development of guidance on a number of points including clinical and performance aspects for specific devices, categories, or groups of devices or specific hazards related to a category or	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
38 continued		group of devices, develop clinical evaluation and performance evaluation guidance in line with the state of the art, and contribute to the identification of concerns and emerging issues on safety and performance.		group of devices, develop clinical evaluation and performance evaluation guidance in line with the state of the art, and contribute to the identification of concerns and emerging issues on safety and performance. ***In this context, the expert panels together with MDCG and its technical groups could play a relevant role in the preparedness for and management of public health crises for medical devices, particularly those of high risk including those devices which have the potential to address public health emergencies without prejudice to tasks and obligations under Regulation (EU) 2017/745 and Regulation (EU) 2017/746.***	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
39	Recital 24	(24) Given the Agency's long-standing and proven record of expertise in the field of medicinal products and considering the Agency's experience from working with a multitude of groups of experts, it is appropriate to establish the appropriate structures within the Agency to monitor potential shortages of medical devices in the context of a public health emergency and to provide the Agency with a mandate to host the expert panels on medical devices. This would allow for long-term sustainability for the functioning of the panels and provide clear synergies with related crisis preparedness work for medicinal products. Those structures would in no way change the regulatory system or the decision-making procedures in the area of medical devices already in place in the Union, which should remain clearly distinct from the one for medicinal products.	**Amendment 30** (24) Given the Agency's long-standing and proven record of expertise in the field of medicinal products and considering the Agency's experience from working with a multitude of groups of experts, it is appropriate to establish the appropriate structures within the Agency to monitor potential shortages of medical devices in the context of a public health emergency and to provide the Agency with a mandate to host the expert panels on medical devices. ***In light of this, all national and, eventually, Union entities engaged in stockpiling of medical devices, should report their stocks to the Agency.*** This would allow for long-term sustainability for the functioning of the panels and provide clear synergies with related crisis preparedness work for medicinal products. Those structures would in no way change the regulatory system or the decision-making procedures in the area of medical devices already in place in the Union, which should remain clearly distinct from the one for medicinal products.	(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~~ ***suitable*** 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.	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
40	Recital 24a (new)			***(24a) To ensure a smooth transition to the Agency, the support for the expert panels should be provided by the Commission, until the 1 March 2022.***	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
41	Recital 25	(25) In order to facilitate the work and the exchange of information under this Regulation, provision should be made for the establishment and management of IT infrastructures and synergies with other existing IT systems or systems under development, including the EUDAMED IT platform for medical devices. That work should also be facilitated by, where appropriate, emerging digital technologies such as computational models and simulations for clinical trials, as well as data from the EU Space Programme such as the Galileo geolocation services, and Copernicus earth observation data.	**Amendment 31** (25) In order to facilitate the work and the exchange of information under this Regulation, provision should be made for the establishment and management of IT infrastructures and synergies with other existing IT systems or systems under development, including the EUDAMED IT platform for medical devices***, alongside enhanced protection of data infrastructure and deterrence from possible cyberattacks***. That work should also be facilitated by, where appropriate, emerging digital technologies such as computational models and simulations for clinical trials, as well as data from the EU Space Programme such as the Galileo geolocation services, and Copernicus earth observation data.	(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~~***and*** systems under development, including the ~~EUDAMED IT platform for~~***European data base on*** medical devices~~.~~ ***EUDAMED. In Eudamed, the European Medical Device Nomenclature (EMDN) system should help to gather relevant information on categorization of medical devices.*** That work should also be facilitated by, where appropriate, emerging digital technologies such as computational models and simulations for clinical trials, as well as data from the EU Space Programme such as the Galileo geolocation services, and Copernicus earth observation data. ***Double or multiple registrations should be avoided to the extent possible.***	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
42	Recital 26	(26) Rapid access and exchange of health data, including real world data i.e. health data generated outside of clinical studies, is essential to ensure effective management of public health emergencies and other major events. This Regulation should allow the Agency to use and facilitate such exchange and be part of the establishment and operation of the European Health Data Space infrastructure.	**Amendment 32** (26) Rapid access and exchange of health data, including real world data i.e. health data generated outside of clinical studies, is essential to ensure effective management of public health emergencies and other major events. This Regulation should allow the Agency to use and facilitate such exchange and be part of the establishment and operation of the European Health Data Space ***interoperable*** infrastructure***, taking advantage of all the potential of supercomputing, artificial intelligence and big data science to develop predicting models and take better and more timely-effective decisions, without compromising the privacy rights***.	(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.	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
43	Recital 26a (new)		**Amendment 33** ***(26a) In order to facilitate the reliable exchange of medicinal product information in a robust and consistent manner, identification of human medicinal products will be based on International Organization for Standardization (ISO) for the identification of medicinal products for human use (IDMP) standards.***		

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
44	Recital 26b (new)		**Amendment 34** ***(26b) The handling of sensitive data, crucial for dealing with potential public health emergencies, requires a high level of protection against cyber-attacks. Health care organisations have been also facing heightened cyber-security threats in the midst of the COVID-19 pandemic. The Agency itself has been the target of a cyber-attack that resulted in some of the unlawfully accessed documents related to COVID-19 medicines and vaccines belonging to third parties being leaked on the internet. There is therefore the need for the Agency to be equipped with a high level of security against cyber-attacks to ensure the normal functioning of the Agency at all times and especially during public health emergencies. To that end, the Agency should establish a plan to prevent, detect, mitigate and respond to cyber-attacks so that its operation is secured at all times, while preventing any illegal access to documentation held by the Agency.***		

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
45	Recital 26c (new)		**Amendment 35** ***(26c) Due to the sensitive nature of health data, the Agency should safeguard and guarantee its processing operations respect the data protection principles of lawfulness, fairness and transparency, purpose limitation, data minimisation, accuracy, storage limitation, integrity and confidentiality. Where it is necessary for the purposes of this Regulation to process personal data, this should be done in accordance with Union law on the protection of personal data. Any processing of personal data based on this Regulation should take place in accordance with Regulations (EU) 2016/679[1a] and (EU) 2018/1725[1b]of the European Parliament and of the Council*** ***[1a] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free***		

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
45 continued			***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).***		

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
46	Recital 26d (new)		**Amendment 36** ***(26d) It is imperative to have in place robust transparency measures and standards regarding the Agency's regulatory activities on medicinal products and medical devices falling under the scope of this Regulation. Those measures should include timely publication of all relevant information on approved products and clinical data, including full clinical trial protocols. The Agency should apply high degree of transparency on the membership, recommendations, opinions and decisions of the newly established Steering Groups and the Emergency Task Force. Members of the Steering Groups and the Emergency Task Force should have no financial or other interests in the pharmaceutical or medical device industry which could affect their impartiality.***		

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
47	Recital 26e (new)		**Amendment 37** ***(26e) Credibility of the Agency and public trust in its decisions relies on a high degree of transparency. Therefore, proactive engagement of adequate communication tools with the general public should be foreseen. In addition, strengthened and accelerated transparency standards and measures regarding the Agency's working bodies and clinical data assessed for the evaluation and surveillance of medicinal products and medical devices are paramount to gain and upheld public trust. This Regulation establishes a framework for those strengthened transparency standards and measures, based on the Agency's efforts, standards and measures put in place during the COVID-19 pandemic.***		

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
48	Recital 27	(27) During a public health emergency or in relation to a major event, the Agency should ensure cooperation with the European Centre for Disease Prevention and Control and other Union Agencies as appropriate. Such cooperation should include data sharing, including data on epidemiological forecasting, regular communication at an executive level, and invitations to representatives of the European Centre for Disease Prevention and Control and other Union Agencies to attend meetings of the Emergency Task Force, the Medicines Steering Group, and the Medical Devices Steering Group, as appropriate.	**Amendment 38** (27) During a public health emergency or in relation to a major event, the Agency should ensure cooperation with the European Centre for Disease Prevention and Control and other Union Agencies as appropriate. Such cooperation should include data sharing, including data on epidemiological forecasting, regular communication at an executive level, and invitations to representatives of the European Centre for Disease Prevention and Control and other Union Agencies to attend meetings of the Emergency Task Force, the Medicines Steering Group, and the Medical Devices Steering Group, as appropriate. ***This cooperation should also include strategic discussions with relevant entities of the Union in a position to boost the research and development of appropriate solutions and technologies to mitigate the effects of the public health emergency or major event, or prevent future similar public health emergencies or major events, such as the proposed HERA.***	(27) During a public health emergency or in relation to a major event, the Agency should ensure cooperation with the European Centre for Disease Prevention and Control and other Union Agencies as appropriate. Such cooperation should include data sharing, including data on epidemiological forecasting, regular communication at an executive level, and invitations to representatives of the European Centre for Disease Prevention and Control and other Union Agencies to attend meetings of the Emergency Task Force, the Medicines ***Shortages*** Steering Group, and the Medical Devices ***Shortages*** Steering Group, as appropriate.	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
49	Recital 27a (new)		**Amendment 39** ***(27a) During a public health emergency or in relation to a major event, the Agency should enable regular exchanges of information with the industry, relevant actors of the pharmaceutical supply chain, representatives of healthcare professionals, patients and consumers, to guarantee early discussions on potential drug shortages in the market and supply constraints, so as to allow better coordination and synergies to mitigate and respond to the public health emergency or the major event.***		
50	Recital 27b (new)		**Amendment 40** ***(27b) Taking into account that the COVID-19 pandemic has not come to an end, and that the duration and evolution of health crises, such as pandemics, are uncertain, provision should be made for a review of the effectiveness of the functioning of the structures and mechanisms established in accordance with this Regulation. In light of that review, the structures and mechanisms should be amended, if appropriate.***		

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
51	Recital 28	(28) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States alone due to the cross-border dimension of public health emergencies and major events and can, therefore, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.		(28) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States alone due to the cross-border dimension of public health emergencies and major events and can, therefore, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.	
52	Recital 29	(29) In order to ensure that sufficient resources are available for the work provided for under this Regulation, expenditure of the Agency should be covered by the contribution from the Union to the Agency's revenue.	**Amendment 41** (29) In order to ensure that sufficient resources***, including appropriate staffing and adequate expertise,*** are available for the work provided for under this Regulation, expenditure of the Agency should be covered by the contribution from the Union to the Agency's revenue.	(29) In order to ensure that sufficient resources are available for the work provided for under this Regulation, expenditure of the Agency should be covered by the contribution from the Union to the Agency's revenue. ***This expenditure should cover activities of Members States' representatives and experts in the Medicines Shortages and Medical Devices Shortages Steering Groups, the Emergency Task Force and their working parties under this Regulation.***	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
53	Recital 29a (new)			***(29a) Moreover, the EU4Health programme is a tool to provide additional support to national competent authorities in the area of shortages, including through the implementation of actions to mitigate shortages of medicines and improve the security of supply. Under the EU4Health programme Member States may request financial support from the Union in accordance with the EU4Health Regulation (EU) 2021/522, specifically in view of the implementation of their obligations set out in Articles 11 and 25 of this Regulation.***	
54	Recital 30	(30) The European Data Protection Supervisor has been consulted in accordance with Article 42(1) of Regulation (EU) No 2018/1725 and has adopted an opinion.		(30) The European Data Protection Supervisor has been consulted in accordance with Article 42(1) of Regulation (EU) No 2018/1725 and has adopted an opinion.	

DRAFT

Item	Citation / Recital Number	Commission text (2020/0321 (COD))	EP amendments voted on 8 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
55	Recital 31	(31) In accordance with Article 168(7) of the Treaty, this Regulation fully respects the responsibilities of the Member States for the definition of their public health policy and for the organisation and delivery of health services and medical care as well as the fundamental rights and principles recognised by the Charter of Fundamental Rights of the European Union including the protection of personal data,		(31) In accordance with Article 168(7) of the Treaty, this Regulation fully respects the responsibilities of the Member States for the definition of their public health policy and for the organisation and delivery of health services and medical care as well as the fundamental rights and principles recognised by the Charter of Fundamental Rights of the European Union including the protection of personal data,	
56		HAVE ADOPTED THIS REGULATION:		HAVE ADOPTED THIS REGULATION:	

DRAFT

Articles

This Annex contains the Articles in the Proposal for a Regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. For explanations of layout and fonts see Annex A.

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
57	Chapter I	**Chapter I** **General Provisions**		**Chapter I** **General Provisions**	
58	Article 1 Article 1 – paragraph 1 Article 1 – paragraph 1 – point a	*Article 1* *Subject Matter* This Regulation provides for, within the European Medicines Agency ('the Agency'), a framework for and the means to: (a) prepare for and manage the impact of major events on medicinal products for human use and of public health emergencies on medicinal products for human use and on medical devices;	**Amendment 42** (a) ***prevent,*** prepare for***, coordinate*** and manage ***at Union level*** the impact of major events on medicinal products for human use and of public health emergencies on medicinal products for human use and on medical devices;	*Article 1* *Subject Matter* This Regulation provides for, within the European Medicines Agency ('the Agency'), a framework for and the means to: (a) prepare for and manage the impact of major events on medicinal products for human use and of public health emergencies on medicinal products for human use and on medical devices;	This Regulation provides for, within the European Medicines Agency ('the Agency'), a framework for and the means to:

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
58 continued	Article 1 – paragraph 1 – point b	(b) monitor and report on shortages of medicinal products for human use and medical devices;	**Amendment 43** (b) ***prevent,*** monitor and report on shortages of medicinal products for human use and ***critical*** medical devices;	(b) monitor and report on shortages of medicinal products for human use, and medical devices;	
	Article 1 – paragraph 1 – point b a (new)		**Amendment 44** ***(ba) set up an interoperable and digital database at Union level to monitor and report on shortages of medicinal products;***		***(ba) set up an interoperable and digital database at Union level to monitor and report on shortages of medicinal products;***
	Article 1 – paragraph 1 – point c	(c) provide advice on medicinal products for human use with the potential to address public health emergencies;		(c) provide advice on medicinal products for human use with the potential to address public health emergencies;	c) provide advice on medicinal products for human use with the potential to address public health emergencies;
	Article 1 – paragraph 1 – point d	(d) provide support for the expert panels designated in accordance with Implementing Decision (EU) 2019/1396.		(d) provide ***administrative*** support for the expert panels designated in accordance with ~~Implementing Decision~~***Article 106(1) of Regulation*** (EU) ~~2019/1396~~***2017/745***.	d) provide ~~***administrative***~~ support for the expert panels designated in accordance with ~~Implementing Decision~~***Article 106(1) of Regulation*** (EU) ~~2019/1396~~***2017/745***.
59	Article 2	*Article 2* *Definitions*		*Article 2* *Definitions*	
	Article 2 – paragraph 1	For the purposes of this Regulation, the following definitions shall apply:		***1.*** For the purposes of this Regulation, the following definitions shall apply:	***1.*** For the purposes of this Regulation, the following definitions shall apply:
	Article 2 – paragraph 1 – point a	(a) *'public health emergency'* means a public health emergency at Union level recognised by the European Commission in accordance with Article 23(1) of Regulation (EU) 2020/[…];		(a) *'public health emergency'* means a public health emergency at Union level recognised by the European Commission in accordance with Article 23(1) of Regulation (EU) 2020/[…];	(a) *'public health emergency'* means a public health emergency at Union level recognised by the European Commission in accordance with Article 23(1) of Regulation (EU) 2020/[…];

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
59 continued	Article 2 – paragraph 1 – point b	(b) *'medicinal product'* means a medicinal product as defined in point (2) of Article 1 of Directive 2001/83/EC of the European Parliament and of the Council;		(b) *'medicinal product'* means a medicinal product as defined in point (2) of Article 1 of Directive 2001/83/EC of the European Parliament and of the Council;	(b) *'medicinal product'* means a medicinal product as defined in point (2) of Article 1 of Directive 2001/83/EC of the European Parliament and of the Council;
	Article 2 – paragraph 1 – point b a (new)		**Amendment 45** ***(ba) 'veterinary medicinal product' means a veterinary medicinal product as defined in point (1) of Article 4 of Regulation(EU) 2019/6 of the European Parliament and the Council[1a];*** ***[1a] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).***		***(ba) 'veterinary medicinal product' means a veterinary medicinal product as defined in point (1) of Article 4 of Regulation(EU) 2019/6 of the European Parliament and the Council[1a];***
	Article 2 – paragraph 1 – point c	(c) *'medical device'* means both a medical device as defined in point (1) of Article 2 of Regulation (EU) 2017/745, read in conjunction with point (a) of Article 1(6) of that Regulation, and an *in vitro* diagnostic medical device as defined in point (2) of Article 2 of Regulation (EU) 2017/746;		(c) *'medical device'* means ~~both~~ a medical device as defined in point (1) of Article 2 of Regulation (EU) 2017/745~~, read in conjunction with point (a) of Article 1(6) of that Regulation, and an *in vitro* diagnostic medical device as defined in point (2) of Article 2 of Regulation (EU) 2017/746~~;	(c) *'medical device'* means ~~both~~ a medical device as defined in point (1) of Article 2 of Regulation (EU) 2017/745~~, read in conjunction with point (a) of Article 1(6) of that Regulation, and an *in vitro* diagnostic medical device as defined in point (2) of Article 2 of Regulation (EU) 2017/746~~;

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
59 continued	Article 2 – paragraph 1 – point c a (EP) (new)		**Amendment 46** ***(ca) 'supply' refers to the total volume of stock of an individual medicinal product or medical device that is placed on the market by a marketing authorisation holder or a manufacturer;***		***(ca) 'supply' refers to the total volume of stock of an individual medicinal product or medical device that is placed on the market by a marketing authorisation holder or the manufacturer;***
	Article 2 – paragraph 1 – point c a (Council) (new)			***(ca) 'accessory' for a medical device means an accessory as defined in point (2) of Article 2 of Regulation (EU) 2017/745 and for an in vitro medical device means accessory as defined in point (4) of Article 2 of regulation (EU) 2017/746;***	***(ca) 'accessory' for a medical device means an accessory as defined in point (2) of Article 2 of Regulation (EU) 2017/745 and for an in vitro medical device means accessory as defined in point (4) of Article 2 of regulation (EU) 2017/746;***
	Article 2 – paragraph 1 – point c b (EP) (new)		**Amendment 47** ***(cb) 'demand' relates to the request for a medicinal product or a medical device by a healthcare professional or patient in response to a clinical need. For demand to be satisfactorily met, the medicinal product or the medical device will need to be acquired in time and sufficient quantity to allow continuity of best care of patients. Wholesalers are usually***		***(cb) 'demand' relates to the request for a medicinal product or a medical device by a healthcare professional or patient in response to a clinical need. For the demand to be satisfactorily met,*** *the legal business entities responsible for market supply should provide the required amounts of medicinal products and medical devices at the appropriate time* ***to allow continuity of best care of patients.*** ~~***For demand to be satisfactorily met, the medicinal product or the medical device will need to be acquired in time and sufficient quantity to allow continuity of best care of patients. Wholesalers are usually a key supply link between***~~

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
			a key supply link between marketing authorisation holders or manufacturers and the users of medicinal products or medical devices, respectively, and in those cases, in order to estimate demand, the quantity requested in wholesale orders should be considered;		~~***marketing authorisation holders or manufacturers and the users of medicinal products or medical devices, respectively, and in those cases, in order to estimate demand, the quantity requested in wholesale orders should be considered;***~~
	Article 2 – paragraph 1 – point c b Council (new)			***(cb) 'in vitro diagnostic medical device' means an in vitro diagnostic medical device as defined in point (2) of Article 2 of Regulation (EU) 2017/746;***	***(cb) 'in vitro diagnostic medical device' means an in vitro diagnostic medical device as defined in point (2) of Article 2 of Regulation (EU) 2017/746;***
	Article 2 – paragraph 1 – point d	(d) *'shortage'* means that supply of a medicinal product for human use or a medical device does not meet demand for that medicinal product or medical device;	**Amendment 48** (d) 'shortage' means that supply of a medicinal product for human use or a medical device does not meet demand for that medicinal product or medical device ***at a national level, whatever the cause***;	(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;	

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
59 continued	Article 2 – paragraph 1 – point e Article 2 – paragraph 1 – point f	(e) *'developer'* means any legal or natural person seeking to generate scientific data with regard to the quality, safety and efficacy of a medicinal product as part of that product's development; (f) *'major event'* means an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State. Such an event concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin or incident that can affect the supply or quality, safety, and efficacy of medicinal products. Such an event may lead to shortages of medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection.	**Amendment 49** (f) 'major event' means an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State. Such an event concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin or incident that can affect the ***manufacturing,*** supply***, demand*** or quality, safety, and efficacy of medicinal products. Such an event may lead to shortages of medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection. ***Recurrent problems of supply of medicinal products are excluded from the scope of this definition.***	(e) *'developer'* means any legal or natural person seeking to generate scientific data with regard to the quality, safety and efficacy of a medicinal product as part of that product's development; (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~~***States***. Such an event concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin or incident that can affect the supply or quality, safety, and efficacy of medicinal products. Such an event may lead to shortages of medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection.	

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
59 continued	Article 2 – paragraph 2 (new)			***2. For the purposes of this Regulation, references to "medical devices" and "in vitro medical devices" shall be understood as covering the medical devices and the in vitro medical devicesand their accessories in the meaning of paragraph 1.***	***2. For the purposes of this Regulation, references to "medical devices" and "in vitro medical devices" shall be understood as covering the medical devices and the in vitro medical devicesand their accessories in the meaning of paragraph 1.***
60	Chapter II	**Chapter II** **Monitoring and mitigating shortages of critical medicinal products and management of major events**		**Chapter II** **Monitoring and mitigating shortages of critical medicinal products and management of major events**	
61	Article 3	*Article 3* *The Executive Steering Group on Shortages and Safety of Medicinal Products*		*Article 3* *"The Executive Steering Group on Shortages and Safety of Medicinal Products*	

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
61 continued	Article 3 – paragraph 1	1. The Executive Steering Group on Shortages and Safety of Medicinal Products ('the Medicines Steering Group') is hereby established as part of the Agency. It shall meet either in person or remotely, in preparation for or during a public health emergency or following a request for assistance referred to in Article 4(3). The Agency shall provide its secretariat.	**Amendment 50** 1. The Executive Steering Group on Shortages and Safety of Medicinal Products ('the Medicines Steering Group') is hereby established as part of the Agency. It shall meet ***at regular intervals*** either in person or remotely***, and whenever the situation requires***, in preparation for or during a public health emergency or following a request for assistance referred to in Article 4(3). The Agency shall provide its secretariat.	1. The Executive Steering Group on Shortages and Safety of Medicinal Products ('the Medicines ***Shortages*** 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 ***Shortages*** Steering Group') is hereby established as part of the Agency. It shall meet *regularly and in addition,* ***whenever the situation requires,*** 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.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
61 continued	Article 3 – paragraph 2	2. The Medicines Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields.	**Amendment 51** 2. The Medicines Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one ***authorised*** senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields. ***The Medicines Steering Group shall also include a representative of the Agency's Patients' and Consumers' Working Party (PCWP) and a representative of the Agency's Healthcare Professionals' Working Party (HCPWP) as observers. The list of the members of the Medicines Steering Group shall be transparent and made public on the Agency's web-portal.***	2. The Medicines ***Shortages*** Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one ~~senior~~ representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields.	2. The Medicines ***Shortages*** Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one ~~senior~~ *appointed* representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields. ~~*The Medicines Steering Group shall also include a representative of the Agency's Patients' and Consumers' Working Party (PCWP) and a representative of the Agency's Healthcare Professionals' Working Party (HCPWP) as observers.*~~ *Representatives of the Agency's Patients' and Consumers' Working Party (PCWP) and a representative of the Agency's Healthcare Professionals' Working Party (HCPWP) may also attend as observers.* ***The list of the members of the Medicines Steering Group shall be transparent and made public on the Agency's web-portal.***

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
61 continued	Article 3 – paragraph 3	3. The Medicines Steering Group shall be chaired by the Agency. The Chair ***may*** invite third parties, including representatives of medicinal product interest groups ***and*** marketing authorisation holders to attend its meetings.	**Amendment 52** 3. The Medicines Steering Group shall be chaired by the Agency. ***Any member of the Medicines Steering Group may propose to*** the Chair ***to*** invite third parties, including representatives of medicinal product interest groups***,*** marketing authorisation holders***, wholesale distributors, or any other appropriate actor in the pharmaceutical supply chain, representatives of healthcare professionals, patients and consumers*** to attend its meetings ***when their contribution may inform the discussions of the Medicines Steering Group***.	3. The Medicines ***Shortages*** Steering Group shall be ***Co-***chaired by the Agency~~.~~ ***and by a representative of a Member State elected by and amongst its members.*** The ~~Chair may~~***Co-Chairs*** invite***, as necessary, representatives of national competent authorities for medicinal products for veterinary use, representatives of other relevant competent authorities and other*** third parties, including representatives of ~~medicinal product~~ interest groups and marketing authorisation holders ***for medicinal products for human and veterinary use*** to attend its meetings. The ***Members of the*** *Medicines* ***Shortages Steering Group may request the Chair to invite third parties to attend its meetings.***	3. The Medicines ***Shortages*** Steering Group shall be ***co-***chaired by the Agency ***and by a representative of a Member State elected by and amongst its members.*** The ~~Chair may~~ ***co-chairs*** *may, on their own initiative or following a request from one or more members, invite, as observers and to provide expert advice* ***representatives of national competent authorities for medicinal products for veterinary use, representatives of other relevant competent authorities and*** third parties, including representatives of medicinal product interest groups***,*** marketing authorisation holders***, wholesale distributors, any other appropriate actor in the pharmaceutical supply chain, representatives of healthcare professionals and patients and consumers,*** to attend its meetings***, as necessary***.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
61 continued					*See new recital* *In order to ensure the inclusivity and transparency of the work of the Medicines Shortages Steering Group, appropriate engagement with relevant third parties, including representatives of medicinal product interest groups, marketing authorisation holders, wholesale distributors, any other appropriate actor in the pharmaceutical supply chain, representatives of healthcare professionals and patients and consumers, needs to be ensured.*
61 continued	Article 3 – paragraph 3 a (new)		**Amendment 53** ***3a. The Medicines Steering Group shall guarantee an open communication and close cooperation with marketing authorisation holders, manufacturers, relevant actors of the pharmaceutical supply chain, and representatives of healthcare professionals, patients and consumers with a view to enabling early notification or identification of potential or actual shortages of medicinal products considered as critical during a major event or a public health emergency as provided for in Article 6.***		***3a. The Medicines** Shortages **Steering Group shall, in coordination with the national competent authorities, facilitate appropriate communication with marketing authorisation holders or their representatives, manufacturers, other relevant actors of the pharmaceutical supply chain, and representatives of healthcare professionals and patients and consumers with a view to receiving relevant information on potential or actual shortages of medicinal products considered as critical during a major event or a public health emergency as provided for in Article 6.***

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
61 continued	Article 3 – paragraph 4	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.		4. The Medicines ***Shortages*** 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.	4. The Medicines ***Shortages*** 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.
	Article 3 – paragraph 5	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 ***Shortages*** 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 ***Shortages*** 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).
	Article 3 – paragraph 6	6. The Medicines Steering Group shall be responsible for fulfilling the tasks referred to in Article 4(4) and Articles 5 to 8.	**Amendment 54** 6. The Medicines Steering Group shall be responsible for fulfilling the tasks referred to in Article ***4(3) and*** (4) and Articles 5 to 8.	6. The Medicines ***Shortages*** Steering Group shall be responsible for fulfilling the tasks referred to in Article 4(4) and Articles 5 to 8.	6. The Medicines ***Shortages*** Steering Group shall be responsible for fulfilling the tasks referred to in ***Article 4(3),*** Article 4(4) and Articles 5 to 8.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
61 continued	Article 3 – paragraph 6a (new)		**Amendment 55** ***6a. The Medicines Steering Group may consult with the Committee for Medicinal Products for Veterinary Use whenever it deems it necessary to deal with public health emergencies and major events related to zoonoses or diseases affecting only animals that have or may have a major impact on human health.***		***6a. The Medicines** Shortages **Steering Group may consult with the Committee for Medicinal Products for Veterinary Use whenever it deems it necessary to deal with public health emergencies and major events related to zoonoses or diseases affecting only animals that have or may have a major impact on human health.***

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
61 continued	Article 3 – paragraph 6b (new)		**Amendment 56** ***6b. Members of the Medicines Steering Group shall not have financial or other interests in the pharmaceutical industry that could affect their impartiality. They shall act in the public interest and in an independent manner and make an annual declaration of their financial interests and update it whenever a relevant change occurs. All indirect interests which could relate to the pharmaceutical industry shall be entered in a register held by the Agency and upon request shall be accessible to the public. The declaration of interests shall be made publicly available on the Agency's web-portal.***		*6b. The Medicines Shortages Steering Group and the Medical Devices Shortages Steering Group shall carry out their activities in an independent, impartial and transparent manner. The members appointed to the Medicines Shortages Steering Group and the Medical Devices Shortages Steering Group and, where relevant, observers, shall not have any financial or other interests in the pharmaceutical or medical devices industry which could affect their independence or impartiality. The members appointed to the Medicines Shortages Steering Group and the Medical Devices Shortages Steering Group and, where relevant, observers shall make a declaration of their financial and other interests and update them annually and whenever necessary. The declaration of interests shall be made publicly available on the Agency's web-portal. They shall disclose any other facts of which they become aware that might in good faith reasonably be expected to involve, or give rise to, a conflict of interest.*

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
61 continued					*The members appointed to the Medicines Shortages Steering Group and the Medical Devices Shortages Steering Group and, where relevant, observers, who participate in meetings of the Medicines Shortages Steering Group and the Medical Devices Shortages Steering Group shall declare, before each meeting, any interests which could be considered to be prejudicial to their independence or impartiality with respect to the items on the agenda. Where the Agency decides that a declared interest constitutes a conflict of interest, that member or observer shall not take part in any discussions or decision-making, or obtain any information concerning that item of the agenda. Such declarations of members or observers and the decisions of the Agency shall be recorded in the summary minutes of the meeting. The members appointed to the Medicines Shortages Steering Group and the Medical Devices Shortages Steering Group and, where relevant, observers shall, even after their duties have ceased, be subject to a requirement of professional secrecy.*

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
62	Article 4 Article 4 – paragraph 1	*Article 4* *Monitoring of events and preparedness for major events and public health emergencies* 1. The Agency shall continuously monitor any event that is likely to lead to a major event or a public health emergency.	**Amendment 57** 1. The Agency shall continuously monitor any event that is likely to lead to a major event or a public health emergency ***in coordination with the national competent authorities***. ***In that regard, the Agency shall cooperate closely with the European Centre for Disease Prevention and Control (ECDC) and other Union agencies, where relevant.***	*Article 4* *Monitoring of events and preparedness for major events and public health emergencies* 1. The Agency***, in collaboration with Member States,*** shall continuously monitor any event ***related to medicinal products*** that is likely to lead to a major event or a public health emergency. ***As necessary, the Agency may seek the support of the ECDC.***	1. The Agency***, in collaboration with Member States,*** shall continuously monitor any event that is likely to lead to a major event or a public health emergency. *As necessary, the Agency shall cooperate with European Centre for Disease Prevention and Control (ECDC) and other Union agencies, where relevant.*

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
62 continued	Article 4 – paragraph 2	2. To facilitate the monitoring task referred to in paragraph 1, the national competent authorities, through the single points of contact referred to in Article 3(5), shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report to the Agency on any event, including a shortage of a medicinal product in a given Member State, that is likely to lead to a major event or a public health emergency. Where a national competent authority informs the Agency of a shortage of a medicinal product in a given Member State, it shall provide the Agency with any information received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC. Based on a report of an event from a national competent authority and in order to understand the impact of the event in other Member States, the	**Amendment 58** 2. To facilitate the monitoring task referred to in paragraph 1, the national competent authorities, through the single points of contact referred to in Article 3(5) ***or the database referred to in Article 12a, once fully functional***, shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report ***without delay*** to the Agency on any event, including a shortage of a medicinal product in a given Member State, that is likely to lead to a major event or a public health emergency. Where a national competent authority informs the Agency of a shortage of a medicinal product in a given Member State, it shall provide the Agency with any information received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC. Based on a report of an event from a national competent authority and in order to understand the impact of the event in other Member States, the	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 ***related to medicinal products***, 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	2. To facilitate the monitoring task referred to in paragraph 1, the national competent authorities, through the single points of contact referred to in Article 3(5), ***or the database referred to in Article 12a, once fully functional*** shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report *in a timely manner* to the Agency on any event, including a shortage of a medicinal product in a given Member State, that is likely to lead to a major event or a public health emergency. Where a national competent authority informs the Agency of *such* 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

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
62 continued	Article 4 – paragraph 3	Agency may request information from the national competent authorities, through the working party referred to in Article 3(5). 3. Where the Agency considers that an actual or imminent major event needs to be addressed, it shall inform the Commission and the Member States thereof. The Commission, on its own initiative or following a request from one or more Member States, or the Executive Director of the Agency ***may*** request the assistance of the Medicines Steering Group to ***address*** the major event.	Agency may request information from the national competent authorities, through the working party referred to in Article 3(5). **Amendment 59** 3. Where the Agency considers that an actual or imminent major event needs to be addressed, it shall inform the Commission and the Member States thereof. The Commission, on its own initiative or following a request from one or more Member States, or the Executive Director of the Agency ***shall then*** request the assistance of the Medicines Steering Group to ***analyse the available information. Based on the analysis of the information, the Medicines Steering Group may propose to the Commission to formally recognise*** the major event ***and, pursuant to Article 5, it shall provide recommendations to address such an event***.	Agency may request information from the national competent authorities, through the working party referred to in Article 3(5). 3. Where the Agency considers that an actual or imminent major event needs to be addressed, it shall ~~inform~~***raise the issue of concern to*** the Commission and the Member States ~~thereof~~***for confirmation of the major event and trigger the actions foreseen in this Regulation***. The Commission, on its own initiative or following a request from one or more Member States, or the Executive Director of the Agency may request the assistance of the Medicines ***Shortages*** Steering Group to address the major event.	Agency may request information from the national competent authorities, through the working party referred to in Article 3(5).

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
62 continued	Article 4 – paragraph 4	4. The Medicines Steering Group shall inform the Commission and the Executive Director of the Agency, once it considers that the major event has been sufficiently addressed. On the basis of that information or on its own initiative, the Commission or the Executive Director may confirm that the assistance of the Medicines Steering Group is no longer needed.		4. The Medicines ***Shortages*** Steering Group shall inform the Commission and the Executive Director of the Agency, once it considers that the major event has been sufficiently addressed. On the basis of that information or on its own initiative, the Commission or the Executive Director may confirm that the assistance of the Medicines ***Shortages*** Steering Group is no longer needed.	4. The Medicines ***Shortages*** Steering Group shall inform the Commission and the Executive Director of the Agency, once it considers that the major event has been sufficiently addressed. On the basis of that information or on its own initiative, the Commission or the Executive Director may confirm that the assistance of the Medicines ***Shortages*** Steering Group is no longer needed.
	Article 4 – paragraph 5	5. In the case of a major event or public health emergency, Articles 5 to 12 shall apply as follows:		5. In the case of a major event or public health emergency, Articles 5 to 12 shall apply as follows:	5. In the case of a major event or public health emergency, Articles 5 to 12 shall apply as follows:
	Article 4 – paragraph 5 – point a	(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 safety, quality, and efficacy of medicinal products, Article 5 shall apply;	(a) where the major event or public health emergency may affect the safety, quality, and efficacy of medicinal products, Article 5 shall apply;
	Article 4 – paragraph 5 – point b	(b) where the major event or public health emergency may lead to shortages of medicinal products in more than one Member State, Articles 6 to 12 shall apply.		(b) where the major event or public health emergency may lead to shortages of medicinal products in more than one Member State, Articles 6 to 12 shall apply.	(b) where the major event or public health emergency may lead to shortages of medicinal products in more than one Member State, Articles 6 to 12 shall apply.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
63	Article 5 Article 5 – paragraph 1	*Article 5* *Evaluation of information and the provision of advice on action in relation to the safety, quality, and efficacy of medicinal products related to public health emergencies and major events* 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.		*Article 5* *Evaluation of information and the provision of advice on action in relation to the safety, quality, and efficacy of medicinal products related to public health emergencies and major events* Following the recognition of a public health emergency or a request for assistance referred to in Article 4(3), the Medicines ***Shortages*** 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 ***Shortages*** 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.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
63 continued	Article 5 – paragraph 2	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.	**Amendment 60** The Medicines Steering Group shall provide advice ***and recommendations*** to the Commission and Member States on any appropriate action it believes should be taken at Union level on the medicinal products concerned in accordance with the provisions of Directive 2001/83/EC or Regulation (EC) No 726/2004.[18] [18] Regulation (EC) No 726/2004	The Medicines ***Shortages*** 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.	The Medicines ***Shortages*** Steering Group shall provide **[…]** ***recommendations*** to the Commission and Member States on any appropriate action it believes should be taken at Union level on the medicinal products concerned in accordance with the provisions of Directive 2001/83/EC or Regulation (EC) No 726/2004. Recital *It is understood that all recommendations, advice, guidance and opinions mentioned in this Regulation are inherently non-binding. Any of these acts allow the Commission, the Agency, the Steering Groups and the ETF to make their views known and to suggest a line of action without imposing any legal obligation on those to whom those acts are addressed*

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
63 continued	Article 5 – paragraph 2a (new)		**Amendment 61** ***The Commission and Member States shall provide a substantiated justification in the event that the recommendations provided by the Medicines Steering Group are not taken into account. The recommendations provided by the Medicines Steering Group, as well as any substantiated justifications provided by the Commission and Member States, shall be made publicly available via the web-portal as referred to in Article 13.***		
	Article 5 – paragraph 2b (new)		**Amendment 62** ***Where a link is established with zoonoses or diseases affecting only animals that have or may have a major impact on human health or where the use of active ingredients of veterinary medicinal products may be useful to address the public health emergency or the major event, or otherwise whenever necessary, the Medicines Steering Group may liaise with the Committee for Medicinal Products for Veterinary Use.***		*The Medicines Steering Group may consult with the Committee for Medicinal Products for Veterinary Use whenever it deems it necessary to deal with public health emergencies and major events related to zoonoses or diseases affecting only animals that have or may have a major impact on human health, or where the use of active ingredients of veterinary medicinal products may be useful to address the public health emergency or the major event, or otherwise whenever necessary.*

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
64	Article 6 Article 6 – paragraph 0 (new)	*Article 6* *Lists of critical medicinal products and information to be provided*		*Article 6* *Lists of critical medicinal products and information to be provided* ***0. Without prejudice to paragraph 2, the Medicines Shortages Steering Group shall define the main therapeutic groups of medicinal products, for ensuring emergency care, surgeries and intensive care which may be adapted as necessary, with a view to respond to a public health emergency or major event.***	

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
64 continued	Article 6 – paragraph 1	1. Following a request for assistance referred to in Article 4(3) and after consultation of its working party, the Medicines Steering Group shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the major event ('the major event critical medicines list '). The list shall be updated whenever necessary until the major event has been sufficiently addressed.	**Amendment 63** 1. Following a request for assistance referred to in Article 4(3) and after consultation of its working party, the Medicines Steering Group shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the major event ('the major event critical medicines list '). The list shall be updated whenever necessary until the major event has been sufficiently addressed ***and it has been confirmed that the assistance of the Medicines Steering Group is no longer needed as referred to in Article 4(4) of this Regulation***.	1. Following a request for assistance referred to in Article 4(3) and after consultation of its working party, the Medicines ***Shortages*** 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 ***Shortages*** Steering Group shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the major event ('the major event critical medicines list '). The list shall be updated whenever necessary until the major event has been sufficiently addressed ***and it has been confirmed that the assistance of the Medicines*** *Shortages* ***Steering Group is no longer needed as referred to in Article 4(4) of this Regulation***.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
64 continued	Article 6 – paragraph 2	2. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medicines Steering Group shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the public health emergency ('the public health emergency critical medicines list'). The list shall be updated whenever necessary until the termination of the recognition of the public health emergency.	**Amendment 64** 2. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medicines Steering Group shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the public health emergency ('the public health emergency critical medicines list'). The list shall be updated whenever necessary until the termination of the recognition of the public health emergency. ***The list may be updated in accordance with the outcomes of the review process under Article 16 of this Regulation, where appropriate, for which the Medicines Steering Group shall liaise with the Emergency Task Force.***	2. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medicines ***Shortages*** 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 ***Shortages*** Steering Group shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the public health emergency ('the public health emergency critical medicines list'). The list shall be updated whenever necessary until the termination of the recognition of the public health emergency. ***The list may be updated in accordance with the outcomes of the review process under Article 16 of this Regulation, where appropriate, for which the Medicines*** *Shortages* ***Steering Group shall liaise with the Emergency Task Force.***

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
64 continued	Article 6 – paragraph 3	3. The Medicines Steering Group shall adopt a set of information necessary to monitor the supply and demand of medicinal products included on the lists referred to in paragraphs 1 and 2 ('the critical medicines lists') and inform its working party thereof.	**Amendment 65** 3. The Medicines Steering Group shall adopt a set of information ***and actions*** necessary to monitor the supply and demand of medicinal products included on the lists referred to in paragraphs 1 and 2 ('the critical medicines lists') and inform its working party thereof. ***Union or national entities that are engaged in stockpiling of medicinal products shall be informed accordingly. The Medicines Steering Group shall report to the Agency and to the Commission in due time on the monitoring and shall notify immediately on any major event or shortage in the supply.***	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 *Shortages* Steering Group shall adopt, *and make publically available* 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. ***The Medicines Steering Group shall report to the Agency and to the Commission*** ~~***in due time***~~ *in a timely manner* ***on the monitoring and shall notify immediately on any major event or shortage in the supply.***
	Article 6 – paragraph 4	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.	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.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
64 continued	Article 6 – paragraph 4 a (new)		**Amendment 66** ***4a. The Agency shall establish a publicly accessible webpage with information on actual shortages of critical medicinal products. Reference to national registries on medicinal products shortages shall also be included. The webpage shall contain information on, but not limited to:*** ***(a) trade name and international non-proprietary name;*** ***(b) indication;*** ***(b) indication;*** ***(c) reason for the shortage;*** ***(d) start and end dates;*** ***(e) Member States affected;*** ***(f) information for healthcare professionals and patients, including information on alternative treatments.***		***4a. The Agency shall establish a publicly accessible webpage with information on actual shortages of critical medicinal products****, where EMA has assessed the shortage and has provided recommendations to patients and healthcare professionals.****Reference to national registries on medicinal products shortages shall also be included. The webpage shall contain information on, but not limited to:*** ***(a) trade name and international non-proprietary name;*** ***(b) indication;*** ***(c) reason for the shortage;*** ***(d) start and end dates;*** ***(e) Member States affected;*** ***(f) information for healthcare professionals and patients,*** *including if alternative treatments are available.*

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
65	Article 7 Article 7 – paragraph 1	*Article 7* *Monitoring shortages of medicinal products on the critical medicines lists* On the basis of the critical medicines lists and the information and data provided in accordance with Articles 10 and 11, the Medicines Steering Group shall monitor supply and demand of medicinal products included on those lists with a view to identifying any potential or actual shortages of those medicinal products. As part of that monitoring, the Medicines Steering Group shall liaise, where relevant, with the Health Security Committee established in Article 4 of Regulation (EU) 2020/[…] and, in the case of a public health emergency, the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation.	**Amendment 67** On the basis of the critical medicines lists and the information and data provided in accordance with Articles 10 and 11***, and the database established in accordance with Article 12a, once fully functional***, the Medicines Steering Group shall monitor supply and demand of medicinal products included on those lists with a view to identifying any potential or actual shortages of those medicinal products. As part of that monitoring, the Medicines Steering Group shall liaise, where relevant, with the Health Security Committee established in Article 4 of Regulation (EU) 2020/[…][19] and, in the case of a public health emergency, the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation***, as well as with the ECDC***.	*Article 7* *Monitoring shortages of medicinal products on the critical medicines lists* ~~On~~***Following the recognition of a public health emergency or a request for assistance referred to in Article 4(3,) on*** the basis of the critical medicines lists and the information and data provided in accordance with Articles 10 and 11, the Medicines ***Shortages*** Steering Group shall monitor supply and demand of medicinal products included on those lists with a view to identifying any potential or actual shortages of those medicinal products. As part of that monitoring, the Medicines Steering Group shall liaise, where relevant, with the Health Security Committee established in Article 4 of Regulation (EU) 2020/[…] and, in the case of a public health emergency, the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation.	~~On~~***Following the recognition of a public health emergency or a request for assistance referred to in Article 4(3,) on*** the basis of the critical medicines lists and the information and data provided in accordance with Articles 10 and 11, ***and the database established in accordance with Article 12a, once fully functional***, the Medicines ***Shortages*** Steering Group shall monitor supply and demand of medicinal products included on those lists with a view to identifying any potential or actual shortages of those medicinal products. As part of that monitoring, the Medicines Steering Group shall liaise, where relevant, with the Health Security Committee established in Article 4 of Regulation (EU) 2020/[…] and, in the case of a public health emergency, the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation ***as well as with the ECDC***.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
66	Article 8 Article 8 – paragraph 1	*Article 8* *Reporting and recommendations on shortages of medicinal products* 1. For the duration of a public health emergency or following a request for assistance referred to in Article 4(3) and until its closure, the Medicines Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article 9(2), and, in particular, signal any potential or actual shortages of medicinal products included on the critical medicines lists.	**Amendment 68** 1. For the duration of a public health emergency or following a request for assistance referred to in Article 4(3) and until its closure, the Medicines Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article 9(2), and, in particular, signal any potential or actual shortages of medicinal products included on the critical medicines lists. ***Those reports may also be made available to other actors in the pharmaceutical supply chain, where relevant.***	*Article 8* *Reporting and recommendations on shortages of medicinal products* 1. For the duration of a public health emergency or following a request for assistance referred to in Article 4(3) and until its closure, the Medicines ***Shortages*** Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article 9(2), and, in particular, signal any potential or actual shortages of medicinal products included on the critical medicines lists.	1. For the duration of a public health emergency or following a request for assistance referred to in Article 4(3) and until its closure, the Medicines **Shortages** Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article 9(2), and, in particular, signal any potential or actual shortages of medicinal products included on the critical medicines lists *or any event that may lead to a major event.* ***Those reports may also be made available to other actors in the pharmaceutical supply chain, where relevant****, and in accordance with relevant competition rules.*

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
66 continued	Article 8 – paragraph 2	2. Where requested by the Commission or the sub-network referred to in Article 9(2), the Medicines Steering Group shall provide aggregated data and forecasts of demand to substantiate its findings. In that regard, the Medicines Steering Group shall liaise with the European Centre for Disease Prevention and Control to obtain epidemiological data to help forecast medicinal product needs, and with the Executive Steering Group on Shortages of Medical Devices referred to in Article 19 where medicinal products included on the critical medicines lists are administered with a medical device.	**Amendment 69** 2. Where requested by the Commission***, one or more national competent authorities*** or the sub-network referred to in Article 9(2), the Medicines Steering Group shall provide aggregated data and forecasts of demand to substantiate its findings. In that regard, the Medicines Steering Group shall ***use data from the database established in accordance with Article 12a, once fully functional, and shall*** liaise with the European Centre for Disease Prevention and Control to obtain epidemiological data***, models and development scenarios*** to help forecast medicinal product needs, and with the Executive Steering Group on Shortages of Medical Devices referred to in Article 19 where medicinal products included on the critical medicines lists are administered with a medical device. ***The aggregated data and forecasts of demand may also be made available to other actors in the***	2. Where requested by the Commission or the sub-network referred to in Article 9(2), the Medicines ***Shortages*** Steering Group shall provide aggregated data and forecasts of demand to substantiate its findings. In that regard, the Medicines ***Shortages*** 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.	

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
66 continued			***pharmaceutical supply chain, where relevant, with a view to better prevent or mitigate potential or actual shortages. The Medicines Steering Group shall also share its findings and conclusions with Union and national actors engaged with stockpiling of medicinal products and medical devices.***		***pharmaceutical supply chain,*** *in respect of competition rules.* ~~***where relevant, with a view to better prevent or mitigate potential or actual shortages. The Medicines Steering Group shall also share its findings and conclusions with Union and national actors engaged with stockpiling of medicinal products and medical devices.***~~
	Article 8 – paragraph 3	3. As part of that reporting, the Medicines Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, as relevant, with the Health Security Committee and, in the case of a public health emergency, the Advisory Committee on public health emergencies.	**Amendment 70** 3. As part of that reporting, the Medicines Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities***, including representatives of healthcare professionals and patient organisations,*** to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, as relevant, with the Health Security Committee and, in the case of a public health emergency, the Advisory Committee on public health emergencies.	3. As part of that reporting, the Medicines ***Shortages*** 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. ***Member States may request the Medicines Shortages Steering Group to provide recommendations on measures.*** 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 ***Shortages*** Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities, ***including representatives of healthcare professionals and patient organisations,*** to prevent or mitigate potential or actual shortages. ***Member States may request the Medicines Shortages Steering Group to provide recommendations on measures.*** 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.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
66 continued	Article 8 – paragraph 4	4. The Medicines Steering Group may, on its own initiative or upon request from the Commission, provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities to ensure preparedness to deal with potential or actual shortages of medicinal products caused by public health emergencies or major events.	**Amendment 71** 4. The Medicines Steering Group may, on its own initiative or upon request from the Commission, provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders***, representatives of healthcare professionals*** and other entities to ensure preparedness to deal with potential or actual shortages of medicinal products caused by public health emergencies or major events.	4. The Medicines ***Shortages*** 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.	4. The Medicines ***Shortages*** 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, ***representatives of healthcare professionals*** and other entities to ensure preparedness to deal with potential or actual shortages of medicinal products caused by public health emergencies or major events.
	Article 8 – paragraph 5	5. The Medicines Steering Group may upon request from the Commission coordinate measures, where relevant, between the national competent authorities, the marketing authorisation holders and other entities to prevent or mitigate potential or actual shortages in the context of a major event or public health emergency.	**Amendment 72** 5. The Medicines Steering Group may upon request from the Commission coordinate measures, where relevant, between the national competent authorities, the marketing authorisation holders and other entities***, including representatives of healthcare professionals and patient organisations,*** to prevent or mitigate potential or actual shortages in the context of a major event or public health emergency.	5. The Medicines ***Shortages*** 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 ***Shortages*** Steering Group may upon request from the Commission coordinate measures, where relevant, between the national competent authorities, the marketing authorisation holders and other entities, ***including representatives of healthcare professionals and patient organisations*** to prevent or mitigate potential or actual shortages in the context of a major event or public health emergency.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
66 continued	Article 8 – paragraph 5 a (new)		**Amendment 73** ***5a. Where the recommendations referred to in paragraphs 3 and 4 are not taken into account or are not implemented, the Commission, Member States and marketing authorisation holders shall provide, where appropriate, a substantiated justification.***		~~***5a. Where the recommendations referred to in paragraphs 3 and 4 are not taken into account or are not implemented, the Commission, Member States and marketing authorisation holders shall provide, where appropriate, a substantiated justification.***~~
67	Article 9 Article 9 – paragraph 1	*Article 9* *Working methods and provision of information on medicinal products* 1. In order to prepare for fulfilling the tasks referred to in Articles 4 to 8, the Agency shall:		*Article 9* *Working methods and provision of information on medicinal products* 1. In order to prepare for fulfilling the tasks referred to in Articles 4 to 8, the Agency, ***together with Member States,*** shall:	1. In order to prepare for fulfilling the tasks referred to in Articles 4 to 8, the Agency shall:

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
67 continued	Article 9 – paragraph 1 – point a	(a) specify the procedures for establishing the critical medicines lists;	**Amendment 74** (a) specify the procedures ***and criteria*** for establishing ***and reviewing*** the critical medicines lists***, ensuring adequate consultation with marketing authorisation holders and other relevant actors in the pharmaceutical supply chain as well as with healthcare professionals, consumers and patients***;	(a) specify the procedures for establishing the critical medicines lists;	(a) specify the procedures ***and criteria*** for establishing ***and reviewing*** the critical medicines lists. *Member States, healthcare professionals, patients, consumers, marketing authorisation holders and other relevant actors in the pharmaceutical supply chain may be consulted as necessary;*
	Article 9 – paragraph 1 – point b	(b) specify the methods of and criteria for the monitoring, data collection and reporting provided for in Articles 4, 7 and 8;	**Amendment 75** (b) specify the methods of and criteria for the monitoring, data collection and reporting provided for in Articles 4, 7 and 8 ***with a basic minimum data set***;	(b) specify the methods of and criteria for the monitoring, data collection and reporting provided for in Articles 4, 7 and 8;	(b) specify the methods of and criteria for the monitoring, data collection and reporting provided for in Articles 4, 7 and 8 ***with a basic minimum data set***;
	Article 9 – paragraph 1 – point c	(c) develop streamlined electronic monitoring and reporting systems;	**Amendment 76** (c) develop streamlined electronic monitoring and reporting systems ***in coordination with the national competent authorities until the database provided for in Article 12a is fully functional, based on harmonised data fields across Member States***;	(c) develop streamlined electronic monitoring and reporting systems ***facilitating the interoperability with other existing IT systems and systems under development***;	(c) develop streamlined electronic monitoring and reporting systems ***facilitating the interoperability with other existing IT systems and systems under development***;

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
67 continued	Article 9 – paragraph 1 – point d	(d) establish and maintain membership of the working party referred to in Article 3(5) comprised of single points of contacts from national competent authorities for medicinal products;		(d) establish and maintain membership of the working party referred to in Article 3(5) comprised of single points of contacts from national competent authorities for medicinal products;	d) establish and maintain membership of the working party referred to in Article 3(5) comprised of single points of contacts from national competent authorities for medicinal products
	Article 9 – paragraph 1 – point e	(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) 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) 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;
67 continued	Article 9 – paragraph 1 – point f	(f) specify the methods for the provision of recommendations, advice and coordination of measures provided for in Articles 5 and 8.		(f) specify the methods for the provision of recommendations, advice and coordination of measures provided for in Articles 5 and 8.	(f) specify the methods for the provision of recommendations, advice and coordination of measures provided for in Articles 5 and 8.
	Article 9 – paragraph 1 – point f a (new)		**Amendment 77** ***(fa) publish information referred to in points (a), (b) and (f) of this paragraph on its web-portal.***		***(fa) publish information referred to in points (a), (b) and (f) of this paragraph on*** *a dedicated space in* ***its web-portal.***
	Article 9 – paragraph 2	2. Following the recognition of a public health emergency or a request for assistance referred to in Article 4(3) the Agency shall:		2. Following the recognition of a public health emergency or a request for assistance referred to in Article 4(3) the Agency shall:	2. Following the recognition of a public health emergency or a request for assistance referred to in Article 4(3) the Agency shall:

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
67 continued	Article 9 – paragraph 2 – point a	(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 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 from marketing authorisation holders based on the medicinal products included on the critical medicines lists;
	Article 9 – paragraph 2 – point b	(b) request information from the points of contact included in the sub-network referred to in point (a) and set a deadline for its submission;	**Amendment 78** (b) request information***, including on the supply of the critical medicines lists,*** from the points of contact included in the sub-network referred to in point (a) and set a deadline for its submission ***if that information is not available in the database provided for in Article 12a***;	(b) request information from the points of contact included in the sub-network referred to in point (a) and set a deadline for its submission;	(b) request information***, including on the supply of*** *medicines in* ***the critical medicines lists,*** from the points of contact included in the sub-network referred to in point (a) and set a deadline for its submission ***if that information is not available in the database provided for in Article 12a***;
	Article 9 – paragraph 2 – point c	(c) request information from the single points of contact from Member States' national competent authorities based on the set of information agreed on by the Medicines Steering Group and set a deadline for its submission.	**Amendement 79** (c) request information from the single points of contact from Member States' national competent authorities based on the set of information agreed on by the Medicines Steering Group and set a deadline for its submission ***if that information is not available in the database provided for in Article 12a***.	(c) request information from the single points of contact from Member States' national competent authorities based on the set of information agreed on by the Medicines ***Shortages*** Steering Group and set a deadline for its submission.	c) request information from the single points of contact from Member States' national competent authorities based on the set of information agreed on by the Medicines ***Shortages*** Steering Group and set a deadline for its submission, ***if that information is not available in the database provided for in Article 12a***.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
67 continued	Article 9 – paragraph 3 Article 9 – paragraph 3 – point a Article 9 – paragraph 3 – point b Article 9 – paragraph 3 – point ba (new) Article 9 – paragraph 3 – point c Article 9 – paragraph 3 – point d	3. The information referred to in point (b) of paragraph 2 shall include at least: (a) the name of the marketing authorisation holder; (b) the name of the medicinal product; (c) the country of authorisation and marketing status in each Member State; (d) details of the potential or actual shortage such as actual or estimated start and end dates and suspected or known cause;	**Amendment 80** (d) details of the potential or actual shortage such as actual or estimated start and end dates and suspected or known cause ***as well as information on potential bottlenecks in the supply chain***;	3. The information referred to in point (b) of paragraph 2 shall include at least: (a) the name of the marketing authorisation holder; (b) the name of the medicinal product; ***(ba) Identification of active manufacturing sites of finished products and active substances;*** (c) the country of authorisation and marketing status in each Member State; (d) details of the potential or actual shortage such as actual or estimated start and end dates and suspected or known cause;	3. The information referred to in point (b) of paragraph 2 shall include at least: (a) the name of the marketing authorisation holder; (b) the name of the medicinal product; ***(ba) Identification of active manufacturing sites of finished products and active substances*** (d) details of the potential or actual shortage such as actual or estimated start and end dates and suspected or known cause ***as well as information on potential*** *vulnerability* ***in the supply chain***;

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
67 continued	Article 9 – paragraph 3 – point e	(e) sales and market share data;		(e) ***Data on stock levels,*** sales and market share ~~data~~;	(e) sales and market share data;
	Article 9 – paragraph 3 – point e a (new)		**Amendement 81** ***(ea) available stocks;***		***(ea) available stocks;***
	Article 9 – paragraph 3 – point e b (new)		**Amendment 82** ***(eb) quantities already delivered;***		***(eb) quantities already delivered;***
	Article 9 – paragraph 3 – point e c (new)		**Amendement 83** ***(ec) projected deliveries;***		***(ec) projected deliveries;***
	Article 9 – paragraph 3 – point f	(f) details of available alternative medicinal products;		(f) details of available alternative medicinal products;	(f) details of available alternative medicinal products;

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
67 continued	Article 9 – paragraph 3 – point g	(g) mitigation plans including production and supply capacity;	**Amendement 84** (g) ***prevention and*** mitigation plans including ***information on*** production and supply capacity***, production sites of the finished pharmaceutical product and of active pharmaceutical ingredients, potential alternative production sites or minimum stock levels, with a view to guarantee continued supply and prevent shortages of medicinal products included on the critical medicines lists.***	(g) mitigation plans including production and supply capacity;	(g) ***prevention and*** mitigation plans, *at least* including ***information on*** production and supply capacity***, production sites of the finished pharmaceutical product and of active pharmaceutical ingredients, potential alternative production sites or minimum stock levels; ~~with a view to guarantee continued supply and prevent shortages of medicinal products included on the critical medicines lists.~~***
	Article 9 – paragraph 3 – point h	***(h) information from the wholesale distributors and legal person entitled to supply the medicinal product to the public***	**Amendment 85** ***deleted***	(h) information from the wholesale distributors and legal person entitled to supply the medicinal product to the public.	

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
68	Article 10 Article 10 – paragraph 1	*Article 10* *Obligations on marketing authorisation holders* 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.		*Article 10* *Obligations on marketing authorisation holders* 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 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.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
68 continued	Article 10 – paragraph 2	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.	**Amendement 86** 2. Marketing authorisation holders of medicinal products authorised in the Union shall, within 6 months from the date of application of this Regulation, provide the information required pursuant to Article 9(1)(e) in the form of an electronic submission in the database referred to in Article 57(1)(l) of Regulation (EC) No 726/2004 ***and in compliance with the standards developed by the International Organization for Standardization (ISO) for the identification of medicinal products for human use (IDMP)***. Those marketing authorisation holders shall update their submission wherever necessary.	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. Those marketing authorisation holders shall update their submission wherever necessary.
	Article 10 – paragraph 3	3. Marketing authorisation holders shall justify the absence of any requested information and any delays in providing it by the deadline set by the Agency.		3. Marketing authorisation holders shall justify the absence of any requested information and any delays in providing it by the deadline set by the Agency.	3. Marketing authorisation holders shall justify the absence of any requested information and any delays in providing it by the deadline set by the Agency.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
68 continued	Article 10 – paragraph 4	4. Where marketing authorisation holders for medicinal products included on the critical medicines lists indicate that the submitted information contains information of a commercially confidential nature, they shall identify the relevant parts and clarify the reasons for such an indication. The Agency shall assess the merits of each request and protect commercially confidential information against unjustified disclosure.	**Amendment 87** 4. Where marketing authorisation holders for medicinal products included on the critical medicines lists indicate that the submitted information ***requested by the Agency or the national competent authorities*** contains information of a commercially confidential nature, they shall identify the relevant parts and clarify the reasons for such an indication. The Agency shall assess the merits of each request and protect commercially confidential information against unjustified disclosure.	4. Where marketing authorisation holders for medicinal products included on the critical medicines lists indicate that the submitted information contains information of a commercially confidential nature, they shall identify the relevant parts and clarify the reasons for such an indication. The Agency shall assess the merits of each request and protect commercially confidential information against unjustified disclosure.	4. Where marketing authorisation holders for medicinal products included on the critical medicines lists indicate that the submitted information ***requested by the Agency or the national competent authorities*** contains information of a commercially confidential nature, they shall identify the relevant parts and clarify the reasons for such an indication. The Agency shall assess the merits of each request and protect commercially confidential information against unjustified disclosure.
	Article 10 – paragraph 5	5. Where marketing authorisation holders for medicinal products included on the critical medicines lists are in possession of any additional information, which provides evidence of a potential or actual shortage they shall immediately provide such information to the Agency.	**Amendement 88** 5. Where marketing authorisation holders for medicinal products included on the critical medicines lists ***and/or other relevant actors in the pharmaceutical supply chain*** are in possession of any additional information, which provides evidence of a potential or actual shortage they shall immediately provide such information to the Agency.	5. Where marketing authorisation holders for medicinal products included on the critical medicines lists are in possession of any additional information, which provides evidence of a potential or actual shortage they shall immediately provide such information to the Agency.	5. Where marketing authorisation holders for medicinal products included on the critical medicines lists ***or other relevant actors in the pharmaceutical supply chain*** are in possession of any additional information, which provides evidence of a potential or actual shortage they shall immediately provide such information to the Agency.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
68 continued	Article 10 – paragraph 6	6. Following the reporting on the results of the monitoring and any recommendations on preventive or mitigating measures in accordance with Article 8, marketing authorisation holders for medicinal products included on the critical medicines list shall:		6. Following the reporting on the results of the monitoring and any recommendations on preventive or mitigating measures in accordance with Article 8, marketing authorisation holders for medicinal products included on the critical medicines list shall:	6. Following the reporting on the results of the monitoring and any recommendations on preventive or mitigating measures in accordance with Article 8, marketing authorisation holders for medicinal products included on the critical medicines list shall:
	Article 10 – paragraph 6 – point a	(a) provide any comments they have to the Agency;		(a) provide any comments they have to the Agency;	(a) provide any comments they have to the Agency;
	Article 10 – paragraph 6 – point b	(b) take into account any recommendations and guidelines and comply with any measures taken at Union and Member State-level pursuant to Articles 11 and 12;		(b) take into account any recommendations and guidelines and comply with any measures taken at Union and Member State-level pursuant to Articles 11 and 12;	(b) take into account any recommendations and guidelines and comply with any measures taken at Union and Member State-level pursuant to Articles 11 and 12;
	Article 10 – paragraph 6 – point c	(c) inform the Medicines Steering Group of any measures taken and report on the results of those measures, including information on the resolution of the potential or actual shortage.	**Amendment 89** (c) inform the Medicines Steering Group of any measures taken and report on the ***monitoring and*** results of those measures, including information on the resolution of the potential or actual shortage.	(c) inform the Medicines ***Shortages*** Steering Group of any measures taken and report on the results of those measures, including information on the resolution of the potential or actual shortage.	(c) inform the Medicines ***Shortages*** Steering Group of any measures taken and report on the ***monitoring and*** results of those measures, including information on the resolution of the potential or actual shortage.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
68 continued	Article 10 – paragraph 6 a (new)		**Amendement 90** ***6a. In order to supplement the shortage prevention and mitigation plans of critical medicinal products, the Agency and national competent authorities may request additional information from wholesale distributors and other relevant actors regarding any logistical challenges incurred by the wholesale supply chain.***		***6a. In order to supplement the shortage prevention and mitigation plans of critical medicinal products, the Agency and national competent authorities may request additional information from wholesale distributors and other relevant actors regarding any logistical challenges incurred by the wholesale supply chain.***
69	Article 11 Article 11 – paragraph 1	*Article 11* *Obligations on Member States in the monitoring and mitigation of shortages of medicinal products* 1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, Member States shall, by the deadline set by the Agency:	**Amendment 91** 1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, Member States shall, by the deadline set by the Agency***, submit the following information provided that it is not available in the database established in Article 12a***:	*Article 11* ~~*Obligations on*~~***Role of*** *Member States in the monitoring and mitigation of shortages of medicinal products* 1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, Member States shall, by the deadline set by the Agency:	*Article 11* ~~*Obligations on*~~***Role of*** *Member States in the monitoring and mitigation of shortages of medicinal products* 1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, Member States shall, by the deadline set by the Agency***, submit the following information provided that it is not available in the database established in Article 12a***:

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
69 continued	Article 11 – paragraph 1 – point a	(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 including available ~~and~~***or*** 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 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);
	Article 11 – paragraph 1 – point b	(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 10(4);***	(b) indicate the existence of any commercially confidential information and clarify the reasons for such an indication~~;~~***, in accordance with article 10(4);***
	Article 11 – paragraph 1 – point c	(c) indicate the absence of any requested information, and any delays in providing requested information by the deadline set by the Agency.		(c) indicate the absence of any requested information, and any delays in providing requested information by the deadline set by the Agency.	c) indicate the absence of any requested information, and any delays in providing requested information by the deadline set by the Agency.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
69 continued	Article 11 – paragraph 2	2. Where necessary to fulfil their reporting obligations set out in paragraph 1, Member States, with the support of the Agency, shall gather information and data on stock levels from wholesale distributors and other legal entities entitled to supply the public with medicinal products included on the critical medicines lists.	**Amendement 92** 2. Where necessary to fulfil their reporting obligations set out in paragraph 1, Member States, with the support of the Agency, shall gather ***relevant*** information and data***, including*** on stock levels***,*** from wholesale distributors and other legal entities ***and persons authorised or*** entitled to supply the public with medicinal products included on the critical medicines lists.	2. Where necessary to fulfil their reporting obligations set out in paragraph 1, Member States, with the support of the Agency, shall gather information and data on stock levels from wholesale distributors and other legal entities entitled to supply the public with medicinal products included on the critical medicines lists.	2. Where necessary to fulfil their reporting obligations set out in paragraph 1, Member States, with the support of the Agency, shall gather ***relevant*** information and data, ***including*** on stock levels***,*** from wholesale distributors and *pharmacists or* other legal entities *or* ***persons authorised or*** entitled to supply the public with medicinal products included on the critical medicines lists.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
69 continued	Article 11 – paragraph 3	3. Where Member States are in possession of any additional information on volume of sales and volumes of prescriptions, including data based on Article 23a of Directive 2001/83/EC, which provides evidence of a potential or actual shortage of a medicinal product included on the critical medicines lists, they shall immediately provide such information to the Medicines Steering Group through their designated points of contact.		3. Where Member States are in possession of any additional information on volume of sales and volumes of prescriptions, including data based on Article 23a of Directive 2001/83/EC, which provides evidence of a potential or actual shortage of a medicinal product included on the critical medicines lists, they shall immediately provide such information to the Medicines ***Shortages*** Steering Group through their designated points of contact.	3. Where Member States are in possession of any additional information on volume of sales and volumes of prescriptions, including data based on Article 23a of Directive 2001/83/EC, which provides evidence of a potential or actual shortage of a medicinal product included on the critical medicines lists, they shall immediately provide such information to the Medicines ***Shortages*** Steering Group through their designated points of contact.
	Article 11 – paragraph 4	4. Following the reporting on the results of the monitoring and any recommendations on preventive or mitigating measures in accordance with Article 8, Member States shall:		4. Following the reporting on the results of the monitoring and any recommendations on preventive or mitigating measures in accordance with Article 8, Member States shall:	4. Following the reporting on the results of the monitoring and any recommendations on preventive or mitigating measures in accordance with Article 8, Member States shall:
	Article 11 – paragraph 4 – point a	(a) take into account any recommendations and guidelines and comply with any measures taken at Union-level pursuant to Article 12;		(a) ~~take into account~~***consider*** any recommendations~~ and~~, guidelines and ~~comply with any~~ measures taken at Union-level pursuant to Article 12~~;~~***(a).***	(a) take into account any recommendations and guidelines and comply with any measures taken at Union-level pursuant to Article 12;

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
69 continued	Article 11 – paragraph 4 – point a	(b) inform the Medicines Steering Group of any measures taken and report on the results of those measures, including information on the resolution of the potential or actual shortage.		(b) inform the Medicines ***Shortages*** Steering Group of any measures taken and report on the results of those measures, including information on the resolution of the potential or actual shortage.	b) inform the Medicines ***Shortages*** Steering Group of any measures taken and report on the results of those measures, including information on the resolution of the potential or actual shortage. *Where an alternative course of action has been taken at national level, the Member States where such alternative occurred, shall share, in a timely manner, the reasons to the Medicines Shortages Steering Group. The recommendations, guidelines and measures taken at Union-level pursuant to Article 12(a) and a summary report of the lessons learned shall be made publicly available via the web-portal as referred to in Article 13.*

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
69 continued	Article 11 – paragraph 4a (new)		**Amendment 93** ***4a. National competent authorities for medicinal products shall facilitate online data collection on the impact of medicine shortages on patients and consumers. Relevant aggregated data from those surveys shall be shared by the sub-network of single points of contact from national competent authorities referred to in Article 3(5) with the Medicines Steering Group to inform recommendations on medicinal products shortage management.***		

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
70	Article 12 Article 12 – paragraph 1 Article 12 – paragraph 1 – point a Article 12 – paragraph 1 – point a a (new)	*Article 12* *Role of the Commission in the monitoring and mitigation of shortages of medicinal products* The Commission shall take into account the information from and recommendations of the Medicines Steering Group and shall: (a) take all necessary action within the limits of the powers conferred on it, with a view to mitigating potential or actual shortages of medicinal products included on the critical medicines lists;	**Amendment 94** ***(aa) facilitate the coordination between manufacturers and other relevant stakeholders to address demand surges;***	*Article 12* *~~Role~~**Obligations** of the Commission in the monitoring and mitigation of shortages of medicinal products* The Commission shall take into account the information from and recommendations of the Medicines ***Shortages*** Steering Group and shall: (a) take all necessary action within the limits of the powers conferred on it, with a view to mitigating potential or actual shortages of medicinal products included on the critical medicines lists;	*Article 12* *Role of the Commission in the monitoring and mitigation of shortages of medicinal products* The Commission shall take into account the information from and recommendations of the Medicines ***Shortages*** Steering Group and shall: (a) take all necessary action within the limits of the powers conferred on it, with a view to mitigating potential or actual shortages of medicinal products included on the critical medicines lists; ***(aa) facilitate the coordination between manufacturers and other relevant stakeholders to address demand surges,*** *where necessary;*

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
70 continued	Article 12 – paragraph 1 – point b	(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities;	**Amendment 95** (b) consider the need for guidelines ***and recommendations*** addressed to Member States, marketing authorisation holders, and other entities***, including from the pharmaceutical supply chain as well as healthcare professionals, to support them in their work and in the communication with patients***;	(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities;	(b) consider the need for guidelines ***and recommendations*** addressed to Member States, marketing authorisation holders, and other entities***, including from the pharmaceutical supply chain,*** *where relevant.*
	Article 12 – paragraph 1 – point c	(c) inform the Medicines Steering Group of any measures taken and report on the results;		(c) inform the Medicines ***Shortages*** Steering Group of any measures taken and report on the results;	(c) inform the Medicines ***Shortages*** Steering Group of any measures taken and report on the results;
	Article 12 – paragraph 1 – point d	(d) request the Medicines Steering Group to provide recommendations or coordinate measures as provided for in Article 8(3), (4) and (5);		(d) request the Medicines ***Shortages*** Steering Group to provide recommendations or coordinate measures as provided for in Article 8(3), (4) and (5);	(d) request the Medicines ***Shortages*** Steering Group to provide recommendations or coordinate measures as provided for in Article 8(3), (4) and (5);
	Article 12 – paragraph 1 – point e	(e) consider the need for medical countermeasures in accordance with Articles 12 and 25(b) of Regulation (EU) 2020/[…];		(e) consider the need for medical countermeasures in accordance with Articles 12 and 25(b) of Regulation (EU) 2020/[…];	(e) consider the need for medical countermeasures in accordance with Articles 12 and 25(b) of Regulation (EU) 2020/[…];

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
70 continued	Article 12 – paragraph 1 – point f	(f) liaise with third countries and relevant international organisations, as appropriate, to mitigate potential or actual shortages of medicinal products included on the critical medicines list or their active pharmaceutical ingredients, where those products or ingredients are imported into the Union and where such potential or actual shortages have international implications.	**Amendment 96** (f) liaise with third countries and relevant international organisations, as appropriate, to mitigate potential or actual shortages of medicinal products included on the critical medicines list or their active pharmaceutical ingredients, where those products or ingredients are imported into the Union and where such potential or actual shortages have international implications***, and report those actions as well as the results obtained to the Medicines Steering Group***.	(f) liaise with third countries and relevant international organisations, as appropriate, to mitigate potential or actual shortages of medicinal products included on the critical medicines list or their active pharmaceutical ingredients, where those products or ingredients are imported into the Union and where such potential or actual shortages have international implications.	f) liaise with third countries and relevant international organisations, as appropriate, to mitigate potential or actual shortages of medicinal products included on the critical medicines list or their active pharmaceutical ingredients, where those products or ingredients are imported into the Union and where such potential or actual shortages have international implications***, and report those actions as well as the results obtained to the Medicines*** *Shortages* ***Steering Group,*** *where relevant*.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
71	Article 12 a (new)		**Amendment 97** ***Article 12a*** ***European Medicines Supply Database*** ***1. The Agency shall, in collaboration with the Commission and Member States, set up, maintain and manage the European medicines supply database (EUMSD) for the following purposes:*** ***(a) to enable the monitoring of supply and demand of medicinal products at Union and Member State level;*** ***(b) to enable the monitoring and reporting of shortages of medicinal products at Union and Member State level;*** ***(c) to enable marketing authorisation holders and wholesale distributors to comply with the information obligations laid down in Article 10;***		

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
71 continued			***(d) to enable the Commission, the Agency and the national competent authorities to carry out their tasks in accordance with this Regulation on a well-informed basis and to enhance the cooperation between them.***		

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
71 continued			***The EUMSD, which shall be functional not only during public health emergencies and major events but also under normal circumstances, shall function as an interoperable and digital database at Union level, based on the data reported through the national electronic platforms established pursuant to paragraph 2. The database shall allow the Agency and the national competent authorities to simultaneously access and share the information provided in the database.*** ***2. Each Member State shall develop an electronic platform with a view to establishing real-time monitoring of the supply of medicinal products, capable of determining the volume of supply of each medicinal product existing at any given moment, and detecting, predicting and preventing shortages of medicinal products. Those platforms, which shall be managed by the national competent authorities, shall be fully operational at Member State level by... [30 months after the date of entry***		

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
			into force of this Regulation].		

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
71 continued			***Data on supply and demand shall be reported at Member State level by the following entities:*** ***(a) marketing authorisation holders*** ***(b) wholesale distributors*** ***(c) community and hospital pharmacies.*** ***3. In addition to paragraph 2, the electronic platforms shall provide the national competent authorities with real-time access to information on unmet demands from wholesale distributors, community pharmacies and hospital pharmacies at national level. Those platforms shall also allow marketing authorisation holders to report any medicinal products supply problems, including manufacturing problems.*** ***4. Member State platforms shall be interoperable and shall replicate their information in the EUMSD managed by the Agency, thereby preventing any duplication of the reporting process by the single points of contact established in Article 9(2).***		

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
71 continued			***5. The data generated by the Member State platforms and consequently by the EUMSD shall make it possible to identify any supply problems along the supply chain and, through the application of big data techniques and, where appropriate, artificial intelligence, shall be able to forecast supply problems in advance.*** ***6. The data submitted shall be compliant with the standards developed by the ISO for IDMP and be based on the four domains of master data in pharmaceutical regulatory processes: substance, product, organisation and referential data.***		

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
71 continued			***7. The Agency shall, in collaboration with the Commission and Member States, draw up the functional specifications for the database, together with a plan for the implementation of the EUMSD and the Member State platforms by... [6 months after the date of entry into force of this Regulation]. That plan shall seek to ensure that the EUMSD is fully functional by ... [48 months after the date of entry into force of this Regulation].*** ***8. Where a national competent authority indicates that the submitted information contains information of a commercially confidential nature, it shall identify the relevant parts and clarify the reasons for such an indication. The Agency shall assess the merits of each request and protect commercially confidential information against unjustified disclosure.***		

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
71 continued			***9. In view of the commercially sensitive nature of the data provided to the EUMSD, access to the database shall be limited to the Commission, the Agency, national competent authorities reporting the data to the database and the Medicines Steering Group.***		
72	Article 13 Article 13 – paragraph 1	*Article 13* *Communication on the Medicines Steering Group* The Agency shall, via its web-portal and other appropriate means, in conjunction with national competent authorities, inform the public and interest groups with regard to the work of the Medicines Steering Group.	**Amendment 98** The Agency shall, via ***a dedicated space on*** its web-portal and other appropriate means, in conjunction with national competent authorities, inform the public and interest groups ***in a timely manner*** with regard to the work of the Medicines Steering Group***, and respond to disinformation targeting the work of the Medicines Steering Group as appropriate***.	*Article 13* *Communication on the Medicines **Shortages** Steering Group* The Agency shall, via its web-portal and other appropriate means, in conjunction with national competent authorities, inform the public and interest groups with regard to the work of the Medicines ***Shortages*** Steering Group.	*Article 13* *Communication on the Medicines **Shortages** Steering Group* The Agency shall, via ***a dedicated space on*** its web-portal and other appropriate means, in conjunction with national competent authorities, inform the public and interest groups ***in a timely manner*** with regard to the work of the Medicines ***Shortages*** Steering Group***, and respond to disinformation targeting the work of the Medicines*** *Shortage* ***Steering Group as appropriate***.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
72 continued	Article 13 – paragraph 1 a (new)		**Amendment 99** ***Proceedings undertaken by the Medicines Steering Group shall be transparent. The agenda and minutes of the Medicines Steering Group as well as the rules of procedure and recommendations and, where appropriate, votes shall be documented and made publicly available, including any dissensions.***		*Proceedings undertaken by the Medicines Shortages Steering Group shall be transparent. The summaries of the agenda and of the minutes of the Medicines Shortages Steering Group as well as the rules of procedure and recommendations shall be documented and made publicly available on the dedicated space on the Agency web portal.*
73	Chapter III	**Chapter III** **Medicinal Products with the potential to address public health emergencies**		**Chapter III** **Medicinal Products with the potential to address public health emergencies**	

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
74	Article 14 Article 14 – paragraph 1	*Article 14* *The Emergency Task Force* 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.	**Amendement 100** 1. The Emergency Task Force is hereby established as part of the Agency. It shall be convened ***in preparation for and*** during public health emergencies, either in person or remotely. The Agency shall provide its secretariat.	*Article 14* *The Emergency Task Force* 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~~.~~***, and cease to be convened after termination of the recognition of a public health emergency pursuant to Article 23(2) of Regulation (EU) […/…].*** The Agency shall provide its secretariat.	1. The Emergency Task Force is hereby established as part of the Agency. It shall be convened ***in preparation for and*** during public health emergencies, either in person or remotely. The Agency shall provide its secretariat.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
74 continued	Article 14 – paragraph 2 Article 14 – paragraph 2 – point a Article 14 – paragraph 2 – point b	2. During public health emergencies, the Emergency Task Force shall undertake the following tasks: (a) providing scientific advice and reviewing the available scientific data on medicinal products with the potential to address the public health emergency, including requesting data from developers and engaging with them in preliminary discussions; (b) reviewing clinical trial protocols and providing advice to developers on clinical trials to be conducted in the Union for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency, in accordance with Article 15;		2. During public health emergencies, the Emergency Task Force shall undertake the following tasks: (a) ***in liaison with the scientific committees, working parties, and scientific advisory groups of the Agency,*** providing scientific advice and reviewing the available scientific data on medicinal products with the potential to address the public health emergency, including requesting data from developers and engaging with them in preliminary discussions; (b) ~~reviewing~~***providing advice on the main aspects of*** 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 ***without prejudice to the tasks of the Member States as regards assessment of submitted clinical trial applications to be conducted on their territories in accordance with Article 6 of Regulation (EU) No 536/2014***;	2. During public health emergencies, the Emergency Task Force shall undertake the following tasks: (a) ***in liaison with the scientific committees, working parties, and scientific advisory groups of the Agency,*** providing scientific advice and reviewing the available scientific data on medicinal products with the potential to address the public health emergency, including requesting data from developers and engaging with them in preliminary discussions; (b) ~~reviewing~~***providing advice on the main aspects of*** 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 ***without prejudice to the tasks of the Member States as regards assessment of submitted clinical trial applications to be conducted on their territories in accordance with Regulation (EU) No 536/2014***;

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
74 continued	Article 14 – paragraph 2 – point c	(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;		(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;	(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;
	Article 14 – paragraph 2 – point d	(d) contributing to the work of the scientific committees, working parties and scientific advisory groups of the Agency;		(d) contributing to the work of the scientific committees, working parties and scientific advisory groups of the Agency;	(d) contributing to the work of the scientific committees, working parties and scientific advisory groups of the Agency;
	Article 14 – paragraph 2 – point e	(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) ***in liaison with the scientific committees, working parties, and scientific advisory groups of the Agency,*** 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) ***in liaison with the scientific committees, working parties, and scientific advisory groups of the Agency,*** 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;

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
74 continued	Article 14 – paragraph 2 – point f	(f) cooperating with Union bodies and agencies, the World Health Organization, third countries, and international scientific organisations on scientific and technical issues relating to the public health emergency and to medicinal products which may have the potential to address public health emergencies, as necessary.	**Amendment 101** (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.	(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.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
74 continued	Article 14 – paragraph 3	3. The Emergency Task Force shall be composed of representatives of the scientific committees, working parties, and staff members of the Agency, the coordination group established in accordance with Article 27 of Directive 2001/83/EC, and the Clinical Trials Coordination and Advisory Group established in accordance with Article 85 of Regulation (EU) 536/2014. External experts may be appointed and representatives of other Union bodies and agencies be invited on an ad hoc basis, as necessary. It shall be chaired by the Agency.	**Amendment 102** 3. The Emergency Task Force shall be composed of representatives of the scientific committees, working parties***, including representatives of the PCWP and the HCPWP***, and staff members of the Agency, the coordination group established in accordance with Article 27 of Directive 2001/83/EC, and the Clinical Trials Coordination and Advisory Group established in accordance with Article 85 of Regulation (EU) 536/2014.[21] External experts may be appointed and representatives of other Union bodies and agencies be invited on an ad hoc basis, as necessary. It shall be chaired by the Agency.	3. The Emergency Task Force shall be composed of representatives ***nominated by the scientific committees, working parties, including (vice)Chairs*** of the scientific committees~~,~~ ~~working parties,~~ and staff members of the Agency, the coordination group established in accordance with Article 27 of Directive 2001/83/EC, and the Clinical Trials Coordination and Advisory Group established in accordance with Article 85 of Regulation (EU) 536/2014~~.~~ ***as well as other clinical trial experts representing competent authorities of the Member States.*** External experts may be appointed and representatives of other Union bodies and agencies ***shall*** be invited on an ad hoc basis, as necessary~~.~~***, especially in cases of public health emergencies which affect also the veterinary medicinal products field.*** It shall be chaired by the Agency ***and co-***	3. The Emergency Task Force shall be composed of representatives, ***nominated by the scientific committees, working parties, including (vice)Chairs*** of the scientific committees, ~~working parties,~~ ***including representatives of the PCWP and the HCPWP***, and staff members of the Agency, the coordination group established in accordance with Article 27 of Directive 2001/83/EC, and the Clinical Trials Coordination and Advisory Group established in accordance with Article 85 of Regulation (EU) 536/2014.~~,~~ ***as well as other clinical trial experts representing competent authorities of the Member States.*** External experts may be appointed and representatives of other Union bodies and agencies ***shall*** be invited on an ad hoc basis, as necessary, ***especially in cases of public health emergencies which affect also the veterinary medicinal products field.*** It shall be chaired by the Agency ***and co-***

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
74 continued				***chaired by the chair or vice-chair of the Committee for Medicinal Products for Human Use. The Emergency Task Force composition should be publicly available***.	***chaired by the chair or vice-chair of the Committee for Medicinal Products for Human Use. The Emergency Task Force composition should be publicly available***
	Article 14 – paragraph 4	4. The composition of the Emergency Task Force shall be approved by the Management Board of the Agency. The Executive Director of the Agency or their representative and representatives of the Commission shall be entitled to attend all meetings.		4. The composition of the Emergency Task Force shall be approved by the Management Board of the Agency- ***taking into account the specific expertise relevant for the therapeutic response to the public health emergency.*** The Executive Director of the Agency or their representative and representatives of the Commission ***and of the Management Board of the Agency*** shall be entitled to attend all meetings.	4. The composition of the Emergency Task Force shall be approved by the Management Board of the Agency- ***taking into account the specific expertise relevant for the therapeutic response to the public health emergency.*** The Executive Director of the Agency or their representative and representatives of the Commission ***and of the Management Board of the Agency*** shall be entitled to attend all meetings.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
74 continued	Article 14 – paragraph 5	5. The Chair may invite representatives of Member States, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, and interest groups representing patients and healthcare professionals to attend its meetings.	**Amendment 103** 5. The Chair may invite representatives of Member States, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, ***independent clinical trial experts and researchers,*** and interest groups representing patients and healthcare professionals to attend its meetings.	5. The ~~Chair~~***Co-chairs*** may invite ***other*** 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~~***Co-Chairs*** may invite ***other*** representatives of Member States, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, ***independent clinical trial experts and researchers,*** and interest groups representing patients and healthcare professionals to attend its meetings.
	Article 14 – paragraph 6	6. The Emergency Task Force shall establish its rules of procedure including rules on the adoption of recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.		6. The Emergency Task Force shall establish its rules of procedure including rules on the adoption of recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.	6. The Emergency Task Force shall establish its rules of procedure including rules on the adoption of recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
74 continued	Article 14 – paragraph 7	7. The Emergency Task Force shall perform its tasks as a body separate from, and without prejudice to the tasks of the scientific committees of the Agency as regards the authorisation, supervision and pharmacovigilance of the concerned medicinal products and related regulatory actions to ensure the quality, safety and efficacy of those medicinal products. The Emergency Task Force shall take account of any scientific opinion issued by those committees in accordance with Regulation (EC) No 726/2004 and Directive 2001/83/EC.		7. The Emergency Task Force shall perform its tasks as ~~a~~***an advisory and support*** body separate from, and without prejudice to the tasks of the scientific committees of the Agency as regards the authorisation, supervision and pharmacovigilance of the concerned medicinal products and related regulatory actions to ensure the quality, safety and efficacy of those medicinal products. ***The Committee for Medicinal Products for Human Use shall take into consideration the Emergency Task Force recommendation, when adopting an independent and scientifically based opinion.*** The Emergency Task Force shall take account of any scientific opinion issued by those committees in accordance with Regulation (EC) No 726/2004 and Directive 2001/83/EC.	7. The Emergency Task Force shall perform its tasks as ~~a~~***an advisory and support*** body separate from, and without prejudice to the tasks of the scientific committees of the Agency as regards the authorisation, supervision and pharmacovigilance of the concerned medicinal products and related regulatory actions to ensure the quality, safety and efficacy of those medicinal products. ***The Committee for Medicinal Products for Human Use shall take into consideration the Emergency Task Force recommendation, when adopting*** *its* ***opinion.*** The Emergency Task Force shall take account of any scientific opinion issued by those committees in accordance with Regulation (EC) No 726/2004 and Directive 2001/83/EC.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
74 continued	Article 14 – paragraph 8	8. Article 63 of Regulation (EC) No 726/2004 shall apply to the Emergency Task Force as regards transparency and the independence of its members.	**Amendment 104** 8. Article 63 of Regulation (EC) No 726/2004 shall apply to the Emergency Task Force as regards transparency and the independence of its members. ***Members of the Emergency Task Force shall update the annual declaration of their financial interests provided for in Article 63 of Regulation (EC) No 726/2004 whenever a relevant change occurs.***	8. Article 63 of Regulation (EC) No 726/2004 shall apply to the Emergency Task Force as regards transparency and the independence of its members.	8. Article 63 of Regulation (EC) No 726/2004 shall apply to the Emergency Task Force as regards transparency and the independence of its members. ***Members of the Emergency Task Force shall update the annual declaration of their financial*** *or other* ***interests provided for in Article 63 of Regulation (EC) No 726/2004 whenever a relevant change occurs.***
	Article 14 – paragraph 9	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 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. ***Before such publication, the Agency shall also inform Member States and the Heath Security Committee, as appropriate.***	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. *Without any undue delay and in any case prior to* ***such publication, the Agency shall inform Member States and the Heath Security Committee, as appropriate.***

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
75	Article 15	*Article 15* *Advice on clinical trials*		*Article 15* *Advice on clinical trials*	
	Article 15 – paragraph 1	1. During a public health emergency, the Emergency Task Force shall review clinical trial protocols submitted or intended to be submitted in a clinical trial application by developers of medicinal products as part of an accelerated scientific advice process.		1. During a public health emergency, the Emergency Task Force shall ~~review~~***provide advice on main aspects of*** clinical trial protocols submitted or intended to be submitted in a clinical trial application***, without prejudice of the responsibility of the Member State(s) according to Regulation (EU) 536/2014,*** by developers of medicinal products as part of an accelerated scientific advice process.	1. During a public health emergency, the Emergency Task Force shall ~~review~~***provide advice on main aspects of*** clinical trial protocols submitted or intended to be submitted in a clinical trial application***, without prejudice of the responsibility of the Member State(s) according to Regulation (EU) 536/2014,*** by developers of medicinal products as part of an accelerated scientific advice process.
	Article 15 – paragraph 2	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 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.	

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
75 continued	Article 15 – paragraph 3 Article 15 – paragraph 4	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. 4. The Emergency Task Force shall involve representatives of the Member State or States where an application for authorisation of a clinical trial is submitted or is intended to be submitted in the preparation of the scientific advice.	**Amendement 105** 3. The Emergency Task Force shall establish procedures ***and guidance*** for the request and submission of the set of information and data required, including information on the Member State or States where an application for authorisation of a clinical trial is submitted or is intended to be submitted.	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. 4. The Emergency Task Force shall involve***, in the preparation of the scientific advice,*** representatives ***with clinical trial expertise*** of the Member ~~State or~~ States ***in particular of those*** where an application for authorisation of a clinical trial is submitted or is intended to be submitted ~~in the preparation of the scientific advice~~.	3. The Emergency Task Force shall establish procedures ***and guidance*** for the request and submission of the set of information and data required, including information on the Member State or States where an application for authorisation of a clinical trial is submitted or is intended to be submitted. 4. ***In preparation of the scientific advice,*** the Emergency Task Force shall involve representatives ***with clinical trial expertise*** of the Member ~~State or~~ States ***in particular of those*** where an application for authorisation of a clinical trial is submitted or is intended to be submitted ~~in the preparation of the scientific advice~~.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
75 continued	Article 15 – paragraph 5	5. When authorising a clinical trial application for which scientific advice has been given, Member States shall take that advice duly into account.	**Amendment 106** 5. When authorising a clinical trial application for which scientific advice has been given, Member States shall take that advice duly into account. ***The scientific advice provided by the Emergency Task Force shall be without prejudice to the ethical review provided for in Regulation (EU) No 536/2014.***	5. When authorising a clinical trial application for which scientific advice has been given, Member States shall ~~take~~***consider*** that advice ~~duly into account~~.	5. When authorising a clinical trial application for which scientific advice has been given, Member States shall *take* that advice *into consideration*. ***The scientific advice provided by the Emergency Task Force shall be without prejudice to the ethical review provided for in Regulation (EU) No 536/2014.***
	Article 15 – paragraph 6	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 submit the data resulting from clinical trials to the Agency following a request made pursuant to Article 16.	
	Article 15 – paragraph 7	7. Without prejudice to the provisions of this Article, the scientific advice shall otherwise be provided to those developers in accordance with the procedures established pursuant to Article 57 of Regulation EC (No) 726/2004.		7. Without prejudice to the provisions of this Article, the scientific advice shall otherwise be provided to those developers in accordance with the procedures established pursuant to Article 57 of Regulation EC (No) 726/2004.	

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
76	Article 15 a (new)		**Amendment 107** ***Article 15a*** ***Public information about clinical trials and marketing authorisation decisions*** ***1. For the duration of a public health emergency, the sponsors of clinical trials conducted in the Union shall:*** ***(a) publish the study protocol at the start of the trial through the EU clinical trials register;*** ***(b) publish the summary of the results through the EU clinical trials register within a timeline set by the Agency that is shorter than the timeline laid down in Article 37 of Regulation (EU) No 536/2014.*** ***2. Where a medicinal product receives a marketing authorisation, the Agency shall publish:*** ***(a) the product information with details of the conditions of use at the time of marketing authorisation;***		***Article 15a*** ***Public information about clinical trials and marketing authorisation decisions*** ***1. For the duration of a public health emergency, the sponsors of clinical trials conducted in the Union shall****, in particular****:*** ***(a) publish the study protocol at the start of the trial through the EU clinical trials register;*** ***(b) publish the summary of the results through the EU clinical trials register within a timeline set by the Agency that is shorter than the timeline laid down in Article 37 of Regulation (EU) No 536/2014.*** ***2. Where a medicinal product receives a marketing authorisation, the Agency shall publish****, in particular****:*** ***(a) the product information with details of the conditions of use at the time of marketing authorisation;***

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
76 continued			***(b) the European public assessment reports as soon as possible and, where possible, within seven days of marketing authorisation;*** ***(c) the clinical data submitted to the Agency in support of the application where possible within two months of authorisation by the Commission, and after personal data have been anonymised and commercially confidential information redacted;*** ***(d) the full body of the Risk Management Plan and any updated versions.***		***(b) the European public assessment reports as soon as possible and, where possible, within seven days of marketing authorisation;*** ***(c) the clinical data submitted to the Agency in support of the application where possible within two months of authorisation by the Commission, and after personal data have been anonymised and commercially confidential information redacted;*** ***(d) the full body of the Risk Management Plan and any updated versions.***

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
77	Article 16 Article 16 – paragraph 1	*Article 16* *Review of medicinal products and recommendations on their use* 1. Following the recognition of a public health emergency, the Emergency Task Force shall undertake a review of the available scientific data on medicinal products, which may have the potential to be used to address the public health emergency. The review shall be regularly updated during the public health emergency.	**Amendment 108** 1. Following the recognition of a public health emergency, the Emergency Task Force shall undertake a review of the available scientific data on medicinal products, which may have the potential to be used to address the public health emergency. The review shall be regularly updated during the public health emergency***, including where agreed by the Emergency Task Force and the Committee for Medicinal Products for Human Use in preparation of the assessment of a marketing authorisation application***.	*Article 16* *Review of medicinal products and recommendations on their use* 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 *whenever needed* during the public health emergency***, including where agreed by the Emergency Task Force and the Committee for Medicinal Products for Human Use in preparation of the assessment of a marketing authorisation application***.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
77 continued	Article 16 – paragraph 2	2. In preparation of the review, the Emergency Task Force may request information and data from marketing authorisation holders and from developers and engage with them in preliminary discussions. The Emergency Task Force may also, where available, make use of observational studies of health data generated outside of clinical studies taking into account their reliability.	**Amendement 109** 2. In preparation of the review, the Emergency Task Force may request information and data from marketing authorisation holders and from developers and engage with them in preliminary discussions. The Emergency Task Force may also, where available, make use of observational studies of health data generated outside of clinical studies taking into account their reliability. ***The Emergency Task Force may liaise with medicine agencies of third countries for additional information and data exchange.***	2. In preparation of the review, the Emergency Task Force may request information and data from marketing authorisation holders and from developers and engage with them in preliminary discussions. The Emergency Task Force may also, where available, make use of ~~observational studies of~~ health data generated outside of clinical studies taking into account their reliability.	2. In preparation of the review, the Emergency Task Force may request information and data from marketing authorisation holders and from developers and engage with them in preliminary discussions. The Emergency Task Force may also, where available, make use of ~~observational studies of~~ health data generated outside of clinical studies taking into account their reliability. ***The Emergency Task Force may liaise with medicine agencies of third countries for additional information and data exchange.***
	Article 16 – paragraph 3	3. Based on a request from one or more Member States, or the Commission, the Emergency Task Force shall provide recommendations to the Committee for Medicinal Products for Human Use for an opinion in accordance with paragraph 4 on the following:		3. Based on a request from one or more Member States, or the Commission, the Emergency Task Force shall provide recommendations to the Committee for Medicinal Products for Human Use for an opinion in accordance with paragraph 4 on the following:	
	Article 16 – paragraph 3 – point a	(a) the compassionate use of medicinal products falling under the scope of Directive 2001/83/EC or Regulation (EC) No 726/2004;		(a) the compassionate use of medicinal products falling under the scope of Directive 2001/83/EC or Regulation (EC) No 726/2004;	

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
77 continued	Article 16 – paragraph 3 – point b Article 16 – paragraph 4 Article 16 – paragraph 5	(b) the use and distribution of an unauthorised medicinal product in accordance with Article 5(2) of Directive 2001/83/EC. 4. Following receipt of the recommendation, the Committee for Medicinal Products for Human Use shall adopt an opinion on the conditions for use, the conditions for distribution and the patients targeted. The opinion shall be updated where necessary. 5. Member States shall take account of the opinions referred to in paragraph 4. Where Member States make use of such an opinion, Article 5(3) and (4) of Directive 2001/83/EC shall apply.		(b) the use and distribution of an unauthorised medicinal product in accordance with Article 5(2) of Directive 2001/83/EC. 4. Following receipt of the recommendation, the Committee for Medicinal Products for Human Use shall adopt an ***independent and scientifically based*** opinion on the conditions for use, the conditions for distribution and the patients targeted. The opinion shall be updated where necessary. 5. Member States shall take account of the opinions referred to in paragraph 4. Where Member States make use of such an opinion, Article 5(3) and (4) of Directive 2001/83/EC shall apply.	4. Following receipt of the recommendation, the Committee for Medicinal Products for Human Use shall adopt *its* opinion on the conditions for use, the conditions for distribution and the patients targeted. The opinion shall be updated where necessary.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
77 continued	Article 16 – paragraph 6	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 informed the~~ ***available from*** 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 informed the~~ ***available from*** 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.
	Article 16 – paragraph 7	***7. The Agency shall publish the opinions adopted pursuant to paragraph 4 including any updates on its web-portal.***	**Amendment 110** ***deleted***	7. The Agency shall publish the opinions adopted pursuant to paragraph 4 including any updates on its web-portal.	***[…]***

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
78	Article 17 Article 17 – paragraph 1	*Article 17* *Communication on the Emergency Task Force* The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Emergency Task Force.	**Amendment 111** The Agency shall, via ***a dedicated space on*** its web-portal and other appropriate means and, in conjunction with national competent authorities, inform ***without delay*** the public and relevant interest groups with regard to the work of the Emergency Task Force***, and respond to disinformation targeting the work of the Emergency Task Force as appropriate***.	*Article 17* *Communication on the Emergency Task Force* The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Emergency Task Force.	The Agency shall, via ***a dedicated space on*** its web-portal and other appropriate means and, in conjunction with national competent authorities, inform *in a timely manner* the public and relevant interest groups with regard to the work of the Emergency Task Force***, and respond to disinformation targeting the work of the Emergency Task Force as appropriate***.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
78 continued	Article 17 – paragraph 1 a (new)		**Amendment 112** ***The list of the members of the Emergency Task Force, the rules of procedure, as well as the recommendations provided pursuant to Article 16 (3) and the opinions adopted pursuant to Article 16 (4) shall be published on the Agency's web-portal.***		*The list of the members of the Emergency Task Force, the rules of procedure and the list of products under review regularly as well as the opinions adopted pursuant to Article 16 (4) shall be published on the Agency's web-portal.* *Recital → "The European Medicines Agency publishes a 'European Public Assessment Report' (EPAR) for products authorised in accordance with Regulation (EC) No 726/2004, which provides information on the related assessment by describing the data assessed and the reasons for recommending whether the medicine should be authorised or not. The report will include detailed information of all relevant pre-submission activities, including with regard to the Emergency Task Force the names of the experts involved, and in case a medicine developer requested scientific advice during the pre-submission phase an overview of the scientific topics discussed during this advice."*

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
79	Article 18 Article 18 – paragraph 1 Article 18 – paragraph 1 – point a	*Article 18* *IT tools and data* To prepare for and support the work of the Emergency Task Force during public health emergencies, the Agency shall: (a) develop and maintain electronic tools for the submission of information and data, including electronic health data generated outside the scope of clinical studies;	**Amendment 113** (a) develop and maintain electronic tools***, including an interoperable and digitalised platform,*** for the submission of information and data, including electronic health data generated outside the scope of clinical studies;	*Article 18* *IT tools and data* To prepare for and support the ***decision making process and the*** work of the Emergency Task Force during public health emergencies, the Agency shall: (a) develop and maintain electronic tools for the submission of information and data, including electronic health data generated outside ~~the scope of clinical studies~~***of clinical studies facilitating interoperability with other existing electronic tools, and tools under development and providing the adequate support to Members States' competent authorities***;	To prepare for and support the work of the Emergency Task Force during public health emergencies, the Agency shall: (a) develop and maintain electronic tools***, including an interoperable and digitalised platform,*** for the submission of information and data, including electronic health data generated outside ~~the scope of clinical studies~~***of clinical studies facilitating interoperability with other existing electronic tools, and tools under development, and providing the adequate support to Members States' competent authorities***;

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
79 continued	Article 18 – paragraph 1 – point b	(b) coordinate independent ***vaccine*** effectiveness and safety monitoring studies using relevant data held by public authorities**.** Such coordination shall be conducted jointly with the European Centre for Disease Prevention and Control and notably through a new vaccine monitoring platform;	**Amendment 114** (b) coordinate independent ***utilisation,*** effectiveness and safety monitoring studies ***of medicinal products intended to treat, prevent or diagnose a disease*** using relevant data held by public authorities***; for vaccines,*** such coordination shall be conducted jointly with the European Centre for Disease Prevention and Control and notably through a new vaccine monitoring platform;	(b) coordinate independent vaccine effectiveness and safety monitoring studies using relevant data held by public authorities. Such coordination shall be conducted jointly with the European Centre for Disease Prevention and Control and notably through a- new vaccine monitoring platform;	*(b) coordinate independent utilisation, effectiveness and safety monitoring studies of medicinal products intended to treat, prevent or diagnose a disease related to the public health emergency using relevant data, including where relevant data held by public authorities;* *(ba) for vaccines, ~~such~~ the coordination referred in point (b) shall be conducted jointly with the European Centre for Disease Prevention and Control and notably through a new vaccine monitoring platform;*
	Article 18 – paragraph 1 – point c	(c) as part of its regulatory tasks, make use of digital infrastructures or tools, to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of clinical studies, and the exchange of such data between Member States, the Agency, and other Union bodies;	**Amendment 115** (c) as part of its regulatory tasks, make use of digital infrastructures or tools, to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of ***interventional*** clinical studies, and the exchange of such data between Member States, the Agency, and other Union bodies;	(c) as part of its regulatory tasks, make use of digital infrastructures or tools, to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of clinical studies, and the exchange of such data between Member States, the Agency, and other Union bodies;	(c) as part of its regulatory tasks, make use of digital infrastructures or tools, to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of clinical studies, and the exchange of such data between Member States, the Agency, and other Union bodies;

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
79 continued	Article 18 – paragraph 1 – point d	(d) provide access to the Emergency Task Force to external sources of electronic health data including, health data generated outside the scope of clinical studies, to which the Agency has access.		(d) provide access to the Emergency Task Force to external sources of electronic health data including, health data generated outside ~~the scope~~ of clinical studies, to which the Agency has access.	(d) provide access to the Emergency Task Force to external sources of electronic health data including, health data generated outside ~~the scope~~ of clinical studies, to which the Agency has access.
80		**Chapter IV** **Monitoring and mitigating shortages of critical medical devices and support for expert panels**		**Chapter IV** **Monitoring and mitigating shortages of critical medical devices and support for expert panels**	
81	Article 19 Article 19 – paragraph 1	*Article 19* *The Executive Steering Group on Medical Devices* 1. The Executive Steering Group on Medical Devices ('the Medical Devices Steering Group') is hereby established as part of the Agency. It shall meet either in person or remotely, in preparation for or during a public health emergency. The Agency shall provide its secretariat.	**Amendment 116** 1. The Executive Steering Group on Medical Devices ('the Medical Devices Steering Group') is hereby established as part of the Agency. It shall meet ***at regular intervals*** either in person or remotely***, and whenever the situation requires***, in preparation for or during a public health emergency. The Agency shall provide its secretariat.	*Article 19* *The Executive Steering Group on* ***Shortages of*** *Medical Devices* 1. The Executive Steering Group on ***Shortages of*** Medical Devices ('the Medical Devices ***Shortages*** 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.	*Article 19* *The Executive Steering Group on* ***Shortages of*** *Medical Devices* 1. The Executive Steering Group on ***Shortages of*** Medical Devices ('the Medical Devices ***Shortages*** Steering Group') is hereby established as part of the Agency. It shall meet *regularly* ***and*** *in addition* ***whenever the situation requires,*** either in person or remotely, in preparation for or during a public health emergency. The Agency shall provide its secretariat.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
81 continued	Article 19 – paragraph 2	2. The Medical Devices Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields.	**Amendment 117** 2. The Medical Devices Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one ***authorised*** senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields. ***The Medical Devices Steering Group shall also include a representative of the PCWP and a representative of the HCPWP as observers. The list of members of the Medical Devices Steering Group shall be transparent and made public on the Agency's web-portal.***	2. The Medical Devices ***Shortages*** Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one ~~senior~~ representative per Member State. Each Member State shall appoint ~~their~~**a** representative ***with expertise in the field of medical devices and or in vitro diagnostic medical devices, as relevant. These representatives may be the same as the one appointed for MDCG where appropriate***. Members may be accompanied by experts in specific scientific or technical fields.	2. The Medical Devices ***Shortages*** Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one ~~senior~~ *appointed* representative per Member State. Each Member State shall appoint ***a*** representative ***with expertise in the field of medical devices*** *or* ***in vitro diagnostic medical devices, as relevant. These representatives may be the same as the one appointed for MDCG where appropriate***. Members may be accompanied by experts in specific scientific or technical fields. *Representatives of the PCWP and of the HCPWP may also attend the meetings of the Medical Devices Shortages Steering Group as observers. The list of members of the Medical Devices Shortages Steering Group shall be transparent and made public on the Agency's web-portal.*

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
81 continued	Article 19 – paragraph 3	3. The Medical Devices Steering Group shall be chaired by the Agency. The Chair ***may*** invite third parties, including representatives of medical device interest groups to attend its meetings.	**Amendment 118** 3. The Medical Devices Steering Group shall be chaired by the Agency. ***Any member of the Medical Devices Steering Group may propose to*** the Chair ***to*** invite third parties, including representatives of medical device interest groups***, such as representatives of manufacturers and notified bodies or any other actor in the medical devices supply chain, as well as representatives of healthcare professionals, patients and consumers*** to attend its meetings ***when their contribution may inform the discussions of the Medical Devices Steering Group***.	3. The Medical Devices ***Shortages*** Steering Group shall be ***Co-***chaired by the Agency~~.~~ ***and by a representative of a Member State elected by and amongst its members.*** The ~~Chair~~***Co-Chairs*** may invite third parties, including representatives of medical device interest groups***, such as representatives from the industry or from notified bodies,*** to attend its meetings.	3. The Medical Devices ***Shortages*** Steering Group shall be ***co-***chaired by the Agency ***and by a representative of a Member State elected by and amongst its members.*** The ***co-***chairs may, *on their own initiative or following a request from one or more members,* invite~~,~~ *as observers and to provide expert advice* third parties including representatives of medical device interest groups***, such as representatives of manufacturers and notified bodies or any other actor in the medical devices supply chain, as well as representatives of healthcare professionals, patients and consumers*** to attend its meetings *as necessary.*

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
81 continued	Article 19 – paragraph 4	4. The Medical Devices Steering Group shall establish its rules of procedure including procedures relating to the working party referred to in paragraph 5, and on the adoption of lists, sets of information and recommendations. The rules of procedures shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.		4. The Medical Devices ***Shortages*** Steering Group shall establish its rules of procedure including procedures relating to the working party referred to in paragraph 5, and on the adoption of lists, sets of information and recommendations. The rules of procedures shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.	4. The Medical Devices ***Shortages*** Steering Group shall establish its rules of procedure including procedures relating to the working party referred to in paragraph 5, and on the adoption of lists, sets of information and recommendations. The rules of procedures shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.
	Article 19 – paragraph 5	5. The Medical Devices Steering Group shall be supported in its work by a working party comprised of single points of contact from national competent authorities for medical devices established in accordance with Article 23(1).		5. The Medical Devices ***Shortages*** Steering Group shall be supported in its work by a working party comprised of single points of contact from national competent authorities ~~for~~***responsible for shortage monitoring and management for medical devices and in vitro diagnostic*** medical devices established in accordance with Article 23(1).	5. The Medical Devices ***Shortages*** Steering Group shall be supported in its work by a working party comprised of single points of contact from national competent authorities ~~for~~ ***responsible for shortage monitoring and management of medical devices and in vitro diagnostic*** medical devices established in accordance with Article 23(1).
	Article 19 – paragraph 6	6. The Medical Devices Steering Group shall be responsible for fulfilling the tasks referred to in Articles 20, 21, and 22.		6. The Medical Devices ***Shortages*** Steering Group shall be responsible for fulfilling the tasks referred to in Articles 20, 21, and 22.	6. The Medical Devices ***Shortages*** Steering Group shall be responsible for fulfilling the tasks referred to in Articles 20, 21, and 22.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
81 continued	Article 19 – paragraph 6 a (new)		**Amendment 119** ***6a. Members of the Medical Devices Steering Group shall not have financial or other interests in the medical devices industry that could affect their impartiality. They shall act in the public interest and in an independent manner and make an annual declaration of their financial interests and update it whenever a relevant change occurs. All indirect interests which could relate to the medical devices industry shall be entered in a register held by the Agency and be accessible to the public, upon request. The declaration of interests shall be made publicly available on the Agency's web-portal.***		

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
82	Article 20 Article 20 – paragraph 2	*Article 20* *List of critical medical devices and information to be provided* 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.		*Article 20* *List of critical medical devices and information to be provided* 1. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medical Devices ***Shortages*** Steering Group shall adopt a list of ***categories of essential medical devices and in vitro diagnostic*** medical devices which it considers as critical during the public health emergency ('the public health emergency critical devices list'). ***To the extent possible, relevant information on medical devices and in vitro diagnostics medical devices and related manufacturers shall be gathered from EUDAMED, when fully functional, and also, as appropriate, from importers and distributors. Until then, available information may be gathered also from national databases or other available sources.*** 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 Shortages Steering Group shall adopt a list of categories of essential medical devices and in vitro diagnostic medical devices which it considers as critical during the public health emergency ('the public health emergency critical devices list'). To the extent possible, synergies with existing and future databases, including EUDAMED, may be considered when the information is gathered. ~~relevant information on medical devices and in vitro diagnostics medical devices and related manufacturers shall be gathered from EUDAMED, when fully functional. Until then, available information may be gathered also from national databases or other available sources.~~ The list shall be updated whenever necessary until the termination of the recognition of the public health emergency.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
82 continued	Article 20 – paragraph 2	2. The Medical Devices Steering Group shall adopt a set of information necessary to monitor the supply and demand of medical devices included on the public health emergency critical devices list and inform its working party thereof.	**Amendment 120** 2. The Medical Devices Steering Group shall adopt a set of information necessary to monitor the supply and demand of medical devices included on the public health emergency critical devices list and inform its working party thereof. ***Union or national entities that are engaged in stockpiling of medical devices shall be informed accordingly.***	2. The Medical Devices ***Shortages*** Steering Group shall ~~adopt~~***pursuant to article 23(3) define*** a set of information necessary to monitor the supply and demand of ***medical devices and in vitro diagnostic*** medical devices included on the public health emergency critical devices list and inform its working party thereof.	2. The Medical Devices ***Shortages*** Steering Group shall adopt *and make publically available* a set of information necessary to monitor the supply and demand of ***medical devices and in vitro diagnostic*** medical devices included on the public health emergency critical devices list and inform its working party thereof.
	Article 20 – paragraph 3	3. The Agency shall publish the public health emergency critical devices list and any updates to that list on its web-portal.	**Amendment 121** 3. The Agency shall publish the public health emergency critical devices list and any updates to that list on ***a dedicated space on*** its web-portal.	3. The Agency shall publish the public health emergency critical devices list and any updates to that list on its web-portal.	3. The Agency shall publish the public health emergency critical devices list and any updates to that list on ***a dedicated space on*** its web-portal.
	Article 20 – paragraph 3 a (new)		**Amendment 122** ***3a. The Agency shall report about the shortage of critical medical devices included on the public health emergency critical devices list through the webpage referred to in Article 6(4a).***		***3a. The Agency shall report information on actual shortages of critical medical devices included on the public health emergency critical devices list through the webpage referred to in Article 6(4a).***

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
83	Article 21 Article 21 – paragraph 1	*Article 21* *Monitoring shortages of medical devices on the public health emergency critical devices list* 1. On the basis of the public health emergency critical devices list and the information and data provided in accordance with Articles 24 and 25, the Medical Devices Steering Group shall monitor supply and demand of medical devices included on that list with a view to identifying any potential or actual shortages of those medical devices. As part of that monitoring, the Medical Devices Steering Group shall liaise, where relevant, with the Health Security Committee established in Article 4 of Regulation (EU) 2020/[…] and the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation.		*Article 21* *Monitoring shortages of medical devices on the public health emergency critical devices list* 1. ~~On~~***During*** the ~~basis~~ ***recognition*** of ~~the~~ ***a*** public health emergency***, and on the basis of the*** critical ***medical devices and in vitro diagnostic medical*** devices list and the information and data provided in accordance with Articles 24 and 25, the Medical Devices ***Shortages*** Steering Group shall monitor supply and demand of ***medical devices and in vitro diagnostic*** medical devices included on that list with a view to identifying any potential or actual shortages of those medical devices. As part of that monitoring, the Medical Devices ***Shortages*** Steering Group shall liaise, where relevant, with ***the MDCG*** the Health Security Committee established in Article 4 of Regulation (EU) 2020/[…] and the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation.	1. ~~On~~ ***During*** the ~~basis~~ ***recognition*** of ~~the~~ ***a*** public health emergency, ***and on the basis of the critical medical devices and in vitro diagnostic medical*** devices list and the information and data provided in accordance with Articles 24 and 25, the Medical Devices ***Shortages*** Steering Group shall monitor supply and demand of ***medical devices and in vitro diagnostic*** medical devices included on that list with a view to identifying any potential or actual shortages of those medical devices. As part of that monitoring, the Medical Devices ***Shortages*** Steering Group shall-liaise, where relevant, with ***the MDCG,*** the Health Security Committee established in Article 4 of Regulation (EU) 2020/[…] and the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
83 continued	Article 21 – paragraph 2	2. As part of the monitoring, the Medical Devices Steering Group may also make use of data from device registries and databanks where such data is available to the Agency. In so doing, the Medical Devices Steering Group shall take into account the data generated pursuant to Article 108 of Regulation (EU) 2017/745 and Article 101 of Regulation (EU) 2017/746.		2. As part of the monitoring, the Medical Devices ***Shortages*** Steering Group may also make use of data from device registries and databanks where such data is available to the Agency. In so doing, the Medical Devices ***Shortages*** Steering Group ~~shall~~***may*** take into account the data generated pursuant to Article 108 of Regulation (EU) 2017/745 and Article 101 of Regulation (EU) 2017/746.	2. As part of the monitoring, the Medical Devices ***Shortages*** Steering Group may also make use of data from device registries and databanks where such data is available to the Agency. In so doing, the Medical Devices ***Shortages*** Steering Group ~~shall~~ ***may*** take into account the data generated pursuant to Article 108 of Regulation (EU) 2017/745 and Article 101 of Regulation (EU) 2017/746.
84	Article 22 Article 22 – paragraph 1	*Article 22* *Reporting and recommendations on shortages of medical devices* 1. For the duration of the public health emergency, the Medical Devices Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article ***23(1)(b)***, and, in particular, signal any potential or actual shortages of medical devices included on the public health emergency critical devices list.	**Amendment 123** 1. For the duration of the public health emergency, the Medical Devices Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article ***23(2)(a)***, and, in particular, signal any potential or actual shortages of medical devices included on the public health emergency critical devices list.	*Article 22* *Reporting and recommendations on shortages of medical devices* 1. For the duration of the public health emergency, the Medical Devices ***Shortages*** Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article 23(~~1)(b~~***2)(a***), and, in particular, signal any potential or actual shortages of ***medical devices and in vitro diagnostic*** medical devices included on the public health emergency critical devices list.	1. For the duration of the public health emergency, the Medical Devices ***Shortages*** Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article 23(~~1)(b~~ ***2)(a)***, and, in particular, signal any potential or actual shortages of ***medical devices and in vitro diagnostic*** medical devices included on the public health emergency critical devices list.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
84 continued	Article 22 – paragraph 2	2. Where requested by the Commission or the sub-network referred to in Article ***23(2)(b)***, the Medical Devices Steering Group shall provide aggregated data and forecasts of demand to support its findings. In that regard, the Steering Group shall liaise with the European Centre for Disease Prevention and Control to obtain epidemiological data to help forecast medical device needs, and with the Medicines Steering Group referred to in Article 3 where medical devices included on the public health emergency critical devices list are used to jointly with a medicinal product.	**Amendment 124** 2. Where requested by the Commission***, one or more national competent authorities,*** or the sub-network referred to in Article ***23(2)(a)***, the Medical Devices Steering Group shall provide aggregated data and forecasts of demand to support its findings. In that regard, the Steering Group shall liaise with the European Centre for Disease Prevention and Control to obtain epidemiological data to help forecast medical device needs, and with the Medicines Steering Group referred to in Article 3 where medical devices included on the public health emergency critical devices list are used to jointly with a medicinal product. ***The Medical Devices Steering Group shall also share its findings and conclusions with Union and national actors engaged with stockpiling of medicinal products and medical devices.***	2. Where requested by the Commission or the sub-network referred to in Article 23(2)(b), the ~~Medical Devices Steering Group~~***Shortages*** 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 ***Shortages*** Steering Group referred to in Article 3 where medical devices ***and in vitro diagnostic 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, *Member States* or the sub-network referred to in Article **23(2)(*a*)**, the Medical Devices ***Shortages*** Steering Group shall provide aggregated data and forecasts of demand to support its findings. In that regard, the Medical Devices Shortages 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 ***Shortages*** Steering Group referred to in Article 3 where medical devices ***and in vitro diagnostic medical devices*** included on the public health emergency critical devices list are used to jointly with a medicinal product. *The findings and conclusions of the Medical Devices Shortages Steering Group may also be made available to other actors in the medical device and in vitro medical device sectors, where relevant, and in accordance with relevant competition rules.*

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
84 continued	Article 22 – paragraph 3	3. As part of the reporting referred to in paragraphs 1 and 2, the Medical Devices Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, medical device manufacturers, notified bodies and other entities to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, where relevant, with the Health Security Committee and the Advisory Committee on public health emergencies.		3. As part of the reporting referred to in paragraphs 1 and 2, the Medical Devices ***Shortages*** Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, medical device manufacturers, notified bodies and other entities to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, where relevant, with the ***MDCG, the*** Health Security Committee and the Advisory Committee on public health emergencies.	3. As part of the reporting referred to in paragraphs 1 and 2, the Medical Devices ***Shortages*** Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, medical device manufacturers, notified bodies and other entities to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, where relevant, with the ***MDCG, the*** Health Security Committee and the Advisory Committee on public health emergencies.
	Article 22 – paragraph 4	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 ***Shortages*** 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 ***and in vitro diagnostic medical devices*** caused by public health emergencies.	4. The Medical Devices ***Shortages*** 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 and ***in vitro diagnostic medical devices*** caused by public health emergencies.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
84 continued	Article 22 – paragraph 5 Article 22 – paragraph 5 a (new)	5. The Medical Devices Steering Group may, upon request from the Commission coordinate measures, where relevant, between the national competent authorities, manufacturers of medical devices, notified bodies, and other entities to prevent or mitigate potential or actual shortages in the context of a public health emergency.	**Amendment 125** ***5a. Where the recommendations referred to in paragraphs 3 and 4 are not taken into account or are not implemented, the Commission, Member States, medical device manufacturers and notified bodies shall provide, where appropriate, a substantiated justification.***	5. The Medical Devices ***Shortages*** 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. *Where relevant,* the Medical Devices ***Shortages*** Steering Group may, upon request from the Commission coordinate measures **[…]** 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.
85	Article 23 Article 23 – paragraph 1	*Article 23* *Working methods and provision of information on medical devices* 1. In order to prepare for fulfilling the tasks referred to in Articles 20, 21, and 22, the Agency shall:		*Article 23* *Working methods and provision of information on medical devices* 1. In order to prepare for fulfilling the tasks referred to in Articles 20, 21, and 22, the Agency ***in liaison with MDCG, as appropriate,*** shall:	1. In order to prepare for fulfilling the tasks referred to in Articles 20, 21, and 22, the Agency shall:

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
85 continued	Article 23 – paragraph 1 – point a	(a) specify the procedures for establishing the public health emergency critical devices list;	**Amendment 126** (a) specify the procedures ***and criteria*** for establishing ***and reviewing*** the public health emergency critical devices list***, ensuring adequate consultation with manufacturers and other relevant actors in the medical devices supply chain as well as with healthcare professionals, consumers and patients***;	(a) specify the procedures for establishing the public health emergency critical devices list;	*(a)* specify the procedures ***and criteria*** for establishing ***and reviewing*** the **[…]** critical devices lists. *MDCG, healthcare professionals, patients, consumers, manufactures and other relevant actors in the medical and in vitro medical device sectors supply chain may be consulted as necessary.*
	Article 23 – paragraph 1 – point b	(b) develop streamlined electronic monitoring and reporting systems;	**Amendment 127** (b) develop streamlined electronic monitoring and reporting systems ***in coordination with the national competent authorities***;	(b) develop streamlined electronic monitoring and reporting systems***, facilitating interoperability with existing electronic tools, namely EUDAMED and providing the adequate support to Members States' competent authorities for monitoring and reporting***;	
	Article 23 – paragraph 1 – point c	(c) establish and maintain membership of the working party referred to in Article 19(5) comprised of single points of contact from Member States' national competent authorities for medical devices;		(c) establish and maintain membership of the working party referred to in Article 19(5) comprised of single points of contact from Member States' national competent authorities ~~for medical devices~~;	(c) establish and maintain membership of the working party referred to in Article 19(5) comprised of single points of contact from Member States' national competent authorities *responsible for shortage monitoring and management of medical devices and in vitro diagnostic medical devices* ~~for medical devices~~;

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
85 continued	Article 23 – paragraph 1 – point d Article 23 – paragraph 1 – point e Article 23 – paragraph 2	***(d) establish and maintain a list of single points of contact from medical device manufacturers, authorised representatives and notified bodies;*** (e) specify the methods for the provision of recommendations and coordination of measures provided for in Article 22. 2. Following the recognition of a public health emergency the Agency shall:	**Amendment 128** ***deleted***	(d) establish and maintain a list of single points of contact from medical device manufacturers, authorised representatives ~~and~~, notified bodies ***and, if appropriate, importers***; (e) specify the methods for the provision of recommendations and coordination of measures provided for in Article 22. 2. Following the recognition of a public health emergency the Agency shall:	(d) establish and maintain a list of single points of contact from medical device manufacturers, authorised representatives, ~~and~~ notified bodies ***and, if appropriate, importers;***

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
85 continued	Article 23 – paragraph 2 – point a	(a) establish and maintain for the duration of the public health emergency, a sub-network of single points of contact from medical device manufacturers and notified bodies based on the medical devices included on the public health emergency critical devices list;	**Amendment 129** (a) establish and maintain for the duration of the public health emergency, a sub-network of single points of contact from medical device manufacturers and notified bodies based on the medical devices included on the public health emergency critical devices list ***based on single points of contact to be included for all medical device manufacturers in the database referred to in Article 33 of Regulation (EU) 2017/745 and Article 30 of Regulation (EU) 2017/746***;	(a) establish and maintain for the duration of the public health emergency, a sub-network of single points of contact from medical device manufacturers***, or their authorised representatives*** and notified bodies based on the medical devices ***and in vitro diagnostic medical devices*** included on the public health emergency critical devices list. ***EUDAMED should be considered as the relevant source of information for the establishment of the sub-network of single points of contact from medical device manufacturers, authorised representatives and notified bodies***;	(a) establish and maintain for the duration of the public health emergency, a sub-network of single points of contact from medical device manufacturers, or their authorised representatives and notified bodies based on the medical devices and in vitro diagnostic medical devices included on the public health emergency critical devices list. Synergies should be established to the extent possible with existing and future databases when gathering the relevant information. ~~EUDAMED should be considered as the relevant source of information for the establishment of the sub-network of single points of contact from medical device manufacturers, authorised representatives and notified bodies;~~
	Article 23 – paragraph 2 – point b	(b) request information from the points of contact included in the sub-network based on the set of information agreed on by the Medical Devices Steering Group and set a deadline for its submission;		(b) request ***relevant*** information from the points of contact included in the sub-network based on the set of information agreed on by the Medical Devices ***Shortages*** Steering Group and set a deadline for its submission~~;~~.	(b) request ***relevant*** information from the points of contact included in the sub-network based on the set of information agreed on by the Medical Devices ***Shortages*** Steering Group and set a deadline for its submission~~;~~.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
85 continued	Article 23 – paragraph 2 – point c	(c) request information from the single points of contact from Member States' national competent authorities based on the set of information agreed on by the Medical Devices Steering Group and set a deadline for its submission.		(c) request ***relevant*** information from the single points of contact from Member States' national competent authorities based on the set of information agreed on by the Medical Devices ***Shortages*** Steering Group and set a deadline for its submission.	(c) request ***relevant*** information from the single points of contact from Member States' national competent authorities based on the set of information agreed on by the Medical Devices ***Shortages*** Steering Group and set a deadline for its submission
	Article 23 – paragraph 2 – point ca (new)			***(ca) other sources, including existing databases and databases in development, may also be used to gather part of the information required under paragraph 3.***	***(ca) other sources, including existing databases and databases in development, may also be used to gather part of the information required under paragraph 3.***
	Article 23 – paragraph 3	3. The information referred to in point (b) of paragraph 2 shall include at least:		3. The information referred to in point (b) of paragraph 2 shall include at least:	
	Article 23 – paragraph 3 – point a	(a) the name of the manufacturer and, if applicable, the name of the authorised representative;		(a) the name of the manufacturer and, if applicable, the name of the authorised representative;	
	Article 23 – paragraph 3 – point b	(b) identification of the medical device and the intended purpose;		(b) identification of the medical device and the intended purpose ***and if applicable specific characteristics***;	(b) identification of the medical device *and in vitro diagnostic medical device* and the intended purpose and *where necessary*, ***specific characteristics;***

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
85 continued	Article 23 – paragraph 3 – point c Article 23 – paragraph 3 – point d Article 23 – paragraph 3 – point e	(c) if applicable, the name and number of the notified body and information on the relevant certificate or certificates; (d) details of the potential or actual shortage such as actual or estimated start and end dates, and the known or suspected cause; (e) sales and market share data;		(c) if applicable, the name and number of the notified body and information on the relevant certificate or certificates; (d) details of the potential or actual shortage such as actual or estimated start and end dates, and the known or suspected cause; (e) sales and market share data;	
	Article 23 – paragraph 3 – point ea (new)		**Amendment 130** ***(ea) available stocks;***		***(ea) available stocks***
	Article 23 – paragraph 3 – point eb (new)		**Amendment 131** ***(eb) quantities already delivered;***		***(eb) quantities already delivered***
	Article 23 – paragraph 3 – point ec (new)		**Amendment 132** ***(ec) projected deliveries;***		***(ec) projected deliveries***
	Article 23 – paragraph 3 – point f	(f) mitigation plans including production and supply capacity;	**Amendment 133** (f) ***prevention and*** mitigation plans including ***information on*** production and supply capacity ***with a view to guarantee continued supply and prevent shortages of medical devices included on the public health emergency critical devices list.***	(f) mitigation plans including production and supply capacity;	(f) ***prevention and*** mitigation plans ***at least*** including ***information on*** production and supply capacity;

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
85 continued	Article 23 – paragraph 3 – point g	(g) information from concerned notified bodies about their resource capacity to process applications and carry out and complete conformity assessments in relation to medical devices included in the public health emergency critical devices list;		(g) information from concerned notified bodies about their resource capacity to process applications and carry out and complete ~~conformity assessments in relation to~~, ***in an appropriate period of time considering the emergency, conformity assessments in relation to medical devices and in vitro diagnostic medical devices included in the public health emergency critical devices list. The notified body concerned shall communicate the date by which the assessment is completed. In this regard notified bodies shall prioritise the conformity assesment of medical devices and in vitro diagnostic*** medical devices included in the public health emergency critical devices list;	(g) information from concerned notified bodies about their resource capacity to process applications and carry out and complete ~~conformity assessments in relation to~~, ***in an appropriate period of time considering the emergency, conformity assessments in relation to medical devices and in vitro diagnostic medical devices included in the public health emergency critical devices list. The notified body concerned shall communicate the date by which the assessment is*** *expected to be* ***completed. In this regard notified bodies shall prioritise the conformity assesment of medical devices and in vitro diagnostic*** medical devices included in the public health emergency critical devices list;
	Article 23 – paragraph 3 – point h	(h) information on the number of applications received by concerned notified bodies in relation to medical devices included in the public health emergency critical devices list and relevant conformity assessment procedures;		(h) information on the number of applications received by concerned notified bodies in relation to medical devices ***and in vitro diagnostic medical devices*** included in the public health emergency critical devices list and relevant conformity assessment procedures;	(h) information on the number of applications received by concerned notified bodies in relation to medical devices ***and in vitro diagnostic medical devices*** included in the public health emergency critical devices list and relevant conformity assessment procedures;

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
85 continued	Article 23 – paragraph 3 – point i	(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.		(i) where conformity assessments are on-going, the status of the conformity assessment by the concerned notified bodies in relation to medical devices ***and in vitro diagnostic medical devices*** included in the public health emergency critical devices list and possible ***critical*** issues ***that have impact and*** which need to be ~~resolved~~***considered*** in order to complete the conformity assessment process.	*(i)* where conformity assessments are on-going, the status of the conformity assessment by the concerned notified bodies in relation to medical devices and ***in vitro diagnostic medical devices*** included in the public health emergency critical devices list and possible ***critical*** issues ***that have impact and*** which need to be ~~resolved~~***considered*** in order to complete the conformity assessment process.
86	Article 24	*Article 24* *Obligations on medical device manufacturers, authorised representatives, and notified bodies*		*Article* 24 *Obligations on medical device manufacturers, authorised representatives,* ***importers, distributors*** *and notified bodies*	

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
86 continued	Article 24 – paragraph 1	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~~***or their authorised representatives, as applicable, and, if appropriate, importers, distributors,*** 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~~ ***or their authorised representatives, as applicable, and, if appropriate, importers*** *and* ***distributors*** *of 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.
	Article 24 – paragraph 2	2. Medical device manufacturers and notified bodies shall justify the absence of any requested information and any delays in providing it by the deadline set by the Agency.		2. Medical device manufacturers ~~and~~***or their authorised representatives, as applicable,*** *notified bodies* ***and, if appropriate, importers and distributors*** shall justify the absence of any requested information and any delays in providing it by the deadline set by the Agency.	2. Medical device manufacturers ~~and~~***or their authorised representatives, as applicable,*** notified bodies ***and, if appropriate, importers*** *and* ***distributors*** *of medical devices* shall justify the absence of any requested information and any delays in providing it by the deadline set by the Agency.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
86 continued	Article 24 – paragraph 3	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.		3. Where manufacturers ~~of~~, ***or their authorised representatives and, if apropriate, importers and distributors of medical devices and in vitro diagnostic*** 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.	3. Where manufacturers ~~of~~, ***or their authorised representatives and, if appropriate, importers and distributors of medical devices and in vitro diagnostic*** 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.
	Article 24 – paragraph 4	4. Where manufacturers of medical devices included on the public health emergency critical devices list and concerned notified bodies are in possession of any additional information, which provides evidence of a potential or actual shortage, they shall immediately provide such information to the Agency.		4. Where manufacturers ***or their authorised representatives and, if apropriate, importers and distributors*** *of* ***medical devices and in vitro diagnostic*** medical devices included on the public health emergency critical devices list and concerned notified bodies are in possession of any additional information, which provides evidence of a potential or actual shortage, they shall immediately provide such information to the Agency.	4. Where manufacturers ***or their authorised representatives and, if appropriate, importers and distributors*** of ***medical devices and in vitro diagnostic*** medical devices included on the public health emergency critical devices list and concerned notified bodies are in possession of any additional information, which provides evidence of a potential or actual shortage, they shall immediately provide such information to the Agency.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
86 continued	Article 24 – paragraph 5	5. Following the reporting on the results of the monitoring and any recommendations on preventive or mitigating measures in accordance with Article 22, manufacturers of medical devices included on the public health emergency critical devices list and concerned notified bodies shall:		5. Following the reporting on the results of the monitoring and any recommendations on preventive or mitigating measures in accordance with Article 22, manufacturers ~~of~~***or their authorised representatives and, if appropriate, importers and distributors of medical devices and in vitro diagnostic*** medical devices included on the public health emergency critical devices list and concerned notified bodies shall:	5. Following the reporting on the results of the monitoring and any recommendations on preventive or mitigating measures in accordance with Article 22, manufacturers ~~of~~ ***or their authorised representatives and, if appropriate, importers and distributors of medical devices and in vitro diagnostic*** medical devices included on the public health emergency critical devices list and concerned notified bodies shall:
	Article 24 – paragraph 5 – point a	(a) provide any comments they have to the Agency;		(a) provide any comments they have to the Agency;	
	Article 24 – paragraph 5 – point b	(b)		(b)~~—~~	
	Article 24 – paragraph 5 – point c	(c) take into account any recommendations and guidelines and comply with any measures taken at Union and Member State-level pursuant to Articles 25 and 26;		(***b***) take into account any recommendations and guidelines and comply with any measures taken at Union and Member State-level pursuant to Articles 25 and 26;	
	Article 24 – paragraph 5 – point d	(d) inform the Medical Devices Steering Group of any measures taken and report on the results, including information on the resolution of the potential or actual shortage.		(~~d~~***c***) inform the Medical Devices ***Shortages*** Steering Group of any measures taken and report on the results, including information on the resolution of the potential or actual shortage.	(~~d~~***c***) inform the Medical Devices ***Shortages*** Steering Group of any measures taken and report on the results, including information on the resolution of the potential or actual shortage.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
86 continued	Article 24 – paragraph 6	6. Where manufacturers of medical devices included on the public health emergency critical devices list are established outside the Union and are unable to provide the information required, in accordance with this Article, it shall be provided by the authorised representatives.		6. Where manufacturers of medical devices ***and in vitro diagnostic medical devices*** included on the public health emergency critical devices list are established outside the Union ~~and are unable to provide~~**,** the information required~~,~~ in accordance with this Article~~, it~~ shall be provided by the authorised representatives~~.~~ ***, or, if appropriate, importers and distributors.***	6. Where manufacturers of medical devices ***and in vitro diagnostic medical devices*** included on the public health emergency critical devices list are established outside the Union~~and are unable to provide~~, the information required~~,~~ in accordance with this Article~~, it~~ shall be provided by the authorised representatives~~.~~ ***, or, if appropriate, importers and distributors.***
87	Article 25 Article 25 – paragraph 1	*Article 25* *Obligations on Member States in the monitoring and mitigation of shortages of medical devices* 1. In order to facilitate the monitoring referred to in Article 21 and following a request from the Agency, Member States shall, by the deadline set by the Agency:		*Article 25* *~~Obligations on~~**Role of** Member States in the monitoring and mitigation of shortages of medical devices* 1. In order to facilitate the monitoring referred to in Article 21 and following a request from the Agency, Member States shall, by the deadline set by the Agency:	*Article 25* *~~Obligations on~~**Role of** Member States in the monitoring and mitigation of shortages of medical devices*

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
87 continued	Article 25 – paragraph 1 – point a	(a) submit the set of information requested by the Agency, including information about needs related to the medical devices included in the public health emergency critical devices list, and available and estimated data on the volume of demand, through its designated point of contact and using the reporting methods and system established pursuant to Article 23(1);		(a) submit the set of information requested by the Agency, including ***available*** information about needs related to the medical devices ***and in vitro diagnostic medical devices*** included in the public health emergency critical devices list, and available ~~and~~***or*** estimated data on the volume of demand, through its designated point of contact and using the reporting methods and system established pursuant to Article 23(1);	(a) submit the set of information requested by the Agency, including ***available*** information about needs related to the medical devices ***and in vitro diagnostic medical devices*** included in the public health emergency critical devices list, and available *and* estimated data on the volume of demand, through its designated point of contact and using the reporting methods and system established pursuant to Article 23(1);
	Article 25 – paragraph 1 – point b	(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 24 (3);***	(b) indicate the existence of any commercially confidential information, and, clarify the reasons for such an indication~~;~~ ***, in accordance with Article 24 (3);***
	Article 25 – paragraph 1 – point c	(c) indicate the absence of any requested information, and any delays in providing requested information by the deadline set by the Agency.		(c) indicate the absence of any requested information, and any delays in providing requested information by the deadline set by the Agency.	

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
87 continued	Article 25 – paragraph 2	2. Where necessary to fulfil their reporting obligations set out in paragraph 1, Member States shall gather information from manufacturers, importers, distributors and notified bodies on medical devices included on the public health emergency critical devices list.	**Amendment 134** 2. Where necessary to fulfil their reporting obligations set out in paragraph 1, Member States shall gather information from manufacturers, importers, distributors***, healthcare professionals*** and notified bodies on medical devices included on the public health emergency critical devices list.	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 ***and in vitro diagnostic 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 *and their authorised representatives,* ***healthcare*** *providers*, importers, distributors*, as applicable,* and notified bodies on medical devices ***and in vitro diagnostic medical devices*** included on the public health emergency critical devices list.
	Article 25 – paragraph 3	3. Where Member States are in possession of any additional information, which provides evidence of a potential or actual shortage, they shall immediately provide such information to the Medical Devices Steering Group through their designated points of contact.		3. Where Member States are in possession of any additional information, which provides evidence of a potential or actual shortage, they shall immediately provide such information to the Medical Devices ***Shortages*** Steering Group through their designated points of contact.	3. Where Member States are in possession of any additional information, which provides evidence of a potential or actual shortage, they shall immediately provide such information to the Medical Devices ***Shortages*** Steering Group through their designated points of contact.
	Article 25 – paragraph 4	4. Following the reporting on the results of the monitoring and any recommendations on preventive or mitigating measures in accordance with Article 22, Member States shall:		4. Following the reporting on the results of the monitoring and any recommendations on preventive or mitigating measures in accordance with Article 22, Member States shall:	

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
87 continued	Article 25 – paragraph 4 – point a	(***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;	**Amendment 135** (***a***) consider the need to provide for temporary exemptions at Member State level pursuant to Article 59(1) of Regulation (EU) 2017/745 or Article 54(1) of Regulation (EU) 2017/746 with a view to mitigating potential or actual shortages of medical devices included on the public health emergency critical devices list***, while at the same time ensuring a high level of patient and product safety***;	(~~b~~***a***) consider the need to provide for temporary exemptions at Member State level pursuant to Article 59(1) of Regulation (EU) 2017/745 or Article 54(1) of Regulation (EU) 2017/746 with a view to mitigating potential or actual shortages of medical devices ***and in vitro diagnostic medical devices*** included on the public health emergency critical devices list;	(~~b~~***a***) consider the need to provide for temporary exemptions at Member State level pursuant to Article 59(1) of Regulation (EU) 2017/745 or Article 54(1) of Regulation (EU) 2017/746 with a view to mitigating potential or actual shortages of medical devices ***and in vitro diagnostic medical devices*** included on the public health emergency critical devices list; ***while at the same time*** *seeking to ensure* ***a high level of patient and product safety;***
	Article 25 – paragraph 4 – point b	(c) take into account any recommendations and guidelines and comply with any measures taken at Union-level pursuant to Article 26;		~~(c) take into account~~***(b) consider*** any recommendations~~ and~~**,** guidelines and ~~comply with any~~ measures taken at Union-level pursuant to Article 26 ***(a)***;	*(~~c~~**b**)* Take into account any recommendations and guidelines and comply with any measures taken at Union level pursuant to Article 26 **(a)**;

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
87 continued	Article 25 – paragraph 4 – point c	(d) inform the Medical Devices Steering Group of any measures taken and report on the results of those measures, including information on the resolution of the potential or actual shortage.		(~~d~~c) inform the Medical Devices ***Shortages*** Steering Group of any measures taken and report on the results of those measures, including information on the resolution of the potential or actual shortage.	*(~~d~~c)* inform the Medical Devices ***Shortages*** Steering Group of any measures taken and report on the results of those measures, including information on the resolution of the potential or actual shortage. *Where an alternative course of action has been taken at national level, the Member States where such alternative occurred, shall share, in a timely manner, the reasons to the Medical Devices Shortages Steering Group. The recommendations, guidelines and measures taken at Union level pursuant to Article 26(a) and a summary report of the lessons learned, shall be made publicly available via the web-portal as referred to in Article 13.*

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
88	Article 26 Article 26 – paragraph 1 Article 26 – paragraph 1 – point a	*Article 26* *Role of the Commission in the monitoring and mitigation of shortages of medical devices* The Commission shall take into account the information from and recommendations of the Medical Devices Steering Group and shall: (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;	**Amendment136** (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***;	*Article 26* *~~Role~~**Obligations**s of the Commission in the monitoring and mitigation of shortages of medical devices* The Commission shall take into account the information from and recommendations of the Medical Devices ***Shortages*** Steering Group and shall: (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 ***and in vitro diagnostic 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 respecting the conditions set in those articles***;	*Role of the Commission in the monitoring and mitigation of shortages of medicinal products* The Commission shall take into account the information from and recommendations of the Medical Devices ***Shortages*** Steering Group and shall: (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 ***and in vitro diagnostic 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 respecting the conditions set in those articles*** *and* ***at the same time*** *seeking to ensure* ***both patient and product safety;***

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
88 continued	Article 26 – paragraph 1 – point b	(b) consider the need for guidelines addressed to Member States, medical device manufacturers, notified bodies and other entities;	**Amendment 137** (b) consider the need for guidelines addressed to Member States, medical device manufacturers, notified bodies, ***healthcare professionals*** and other entities ***where this is proportionate, justified and necessary***;	(b) consider the need for guidelines addressed to Member States, medical device manufacturers, notified bodies and other entities;	(b) consider the need for guidelines *and recommendations* addressed to Member States, medical device manufacturers, notified bodies, and other entities***,*** *where relevant**;***
	Article 26 – paragraph 1 – point c	(c) request the Medical Devices Steering Group to provide recommendations or coordinate measures pursuant to Article 22(3), (4) and (5);		(c) request the Medical Devices ***Shortages*** Steering Group to provide recommendations or coordinate measures pursuant to Article 22(3), (4) and (5);	*(c)* request the Medical Devices ***Shortages*** Steering Group to provide recommendations or coordinate measures pursuant to Article 22(3), (4) and (5);
	Article 26 – paragraph 1 – point d	(d) consider the need for medical countermeasures in accordance with Articles 12 and 25(b) of Regulation (EU) 2020/[…];		(d) consider the need for medical countermeasures in accordance with Articles 12 and 25(b) of Regulation (EU) 2020/[…];	

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
88 continued	Article 26 – paragraph 1 – point e	(e) liaise with third countries and relevant international organisations, as appropriate, to mitigate potential or actual shortages of medical devices included on the critical devices list or their component parts, where those devices or parts are imported into the Union, and where such potential or actual shortages have international implications.	**Amendment 138** (e) liaise with third countries and relevant international organisations, as appropriate, to mitigate potential or actual shortages of medical devices included on the critical devices list or their component parts, where those devices or parts are imported into the Union, and where such potential or actual shortages have international implications***, and report these actions as well as the results obtained to the Medical Devices Steering Group***.	(e) liaise with third countries and relevant international organisations, as appropriate, to mitigate potential or actual shortages of medical devices ***and in vitro diagnostic 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 ***and in vitro diagnostic medical devices*** included on the critical devices list or their component parts, where those devices or parts are imported into the Union, and where such potential or actual shortages have international implications***, and report these actions as well as the results obtained to the Medical Devices Shortages Steering Group, where relevant.***

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
89	Article 27 Article 27 – paragraph 1 Article 27 – paragraph 1a (new)	*Article 27* *Communication on 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.	**Amendment 139** The Agency shall, via ***a dedicated space in*** its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups ***in a timely manner*** with regard to the work of the Medical Devices Steering Group ***and respond to disinformation targeting the work of the Medical Devices Steering Group as appropriate***. **Amendment 140** ***Proceedings undertaken by the Medical Devices Steering Group shall be transparent. The agenda and minutes of the Medical Devices Steering Group as well as the rules of procedure and recommendations and, where appropriate, votes shall be documented and made publicly available, including any dissensions.***	*Article 27* *Communication on the Medical Devices **Shortages** 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 **Shortages** Steering Group.	*Communication on the Medical Devices **Shortages** Steering Group* The Agency shall, ***via a dedicated space in*** its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups ***in a timely manner*** with regard to the work of the Medical Devices **Shortages** Steering Group ***and respond to disinformation targeting the work of the Medical Devices Shortages Steering Group as appropriate.***

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
90	Article 28	*Article 28* *Support for the expert panels on medical devices*		*Article 28* *Support for the expert panels on medical devices*	*Article 28* *Support for the expert panels on medical devices*
			Amendment 141		
		The Agency shall, on behalf of the Commission***, from 1 March 2022 onwards***, provide the secretariat of the expert panels designated in accordance with Implementing Decision (EU) 2019/1396 and provide the support necessary to ensure that those panels can efficiently perform their tasks as set out in Article 106(9) and (10) of Regulation (EU) 2017/745. The Agency shall:	The Agency shall, on behalf of the Commission, provide the secretariat of the expert panels designated in accordance with Implementing Decision (EU) 2019/1396 and provide the support necessary to ensure that those panels can efficiently perform their tasks as set out in Article 106(9) and (10) of Regulation (EU) 2017/745. The Agency shall:	***1.*** The Agency shall, on behalf of the Commission, from 1 March 2022 onwards, provide the secretariat of the expert panels designated in accordance with ~~Implementing Decision~~***Article 106(1) of Regulation*** (EU) ~~2019/1396~~***2017/745*** and provide the support necessary to ensure that those panels can efficiently perform their tasks as set out in Article 106(9) and (10) of Regulation (EU) 2017/745. The Agency shall:	The Agency shall, on behalf of the Commission, ***from 1 March 2022 onward,*** provide the secretariat of the expert panels designated in accordance with ~~Implementing Decision~~***Article 106(1) of Regulation*** (EU) ~~2019/1396~~***2017/745*** and provide the support necessary to ensure that those panels can efficiently perform their tasks as set out in Article 106(9) and (10) of Regulation (EU) 2017/745. The Agency shall:
			Amendment 142		
	Article 28 – paragraph 1 – point a	(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;	(a) provide administrative and technical support to the expert panels for the provision of scientific opinions, views and advice;	(a) provide administrative and technical support to the expert panels for the provision of scientific opinions, views and advice;
	Article 28 – paragraph 1 – point b	(b) facilitate and manage remote and physical meetings of the expert panels;		(b) facilitate and manage remote and physical meetings of the expert panels;	

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
90 continued	Article 28 – paragraph 1 – point c	(c) ensure that the work of the expert panels is carried out in an independent manner in accordance with Article 106(3), second subparagraph of Regulation (EU) 2017/745 and establish systems and procedures to actively manage and prevent potential conflicts of interest in accordance with Article 106(3), third subparagraph and Article 107 of that Regulation;		(c) ensure that the work of the expert panels is carried out in an independent manner in accordance with Article 106(3), second subparagraph ***and Article 107*** of Regulation (EU) 2017/745 and ~~establish~~***with the*** systems and procedures ***established by the Commission*** to actively manage and prevent potential conflicts of interest in accordance with Article 106(3), third subparagraph ~~and Article 107~~ of that Regulation;	(c) ensure that the work of the expert panels is carried out in an independent manner in accordance with Article 106(3), second subparagraph ***and Article 107*** of Regulation (EU) 2017/745 and ~~establish~~***with the*** systems and procedures ***established by the Commission*** to actively manage and prevent potential conflicts of interest in accordance with Article 106(3), third subparagraph ~~and Article 107~~ of that Regulation;
	Article 28 – paragraph 1 – point d	(d) maintain and regularly update a web-page for the expert panels and make publicly available on the web-page all information necessary to ensure the transparency of the activities of the expert panels, including justifications of notified bodies where they did not follow the advice of the expert panels provided pursuant to Article 106(9) of Regulation (EU) 2017/745;		(d) maintain and regularly update a web-page for the expert panels and make publicly available on the web-page all information necessary ***not already publicly available in EUDAMED*** to ensure the transparency of the activities of the expert panels, including justifications of notified bodies where they did not follow the advice of the expert panels provided pursuant to Article 106(9) of Regulation (EU) 2017/745;	(d) maintain and regularly update a web-page for the expert panels and make publicly available on the web-page all information necessary ***not already publicly available in EUDAMED*** to ensure the transparency of the activities of the expert panels, including justifications of notified bodies where they did not follow the advice of the expert panels provided pursuant to Article 106(9) of Regulation (EU) 2017/745;

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
90 continued	Article 28 – paragraph 1 – point e	(e) publish the scientific opinions, views, and advice of the panels while ensuring confidentiality in accordance with Article106(12) second subparagraph and Article 109 of Regulation (EU) 2017/745;		(e) publish***, on behalf of the Commission,*** the scientific opinions, views, and advice of the panels while ensuring confidentiality in accordance with Article106(12) second subparagraph and Article 109 of Regulation (EU) 2017/745;	(e) publish the scientific opinions, views, and advice of the panels while ensuring confidentiality in accordance with Article 106(12) second subparagraph and Article 109 of Regulation (EU) 2017/745;
	Article 28 – paragraph 1 – point f	(f) ensure that remuneration and expenses are provided to the experts in accordance with Article 11 of Implementing Decision (EU) 2019/1396;		(f) ensure that remuneration and expenses are provided to the experts in accordance with ***implementing acts adopted by the Commission pursuant to*** Article ~~11~~***106(1)*** of ~~Implementing Decision~~***Regulation*** (EU) ~~2019/1396~~***2017/745***;	(f) ensure that remuneration and expenses are provided to the experts in accordance with ***implementing acts adopted by the Commission pursuant to*** Article ~~11~~***106(1)*** of ~~Implementing Decision~~***Regulation*** (EU) ~~2019/1396~~***2017/745***;
	Article 28 – paragraph 1 – point g	(g) monitor compliance with the panels' common rules of procedure and available guidelines and methodologies relevant to the functioning of the panels;		(g) monitor compliance with the panels' common rules of procedure and available guidelines and methodologies relevant to the functioning of the panels;	(g) monitor compliance with the panels' common rules of procedure and available guidelines and methodologies relevant to the functioning of the panels;
	Article 28 – paragraph 1 – point h	(h) provide annual reports to the Commission on the work undertaken by the expert panels, including the number of opinions, views and advice delivered.		(h) provide annual reports to the Commission ***and the MDCG*** on the work undertaken by the expert panels, including the number of opinions, views and advice delivered.	(h) provide annual reports to the Commission ***and the MDCG*** on the work undertaken by the expert panels, including the number of opinions, views and advice delivered.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
90 continued	Article 28 – paragraph 2 (new) Article 28 – paragraph 3 (new)			***2. In order to perform the Agency's tasks, as described under the previous paragraph, the Agency shall establish a collaborative strategy on the administrative and technical support of the work of the expert panels together with Commission and MDCG.*** ***3. The Agency should periodically, at least twice a year, consult the MDCG on the ongoing work of the expert panels in order to present a report of the tasks performed and to discuss and align the strategy defined in point 2.***	
91	Chapter V	**Chapter V** **Final Provisions**		**Chapter V** **Final Provisions**	
92	Article 29 Article 29 – paragraph 1	*Article 29* *Cooperation between Steering Groups* 1. The Agency shall ensure cooperation between the Medicines and Medical Devices Steering Groups in relation to measures to address major events and public health emergencies.		*Article 29* *Cooperation between Steering Groups**, Emergency Task Force and the expert panels*** 1. The Agency shall ensure cooperation between the Medicines and Medical Devices ***Shortages*** Steering Groups in relation to measures to address major events and public health emergencies.	*Article 29* *Cooperation between Steering Groups**, Emergency Task Force and the expert panels*** 1. The Agency shall ensure cooperation between the Medicines and Medical Devices ***Shortages*** Steering Groups in relation to measures to address major events and public health emergencies.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
92 continued	Article 29 – paragraph 2 Article 29 – paragraph 3 Article 29 – paragraph 4 (new)	2. Members of the Medicines and Medical Devices Steering Groups and their working parties may attend each other's meetings and working parties and, where appropriate, cooperate on monitoring exercises, reporting and opinions. 3. In agreement with the Chairs, joint meetings of the Medicines and Medical Devices Steering Groups may be held.		2. Members of the Medicines and Medical Devices ***Shortages*** Steering Groups and their working parties may attend each other's meetings and working parties and, where appropriate, cooperate on monitoring exercises, reporting and opinions. 3. In agreement with the ***(Co-)*** Chairs, joint meetings of the Medicines and Medical Devices Steering ~~Groups~~***Shortages Group*** may be held. ***4. Where relevant, the Agency shall ensure cooperation between the Emergency Task Force and the expert panels in relation to preparedness and management of public health crises.***	2. Members of the Medicines and Medical Devices ***Shortages*** Steering Groups and their working parties may attend each other's meetings and working parties and, where appropriate, cooperate on monitoring exercises, reporting and opinions. 3. In agreement with the ***(Co-)*** Chairs, joint meetings of the Medicines and Medical Devices Steering ~~Groups~~***Shortages Group*** may be held. ***4. Where relevant, the Agency shall ensure cooperation between the Emergency Task Force and the expert panels in relation to preparedness and management of public health crises.***

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
93	Article 29 a (new)		**Amendment 143** ***Article 29a*** ***Protection against cyber-attacks*** ***The Agency shall be equipped with a high level of security controls and processes against cyber-attacks, cyber-espionage and other data breaches to ensure the protection of health data and the normal functioning of the Agency at all times, and especially during public health emergencies or major events at Union level. To that end, the Agency shall actively pursue and implement best cybersecurity practices within Union institutions, bodies, offices and agencies to prevent, detect, mitigate, and respond to cyber-attacks.***		***Article 29a*** ***Protection against cyber-attacks*** ***The Agency shall be equipped with a high level of security controls and processes against cyber-attacks, cyber-espionage and other data breaches to ensure the protection of health data and the normal functioning of the Agency at all times, and especially during public health emergencies or major events at Union level. To that end, the Agency shall actively pursue and implement best cybersecurity practices within Union institutions, bodies, offices and agencies to prevent, detect, mitigate, and respond to cyber-attacks.***

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
94	Article 29 b (new)		**Amendment 144** ***Article 29b*** ***Penalties*** ***Member States shall lay down the rules on penalties applicable to infringements of the obligations established in Articles 10 and 24 and shall take all measures necessary to ensure that they are implemented. The penalties provided for, including financial, shall be effective, proportionate, and dissuasive. Member States shall by... [six months after the date of entry into force of this Regulation] notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.***		

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
95	Article 30 Article 30 – paragraph 1	*Article 30* *Confidentiality* 1. Unless otherwise provided for in this Regulation and without prejudice to Regulation (EC) No 1049/2001 and existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:	**Amendment 145** 1. Unless otherwise provided for in this Regulation and without prejudice to Regulation (EC) No 1049/2001[24] ***and Directive (EU) 2019/1937 of the European Parliament and of the Council***[24a], and existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following: [24a] ***Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of persons who report breaches of Union law (OJ L 305, 26.11.2019, p. 17).***	*Article 30* ~~*Confidentiality*~~ ***Commercially confidential information*** 1. Unless otherwise provided for in this Regulation and without prejudice to Regulation (EC) No 1049/2001 and existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect ~~the following:~~	*Article 30* *Confidentiality* 1. Unless otherwise provided for in this Regulation and without prejudice to Regulation (EC) No 1049/2001[24] ***and Directive (EU) 2019/1937 of the European Parliament and of the Council***[24a], and existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
95 continued	Article 30 – paragraph 1 – point a	***(a) personal data in accordance with Article 32;***	**Amendment 146** ***deleted***	~~(a) personal data in accordance with Article 32;~~	~~a) personal data in accordance with Article 32;~~
	Article 30 – paragraph 1 – point b	(b) ***commercially confidential information and*** trade secrets of a natural or legal person***, including*** intellectual property rights;	**Amendment 147** (b) trade secrets of a natural or legal person ***in accordance with Directive (EU) 2016/943 of the European Parliament and of the Council[1a], as well as other commercially confidential information and*** intellectual property rights; ***[1a] Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (OJ L 157, 15.6.2016, p. 1).***	~~(b)~~ commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights~~;~~.	(b) *commercially confidential information and* trade secrets of a natural or legal person ***in accordance with Directive (EU) 2016/943 of the European Parliament and of the Council[1a], ~~as well as other commercially confidential information and~~*** intellectual property rights;
	Article 30 – paragraph 1 – point c	(c) the effective implementation of this Regulation.		~~(c) the effective implementation of this Regulation.~~	~~(c) the effective implementation of this Regulation.~~

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
95 continued	Article 30 – paragraph 2	2. All parties involved in the application of this Regulation shall ensure that no commercially confidential information is shared in a way which has the potential to enable undertakings to restrict or distort competition in the meaning of Article 101 TFEU.		2. ***Without prejudice to paragraph 1,*** ~~A~~all parties involved in the application of this Regulation shall ensure that no commercially confidential information is shared in a way which has the potential to enable undertakings to restrict or distort competition in the meaning of Article 101 TFEU.	2. ***Without prejudice to paragraph 1,*** ~~A~~all parties involved in the application of this Regulation shall ensure that no commercially confidential information is shared in a way which has the potential to enable undertakings to restrict or distort competition in the meaning of Article 101 TFEU.
	Article 30 – paragraph 3	3. Without prejudice to paragraph 1, information exchanged on a confidential basis between competent authorities and between competent authorities and the Commission and the Agency shall not be disclosed without the prior agreement of the authority from which that information originates.		3. Without prejudice to paragraph 1, information exchanged on a confidential basis between competent authorities and between competent authorities and the Commission and the Agency shall not be disclosed without the prior agreement of the authority from which that information originates.	3. Without prejudice to paragraph 1, information exchanged on a confidential basis between competent authorities and between competent authorities and the Commission and the Agency shall not be disclosed without the prior agreement of the authority from which that information originates.
	Article 30 – paragraph 4	4. Paragraphs 1, 2, and 3 shall not affect the rights and obligations of the Commission, the Agency, Member States and other actors identified in this Regulation with regard to the exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.		4. Paragraphs 1, 2, and 3 shall not affect the rights and obligations of the Commission, the Agency, Member-States and other actors identified in this Regulation with regard to the exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.	4. Paragraphs 1, 2, and 3 shall not affect the rights and obligations of the Commission, the Agency, Member-States and other actors identified in this Regulation with regard to the exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
95 continued	Article 30 – paragraph 5	5. The Commission, the Agency, and Member States may exchange commercially confidential information ***and, where necessary to protect public health, personal data,*** with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.	**Amendment 148** ***5. The Commission, the Agency, and Member States may exchange commercially confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.***	5. The Commission, the Agency, and Member States may exchange commercially confidential information ~~and, where necessary to protect public health, personal data,~~ with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.	***5. The Commission, the Agency, and Member States may exchange commercially confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.***
96	Article 30a (new)		**Amendment 149** ***Article 30a*** ***Personal data protection*** ***1. Transfers of personal data under this Regulation shall be subject to Regulations (EU) 2016/679 and (EU) 2018/1725 as applicable.***	***Article 30a*** ***Personal data protection*** ***1. Transfers of personal data under this Regulation shall be subject to Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 as applicable.***	***Article 30a*** ***Personal data protection*** ***1. Transfers of personal data under this Regulation shall be subject to Regulations (EU) 2016/679 and (EU) 2018/1725 as applicable.***

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
96 continued			***2. For transfers of personal data to a third country, in the absence of an adequacy decision, or of appropriate safeguards, as referred to in Article 49(1) of Regulation (EU) 2016/679 and Article 50(1) of Regulation (EU) 2018/1725, the Commission, the Agency, and Member States may exchange personal data with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements where it is necessary for important reasons of public interest, such as to protect public health.***	***2. In the absence of an adequacy decision, or of appropriate safeguards, as referred to in Article 49(1) of Regulation (EU) 2016/679 and Article 50(1) of Regulation (EU) 2018/1725, the Commission, the Agency, and Member States may exchange personal data with regulatory authorities of third countries where necessary for the prevention of or response to a serious threat to public health of a Member State or a third country.***	***2. For transfers of personal data to a third country, in the absence of an adequacy decision, or of appropriate safeguards, as referred to in Article 49(1) of Regulation (EU) 2016/679 and Article 50(1) of Regulation (EU) 2018/1725, the Commission, the Agency, and Member States may exchange personal data with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements where it is necessary for important reasons of public interest, such as to protect public health.***

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
97	Article 30b (EP) Article 30c (Council) (new)		**Amendment 150** ***Article 30b*** ***Review*** ***By 31 December 2026 the Commission shall submit to the European Parliament and to the Council an evaluation report on the functioning of this Regulation, accompanied, if appropriate, by a legislative proposal to amend it. This report shall specifically consider the possible extension of the scope to medicinal products for veterinary use.***	***Article 30c*** ***Evaluation and Reporting*** ***By [xxx] and every [xxx] years thereafter the Commission shall carry out an evaluation of this Regulation and present a report on the main findings to the European Parliament and the Council, on the crisis preparedness and management framework for medicines and medical devices, including the use of periodic stress tests, accompanied by legislative proposals as appropriate, considering the possible extension of the scope to medicinal products for veterinary use and to PPE for medical use and the possible need to adapt the definitions provided for in Article 2.***	***Article 30c*** ***Evaluation and Reporting*** ***By [xxx] and every [xxx] years thereafter the Commission shall carry out an evaluation of this Regulation and present a report on the main findings to the European Parliament and the Council, on the crisis preparedness and management framework for medicines and medical devices, including the use of periodic stress tests, accompanied by legislative proposals as appropriate, considering the possible extension of the scope to medicinal products for veterinary use and to PPE for medical use and the possible need to adapt the definitions provided for in Article 2.*** *+ recital and a definition of "stress tests"*

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
98	Article 30b (Council) (new)			***Article 30b*** ***Union funding*** ***1. The financing of the Agency's activities in support of the work of the Medicines Shortages and Medical Devices Shortages Steering Groups, the Emergency Task Force, their working parties and expert panels, involving its cooperation with the Commission and the European Centre for Disease Prevention and Control shall be ensured by the Union. The Union's financial assistance to the activities under this Regulation shall be implemented in accordance with Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council.***	***Article 30b*** ***Union funding*** ***1. The financing of the Agency's activities in support of the work of the Medicines Shortages and Medical Devices Shortages Steering Groups, the Emergency Task Force, their working parties and expert panels, involving its cooperation with the Commission and the European Centre for Disease Prevention and Control shall be ensured by the Union. The Union's financial assistance to the activities under this Regulation shall be implemented in accordance with Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council.***

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
98 continued				***2. The Agency shall remunerate the activities of the Members States' representatives and experts in relation to the Emergency Task Force under this Regulation and reimburse the costs of the Member States' representatives and experts related to the meetings of the Medicines Shortages and Medical Devices Shortages Steering Groups, the Emergency Task Force and their working parties, in accordance with financial arrangements established by the Management Board. Such remuneration shall be paid to national competent authorities.***	***2. The Agency shall remunerate the activities of the Members States' representatives and experts in relation to the Emergency Task Force under this Regulation and reimburse the costs of the Member States' representatives and experts related to the meetings of the Medicines Shortages and Medical Devices Shortages Steering Groups, the Emergency Task Force and their working parties, in accordance with financial arrangements established by the Management Board. Such remuneration shall be paid to national competent authorities.*** ***OR*** ***2. The Agency shall remunerate the*** *assessment* ***activities of the*** *rapporteurs* ***in relation to the Emergency Task Force under this Regulation,*** *in addition to reimbursing the expenses of* ***the Member States' representatives and experts related to the meetings of the Medicines Shortages and Medical Devices Shortages Steering Groups, the Emergency Task Force and their working parties, in accordance with financial arrangements established by the Management Board. Such remuneration shall be paid to the*** *relevant* ***national competent authorities***

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
98 continued				***3. The Union contribution provided for in Article 67 of Regulation (EC) No 726/2004 shall cover the work of the Agency provided for under this Regulation, including for full remuneration paid to national competent authorities where fee exemptions apply in accordance with Regulation 297/95.***	***3. The Union contribution provided for in Article 67 of Regulation (EC) No 726/2004 shall cover the work of the Agency provided for under this Regulation, including for full remuneration paid to national competent authorities where fee exemptions apply in accordance with Regulation 297/95.***

DRAFT

Item	Article Number	Commission text (2020/0321 (COD))	EP amendments voted on 7 July 2021	Text approved by Council on 15 June 2021	Tentatively agreed text, compromise proposals and comments
99	Article 31 Article 31 – paragraph 1 Article 31 – paragraph 1 a (new) Article 31 – paragraph 2 (new)	*Article 31* *Entry into Force* 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 shall be binding in its entirety and directly applicable in all Member States. Done at Brussels,	**Amendment 151** Entry into Force ***and date of application*** **Amendment 152** ***Chapter IV shall apply from... [date of entry into force + 12 months].***	*Article 31* *Entry into Force* ***and date of application*** ***1.*** This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*. ***2. It shall apply from [date of application]*** This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels,	

DRAFT