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11751/21

Interinstitutional File: 2020/0321(COD)

LIMITE

SAN 544 PHARM 168 MI 666 COMPET 626 COVID-19 336 CODEC 1207

NOTE

From:	General Secretariat of the Council			
To:	Permanent Representatives Committee			
No. prev. doc.:	9764/21			
No. Cion doc.: 12971/20				
Subject:	Proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices			
	- Preparation for the trilogue			

I. BACKGROUND

- On 12 November 2020, the Commission submitted the proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices to the Council and to the European Parliament.
- 2. The proposal is based on Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union (TFEU). The ordinary legislative procedure is applicable.

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- 3. The proposal is part of a set of three proposals aiming to strengthen the EU's health security framework and to reinforce the crisis preparedness and response role of key EU agencies.

 Together they are the first building block of the European Health Union. The proposal was not accompanied by an impact assessment. The objectives of the proposal are to:
 - monitor and mitigate potential and actual shortages of medicinal products and medical devices considered as critical in order to address public health emergencies and other major events which may have a serious impact on public health;
 - ensure timely development of high quality, safe and efficacious medicinal products with a particular focus on addressing public health emergencies;
 - provide the structure for the functioning of expert panels that assess high-risk medical devices and provide essential advice in crisis preparedness and management.
- 4. Member States' National Parliaments were consulted on the compliance of the proposed provisions with the principle of subsidiarity and proportionality. While the French Senate raised subsidiarity concerns, the Portuguese and the Spanish Parliaments considered that the proposal complied with the subsidiarity principle.
- 5. The European Economic and Social Committee and the Committee of the Regions were both consulted. The Committee of the Regions adopted its opinion on the proposal during its 144th plenary session (5-7 May 2021). The European Economic and Social Committee has not yet sent its opinion on the proposal.
- 6. At the European Parliament, the Committee on the Environment, Public Health and Food Safety (ENVI) is responsible for the file. The European Parliament has appointed MEP Nicolás González Casares (S&D, ES) as Rapporteur. The latter presented his draft report on 30 March 2021 and the deadline for amendments was set to 28 April 2021. The ENVI Committee voted on the file on 21 June 2021.
- 7. Council reached a General Approach on 15 June 2021. This was the basis for the Presidency to enter into negotiations at the first political trilogue on 13 July 2021. Coreper was debriefed on the first political trilogue at its meeting of 14 July 2021.

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II. STATE OF PLAY

- 8. So far six technical meetings have been held on 2, 6, 13, 14, 15 and 20 September 2021 with the European Parliament and the Commission since the political trilogue. Good progress has been made.
- 9. The first five technical meetings discussed and provisionally agreed on a number of provisions highlighted in green in the 4th column of the 4 column table in doc. 11544/21 which were presented to the Members of the Working Party on Pharmaceuticals and Medical Devices during a meeting by videoconference on 17 September 2021. The Members Working Party also gave guidance on the political issues that had been identified at the first five technical meetings. However, at the last technical meeting on 20 September 2021, the EP side made it clear that some technical issues, such as the Council proposal for Article 6.0 which relates to the essential therapeutic groups of medicinal products, would have to be taken to the political level in order to get an opinion from the other political groups and shadows, as stated in point 10. c) in this note.
- 10. The outstanding issues for the second political trilogue on 30 September 2021 can be grouped as follows:

a) Amendments that the Council cannot accept

i) EP AM 93 on patient data (Article 11(4)(a) new)

Collecting such patient data is costly and burdensome with little added value.

It is suggested not to accept the amendment.

ii) EP AM 99 and AM 140 on transparency (Articles 13(1)(a) new and 27(1)(a) new)

The compromise text in the 4th column of the 4 column table in <u>Annex I</u> is the maximum that can be offered. Publishing voting and dissenting opinions is a red line for the Council. This was also rejected in the agreement reached on the proposal on Health Technology Assessment.

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b) Amendments on which the Council might have to move towards the EP if an agreement is to be reached

i) EP AM 97 on an EU database (Article 12a (new))

The EP has proposed to introduce a European Medicines Supply Database that would consist of two parts. In the first part, the database would enable monitoring supply and demand and managing shortages. In the second part, member states would have to create national databases that would enable real-time tracking of supply of medicinal products.

Having such a new database is considered by delegations costly, burdensome and disproportionate.

The EP counters the argument of cost by citing the example of electronic prescriptions that were funded with EU funding and insists on this amendment.

The Presidency suggests as an alternative:

- to propose to update the existing database referred to in article 57(1)i of Regulation 726/2004 with a dataset enabling high level reporting of status of supply, demand and shortages of medicinal products at Union and MS level (for more details see <u>Annex II</u>).
- to propose to reject the proposed new national databases used for real time monitoring as real time monitoring is already established with the falsified medicines database. A fallback option could be to suggest to amend Article 39 of the falsified medicines directive to allow for such monitoring.

ii) EP AM 144 on penalties (Article 29b (new))

The proposal of the EP, that Member States impose penalties on market authorisation holders (Article 10) and medical device manufacturers, authorised representatives, importers, distributors and notified bodies (Article 24) is seen by delegations as ineffective, impractical and too slow in a crisis. In addition, it risks further discouraging marketing authorisation holders from placing their products on the markets of certain smaller member states.

The Presidency suggests instead to add to the clause on evaluation and reporting (Article 30c (new)) the following text:

"The Commission shall, based on the input of Medicines Shortages Steering Group, also report on the compliance of stakeholders to the requirements of this Regulation."

iii) EP AM 48 on definition of "shortage" (Article 2(1)(d)

The Presidency suggests to possibly accept part of the EP's amendment which refers to "at a national level" as that wording is already in the HMA definition.

The EP has explained that "whatever the cause" that they propose at the end of the definition is meant to cover situations, when the product is not licensed or not marketed in a member state.

Accepting the addition of the aspects of licensing and marketing into the Regulation is not acceptable because it is outside the scope of the Regulation. The Presidency, therefore suggests to:

- reject the introduction of "whatever the cause";
- as the last possible compromise: add a step in Article 4, where member states confirm that they have the products in question available.

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iv) Agreement on the date of transfer of the administration of the expert panels for medical devices from the Commission (JRC) to the EMA

AM 141 on date of transfer to EMA of the expert panels (Article 28(1) which is linked to AM 151 and 152 on entry into force and date of application (Article 31)

Council supports the Commission's proposal of 1 March 2022 for the transfer of the administration of the expert panels for medical devices from the Commission (JRC) to the EMA. Any delay risks creating a gap in new medical devices being approved.

The EP, having been approached by EMA several months ago, is seeking a delay in the transfer.

The Commission has repeatedly informed the EP that the transfer is proceeding smoothly. Funds for the transfer have been provided to EMA. Staff have been recruited and are being trained. EMA is now confident about taking over the administration of these panels on 1 March 2022.

The Presidency suggests to maintain the Council position on Article 28(1) and not to accept AM 141.

On the other hand, the Presidency suggests to possibly accept AM 152 delaying the date of application for one year for medical devices, except for these panels, as it is accepted that EMA may need more time to take on board its new responsibilities as regards medical devices.

c) <u>Technical issues that the EP has decided to raise to the political level and for which</u>
the Presidency suggests the Council should stick to the proposals, tabled in the 4th
column document

Council should stick to its proposals on:

- The definition of demand (EP AM 47) (Article 2(1)(cb);
- Article 6.0 defining the main therapeutic groups of medicinal products;
- Articles 11(4)(a) and 25(4)(b) on recommendations not being binding on member states;
- Article 30b(2) on Union funding but could consider the Commission's suggestions as identified in the 4th column of the 4 column table if considered appropriate by delegations.
- 11. Based on the discussion so far, it is clear that the current mandate does not provide the sufficient margin to the Presidency to negotiate with the European Parliament. To be able to progress efficiently during the negotiations, the Presidency believes that this mandate needs to be updated. Some margin of manoeuvre is required on the political issues referred to under point 10 along the lines suggested therein.

III. CONCLUSION

- 12. In the light of the above, the <u>Permanent Representatives Committee</u> is invited to:
 - take note of the four-column table <u>in Annex 1</u> as some of the text still needs to be
 aligned with the issues that remain open;
 - discuss the main political issues referred to in point 10 above and grant the necessary flexibility along the lines outlined therein to the Presidency with a view to moving forward successfully the discussion with the European Parliament on these issues.

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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.

Explanation of the table layout¹

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
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 tentatively agreed 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.

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

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	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number				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)	ponetes and activities.	Amendment 1	ponetes and activities.	
			(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,		

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	Trumoci -		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.		Comments

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	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number				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		

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.		
			Ta 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		Amendment 3		
		(2) The unprecedented experience of the COVID-19 pandemic has demonstrated <i>that the Union should</i> 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.	(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.	

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.	

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.		

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

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	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number		, and the second		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.		

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

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

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	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number				comments
11 continued		therefore appropriate to establish long-term structures within an appropriate Union body to ensure monitoring of shortages of medical devices <i>resulting from</i> 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	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)		mitigate those shortages. Amendment 10		
12			(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.		

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	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number				
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, <i>and</i> 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	comments

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	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
		(2020/0321 (COD))	011 8 July 2021	011 13 Julie 2021	1 1
	Number				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.	

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

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

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

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

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

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number		-		comments
20	Recital 11 a (new)		Amendment 18		
20					
			(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} .		
			Ta Regulation (EC) No 726/2004		
			of the European Parliament and		
			of the Council of 31 March 2004		

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).		

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		Amendment 19		Comments
		(12) In order to improve crisis preparedness and management for medicinal products and medical devices and increase resilience and solidarity across the Union, the procedures and the respective roles and obligations of different concerned entities involved should be clarified. The framework should build on the ad hoc solutions identified so far in the response to the COVID-19 pandemic.	(12) In order to improve crisis preparedness and management for medicinal products and medical devices and increase resilience and solidarity across the Union, the procedures and the respective roles and obligations of different concerned entities involved should be clarified. The framework should build on the ad hoc solutions identified so far in the response to the COVID-19 pandemic that have proven effective, and on experience and examples in other countries, while remaining flexible enough to tackle any future health crisis in the most efficient way to the benefit of public health and patients.	(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.	

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number				comments
22	Recital 13		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 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	(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	

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number				comments
22 continued	Number	products which may have the potential to <i>address</i> 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 <i>mitigate</i> 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, <i>while avoiding any duplication of the information requested and submitted</i> .	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.	Comments

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

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		

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number				comments
23			Parliament and of the Council 1a .		
_					
continued			^{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).		

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number				comments
23	Recital 13 a			(13a) In the event that the actual	
	(Council) (new)			future demand is unknown due to	
bis				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	
				<u>demand.</u>	

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

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number		_		comments
25	Recital 15		Amendment 22		
23					
		(15) With respect to medicinal	(15) With respect to medicinal	(15) With respect to medicinal	
		products, an executive steering	products, an executive steering	products, an executive steering	
		group should be established within	group should be established within	group should be established within	
		the Agency to ensure a robust	the Agency to ensure a robust	the Agency to ensure a robust	
		response to major events and to	response to major events and to	response to major events and to	
		coordinate urgent actions within	coordinate urgent actions within	coordinate urgent actions within	
		the Union in relation to the management of issues relating to	the Union in relation to the management of issues relating to	the Union in relation to the management of issues relating to	
		the supply of medicinal products.	the supply of medicinal products.		
		The Steering Group should	The Steering Group should	the supply of medicinal products.	
		establish lists of critical medicinal	establish lists of critical medicinal	The Steering Group should establish lists of critical medicinal	
		products to ensure monitoring of	products to ensure monitoring of	products to ensure monitoring of	
		those products and it should be	those products and it should be	those products and it should be	
		able to provide advice on the	able to provide advice <i>and</i>	able to provide advice on the	
		necessary action to take to	recommendations on the	necessary action to take to	
		safeguard the quality, safety, and	necessary action to take to	safeguard the quality, safety, and	
		efficacy of medicinal products and	safeguard the quality, safety, and	efficacy of medicinal products and	
		ensure a high level of human	efficacy of medicinal products as	ensure a high level of human	
		health protection.	well as their supply and ensure a	health protection.	
			high level of human health		
	Recital 16	(16) The Frenchise Street,	protection.	(16) The Free Greening	
26	Recital 16	(16) The Executive Steering Group on Shortages and Safety of		(16) The Executive Steering Group on Shortages and Safety of	
		Medicinal Products should benefit		Medicinal Products should benefit	
		from the Agency's extensive		from the Agency's extensive	
		scientific expertise as regards the		scientific expertise as regards the	
		evaluation and supervision of		evaluation and supervision of	
		medicinal products and should		medicinal products and should	
		further develop the Agency's		further develop the Agency's	
		leading role in coordinating and		leading role in coordinating and	
		supporting the response to		supporting the response to	
		shortages during the COVID-19		shortages during the COVID-19	
		pandemic.		pandemic.	

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number				comments
27	Number 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	
				Member States, in accordance with Regulation (EU) No 536/2014.	

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

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number				comments
29	Recital 19		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.	(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.	

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number				comments
30	Recital 19 a (EP) (new)		Amendment 25		
	(new)		(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.		

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number				comments
20	Recital 19 a			(19a) Whenever necessary and	
30	(Council) (new)			considering that human	
bis				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)		Amendment 26	Should be foreseen.	
31	(new)				
			(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).		

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number				comments
32	Recital 20		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	(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.	

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 <i>appropriate</i> 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	

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

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number				comments
34	Recital 21a (new)			(21a) In order to establish the	
34				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	
				<u>manfacturer.</u>	

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number				comments
35		(2020/0321 (COD))	on 8 July 2021	(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	1 1 1
				of recommendations by the Executive Steering Group on	
				Shortages of medical devices.	

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

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

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

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

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number				comments
39	Recital 24		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. 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.	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.	

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number				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	
				<u>2022.</u>	

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number				comments
/11	Recital 25		Amendment 31		
41		(25) In order to facilitate the work and the exchange of information under this Regulation, provision should be made for the establishment and management of IT infrastructures and synergies with other existing IT systems or systems under development, including the EUDAMED IT platform for medical devices. That work should also be facilitated by, where appropriate, emerging digital technologies such as computational models and simulations for clinical trials, as well as data from the EU Space Programme such as the Galileo geolocation services, and Copernicus earth observation data.	(25) In order to facilitate the work and the exchange of information under this Regulation, provision should be made for the establishment and management of IT infrastructures and synergies with other existing IT systems or systems under development, including the EUDAMED IT platform for medical devices, alongside enhanced protection of data infrastructure and deterrence from possible cyberattacks. That work should also be facilitated by, where appropriate, emerging digital technologies such as computational models and simulations for clinical trials, as well as data from the EU Space Programme such as the Galileo geolocation services, and Copernicus earth observation data.	(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 orand 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.	

Item	Citation / Recital	Commission text (2020/0321 (COD))	EP amendments voted	Text approved by Council on 15 June 2021	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 8 July 2021	on 13 June 2021	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.	(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.	

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

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number		,		comments
4.4	Recital 26b (new)		Amendment 34		Comments
44	Recital 200 (new)		7 thierament 54		
			(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.		

Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
Number				comments
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) 2016/679¹a and (EU) 2018/1725¹b of the European Parliament and of the Council		
		Ta Regulation (EU) 2016/679 of the European Parliament and of		
		the Council of 27 April 2016 on		
		the protection of natural persons		
	Number	Number	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) 2016/679¹a and (EU) 2018/1725¹b of the European Parliament and of the Council	Number 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 Regulations skell 2016/679¹a and (EU) 2018/1725¹b of the European Parliament and of the Council The 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

Item	Citation / Recital	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
	Number				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).		
			the European Parliament and 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).		

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number				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		
İ			could affect their impartiality.		

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number		-		comments
47	Recital 26e (new)		Amendment 37		
4/			(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.		

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number	(2020/0321 (202))	011 0 0 011 1 2021	011 10 04110 2021	comments
4.0	Recital 27		Amendment 38		Comments
48	Recital 27		Amenument 36		
		(27) During a public health emergency or in relation to a major event, the Agency should ensure cooperation with the European Centre for Disease Prevention and Control and other Union Agencies as appropriate. Such cooperation should include data sharing, including data on epidemiological forecasting, regular communication at an executive level, and invitations to representatives of the European Centre for Disease Prevention and Control and other Union Agencies to attend meetings of the Emergency Task Force, the Medicines Steering Group, and the Medical Devices Steering Group, as appropriate.	(27) During a public health emergency or in relation to a major event, the Agency should ensure cooperation with the European Centre for Disease Prevention and Control and other Union Agencies as appropriate. Such cooperation should include data sharing, including data on epidemiological forecasting, regular communication at an executive level, and invitations to representatives of the European Centre for Disease Prevention and Control and other Union Agencies to attend meetings of the Emergency Task Force, the Medicines Steering Group, and the Medical Devices Steering Group, as appropriate. This cooperation should also include strategic discussions with relevant entities of the Union in a position to boost the research and development of appropriate solutions and technologies to mitigate the effects of the public health emergency or major event, or prevent future similar public health emergencies or major events, such as the proposed HERA.	(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 <i>Shortages</i> Steering Group, and the Medical Devices <i>Shortages</i> Steering Group, as appropriate.	

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number				comments
49	Recital 27a (new)		Amendment 39		
49					
			(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		
	D : 1071 ()		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.		
			ij appropriaic.		

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number			On 10 0 m 2 0 2 1	comments
7 1	Recital 28	(28) Since the objectives of this		(28) Since the objectives of this	Comments
51	Recital 26	Regulation cannot be sufficiently		Regulation cannot be sufficiently	
		achieved by the Member States		achieved by the Member States	
		alone due to the cross-border		alone due to the cross-border	
		dimension of public health		dimension of public health	
		emergencies and major events and		emergencies and major events and	
		can, therefore, be better achieved		can, therefore, be better achieved	
		at Union level, the Union may		at Union level, the Union may	
		adopt measures, in accordance		adopt measures, in accordance	
		with the principle of subsidiarity		with the principle of subsidiarity	
		as set out in Article 5 of the Treaty		as set out in Article 5 of the Treaty	
		on European Union. In accordance		on European Union. In accordance	
		with the principle of		with the principle of	
		proportionality, as set out in that		proportionality, as set out in that	
		Article, this Regulation does not		Article, this Regulation does not	
		go beyond what is necessary in		go beyond what is necessary in	
		order to achieve those objectives.		order to achieve those objectives.	
52	Recital 29		Amendment 41		
		(29) In order to ensure that	(29) In order to ensure that	(29) In order to ensure that	
		sufficient resources are available	sufficient resources, including	sufficient resources are available	
		for the work provided for under	appropriate staffing and	for the work provided for under	
		this Regulation, expenditure of the	adequate expertise, are available	this Regulation, expenditure of the	
		Agency should be covered by the	for the work provided for under	Agency should be covered by the	
		contribution from the Union to the	this Regulation, expenditure of the	contribution from the Union to the	
		Agency's revenue.	Agency should be covered by the	Agency's revenue. <u>This</u>	
			contribution from the Union to the	expenditure should cover	
			Agency's revenue.	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.	

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number				comments
53	Recital 29a (new)			(29a) Moreover, the EU4Health	
33				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	
	D :: 120	(20) TI E D (and 25 of this Regulation.	
54	Recital 30	(30) The European Data		(30) The European Data	
		Protection Supervisor has been		Protection Supervisor has been	
		consulted in accordance with		consulted in accordance with	
		Article 42(1) of Regulation (EU)		Article 42(1) of Regulation (EU)	
		No 2018/1725 and has adopted an		No 2018/1725 and has adopted an	
		opinion.		opinion.	

Item	Citation /	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Recital	(2020/0321 (COD))	on 8 July 2021	on 15 June 2021	compromise proposals and
	Number				comments
55	Recital 31	(31) In accordance with Article		(31) In accordance with Article	
33		168(7) of the Treaty, this		168(7) of the Treaty, this	
		Regulation fully respects the		Regulation fully respects the	
		responsibilities of the Member		responsibilities of the Member	
		States for the definition of their		States for the definition of their	
		public health policy and for the		public health policy and for the	
		organisation and delivery of health		organisation and delivery of health	
		services and medical care as well		services and medical care as well	
		as the fundamental rights and		as the fundamental rights and	
		principles recognised by the		principles recognised by the	
		Charter of Fundamental Rights of		Charter of Fundamental Rights of	
		the European Union including the		the European Union including the	
		protection of personal data,		protection of personal data,	
56		HAVE ADOPTED THIS		HAVE ADOPTED THIS	
50		REGULATION:		REGULATION:	

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 Subject Matter		Article 1 Subject Matter	Article 1 Subject Matter
	Article 1 – paragraph 1	This Regulation provides for, within the European Medicines Agency ('the Agency'), a framework for and the means to:		This Regulation provides for, within the European Medicines Agency ('the Agency'), a framework for and the means to:	This Regulation provides for, within the European Medicines Agency ('the Agency'), a framework for and the means to:
	Article 1 – paragraph 1 – point a	(a) prepare for and manage the impact of major events on medicinal products for human use and of public health emergencies on medicinal products for human use and on medical devices;	(a) <i>prevent</i> , prepare for, <i>coordinate</i> and manage <i>at Union level</i> the impact of major events on medicinal products for human use and of public health emergencies on medicinal products for human use and on medical devices;	(a) prepare for and manage the impact of major events on medicinal products for human use and of public health emergencies on medicinal products for human use and on medical devices;	(a) prepare for, <i>prevent</i> , <i>coordinate</i> 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 <i>at Union level</i> ;

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
			j		comments
58 continued	Article 1 – paragraph 1 – point b	(b) monitor and report on shortages of medicinal products	Amendment 43 (b) <i>prevent</i> , monitor and report on shortages of medicinal	(b) monitor and report on shortages of medicinal products	(b) monitor, <i>prevent</i> , and report on shortages of medicinal products for human use and <i>critical</i> medical devices;
		for human use and medical devices;	products for human use and <i>critical</i> medical devices;	for human use, and medical devices;	
	Article 1 – paragraph 1 – point b a (new)		Amendment 44 (ba) set up an interoperable		(ba) set up an interoperable and digital database at Union level to monitor and report on shortages of
			and digital database at Union level to monitor and report on shortages of medicinal products;		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 <u>administrative</u> support for the expert panels designated in accordance with <u>Implementing Decision</u> (EU) <u>2019/13962017/745</u> .	d) provide administrative support for the expert panels designated in accordance with Implementing Decision Article 106(1) of Regulation (EU) 2019/13962017/745.
59	Article 2	Article 2 Definitions		Article 2 Definitions	Article 2 Definitions
	Article 2 – paragraph 1 Article 2 – paragraph 1 – point a	For the purposes of this Regulation, the following definitions shall apply: (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/[];		1. For the purposes of this Regulation, the following definitions shall apply: (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/[];	1. For the purposes of this Regulation, the following definitions shall apply: (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/[];

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 Article 2 – paragraph 1 – point b a (new)	(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;	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} ;	(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; (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;	Ta 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).	(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;

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
59	Article 2 – paragraph 1 –		Amendment 46		(ca) 'supply' refers to the total volume of stock of an individual medicinal
continued	point c a (EP)		(ca) 'supply' refers to the		product or medical device that is placed
	(new)		total volume of stock of an individual medicinal product or		on the market by a marketing authorisation holder or the
			medical device that is placed on		manufacturer;
			the market by a marketing authorisation holder or a		
			manufacturer;		
	Article 2 –			(ca) 'accessory' for a medical	(ca) 'accessory' for a medical device
	paragraph 1 –			device means an accessory as	means an accessory as defined in point
	point c a (Council)			defined in point (2) of Article 2 of Regulation (EU) 2017/745	(2) of Article 2 of Regulation (EU) 2017/745 and for an in vitro medical
	(new)			and for an in vitro medical	device means accessory as defined in
				device means accessory as	point (4) of Article 2 of regulation (EU)
				defined in point (4) of Article 2	<u>2017/746;</u>
				of regulation (EU) 2017/746;	

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 b (EP) (new)		(cb) 'demand' relates to the request for a medicinal product or a medical device by a healthcare professional or patient in response to a clinical need. For demand to be satisfactorily met, the medicinal product or the medical device will need to be acquired in time and sufficient quantity to allow continuity of best care of patients. Wholesalers are usually a key supply link between marketing authorisation holders or manufacturers and the users of medicinal products or medical devices, respectively, and in those cases, in order to estimate demand, the quantity requested in wholesale orders should be considered;		(cb) 'demand' means 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 appropriate time and sufficient quantity to allow continuity of best care of patients. Wholesalers are usually a key supply link between marketing authorisation holders or manufacturers and the users of medicinal products or medical devices, respectively, and in those cases, in order to estimate demand, the quantity requested in wholesale orders should be considered;

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 b Council (new) Article 2 –		Amendment 48	(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;
	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;	(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;	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;
	Article 2 – paragraph 1 – point e	(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;	tevet, whitever the clause,	(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;	(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;

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

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

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

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	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	2. The Medicines <u>Shortages</u> 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 <u>Shortages</u> Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one <u>senior</u> 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.		Steering Group shall be transparent and made public on the Agency's web-portal.

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
61 continued	Article 3 – paragraph 3	2 The Madisius Steering	Amendment 52	2 The Medicines Charteness	The Madician Chanter Chanter
Continued		3. The Medicines Steering Group shall be chaired by the	3. The Medicines Steering Group shall be chaired by the	3. The Medicines Shortages Steering Group shall be Co-	3. The Medicines <u>Shortages</u> Steering Group shall be <u>co-</u> chaired by the Agency
		Agency. The Chair <i>may</i> invite	Agency. Any member of the	chaired by the Agency- and by a	and by a representative of a Member
		third parties, including	Medicines Steering Group may	representative of a Member	State elected by and amongst its
		representatives of medicinal	propose to the Chair to invite	State elected by and amongst its	members.
		product interest groups <i>and</i>	third parties, including	members. The Chair may Co-	
		marketing authorisation holders	representatives of medicinal	<u>Chairs</u> invite, as necessary,	The Chair may co-chairs may, on their
		to attend its meetings.	product interest groups,	representatives of national	own initiative or following a request from
			marketing authorisation holders,	competent authorities for	one or more members, invite, as
			wholesale distributors, or any	medicinal products for	observers and to provide expert advice
			other appropriate actor in the	veterinary use, representatives	representatives of national competent
			pharmaceutical supply chain,	of other relevant competent	authorities for medicinal products for
			representatives of healthcare	authorities and other third	veterinary use, representatives of other
			professionals, patients and	parties, including representatives	relevant competent authorities and third
			consumers to attend its	of medicinal product interest	parties, including representatives of
			meetings when their contribution may inform the	groups and marketing authorisation holders <i>for</i>	medicinal product interest groups, marketing authorisation holders,
			discussions of the Medicines	medicinal products for human	wholesale distributors, any other
			Steering Group.	and veterinary use to attend its	appropriate actor in the pharmaceutical
			Sieering Group.	meetings. The <i>Members of the</i>	supply chain, representatives of
				Medicines Shortages Steering	healthcare professionals and patients
				Group may request the Chair to	and consumers, to attend its meetings, as
				invite third parties to attend its	necessary.
				meetings.	

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
61					See new recital
continued	Article 3 –		Amendment 53		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.
	paragraph 3 a (new)		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.		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.

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	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		4. The Medicines <u>Shortages</u> Steering Group shall establish its rules of procedure including procedures relating to the working party referred to the paragraph 5 and on the adoption	4. The Medicines <u>Shortages</u> Steering Group shall establish its rules of procedure including procedures relating to the working party referred to <i>the</i> paragraph 5 and on the adoption of lists, sets of information, and
		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.		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.	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 <u>Shortages</u> 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 <u>Shortages</u> 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 <u>Shortages</u> Steering Group shall be responsible for fulfilling the tasks referred to in <i>Article 4(3)</i> , Article 4(4) and Articles 5 to 8.

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.

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
61 continued	Article 3 – paragraph 6b (new)	(2020/0321 (COD))	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 webportal.	on 15 June 2021	1 1 1
					which they become aware that might in good faith reasonably be expected to involve, or give rise to, a conflict of interest.

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	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
					be subject to a requirement of professional secrecy.

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
62	Article 4	Article 4		Article 4	
		Monitoring of events and		Monitoring of events and	
		preparedness for major events		preparedness for major events	
		and public health emergencies		and public health emergencies	
	Article 4 –		Amendment 57		
	paragraph 1	1 701 4 1 11	1 751 4 1 11	1 771 4	
		1. The Agency shall	1. The Agency shall	1. The Agency, in	1. The Agency, in collaboration
		continuously monitor any event that is likely to lead to a major	continuously monitor any event that is likely to lead to a major	collaboration with Member States, shall continuously	with Member States, shall continuously monitor any event that is likely to lead to
		event or a public health	event or a public health	monitor any event <u>related to</u>	a major event or a public health
		emergency.	emergency in coordination with	medicinal products that is likely	emergency. As necessary, the Agency
		emergency.	the national competent	to lead to a major event or a	shall cooperate with European Centre for
			authorities. In that regard, the	public health emergency. <u>As</u>	Disease Prevention and Control (ECDC)
			Agency shall cooperate closely	necessary, the Agency may seek	and other Union agencies, where
			with the European Centre for	the support of the ECDC.	relevant.
			Disease Prevention and		
			Control (ECDC) and other		
			Union agencies, where		
			relevant.		

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

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	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).	Agency may request information from the national competent authorities, through the working party referred to in Article 3(5). Amendment 59	Agency may request information from the national competent authorities, through the working party referred to in Article 3(5).	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 <i>may</i> request the assistance of the Medicines Steering Group to <i>address</i> the major event.	3. Where the Agency considers that an actual or imminent major event needs to be addressed, it shall inform the Commission and the Member States thereof. The Commission, on its own initiative or following a request from one or more Member States, or the Executive Director of the Agency shall then request the assistance of the Medicines Steering Group to analyse the available information. Based on the analysis of the information, the Medicines Steering Group may propose to the Commission to formally recognise the major event and, pursuant to Article 5, it shall provide recommendations to address such an event.	3. Where the Agency considers that an actual or imminent major event needs to be addressed, it shall informraise the issue of concern to the Commission and the Member States thereoffor 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.	3. Where the Agency considers that an actual or imminent major event needs to be addressed it shall raise the issue of concern to the Medicines Shortages Steering Group. Following a positive opinion of the Medicines Shortages Steering Group, the Commission may recognise the major event and trigger the actions foreseen in this regulation. The Commission or at least one member state may also raise the issue of concern to MSSG on their own initiative.

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	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		4. The Medicines <u>Shortages</u> Steering Group shall inform the Commission and the Executive Director of the Agency, once it considers that the major event	4. The Medicines <u>Shortages</u> 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
		has been sufficiently addressed. On the basis of that information		has been sufficiently addressed. On the basis of that information	of that information or on its own initiative, the Commission or the
		or on its own initiative, the Commission or the Executive		or on its own initiative, the Commission or the Executive	Executive Director may confirm that the assistance of the Medicines Shortages
		Director may confirm that the assistance of the Medicines Steering Group is no longer needed.		Director may confirm that the assistance of the Medicines <u>Shortages</u> Steering Group is no longer needed.	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.

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

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 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 <i>Shortages</i> Steering Group shall provide [] <i>recommendations</i> 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

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
62	Article 5 –		Amendment 61		
63	paragraph 2a				
continued	(new)		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 –		Amendment 62		
	paragraph 2b				The Medicines Steering Group may
	(new)		Where a link is established with		consult with the Committee for Medicinal
			zoonoses or diseases affecting		Products for Veterinary Use whenever it
			only animals that have or may		deems it necessary to deal with public
			have a major impact on human		health emergencies and major events
			health or where the use of		related to zoonoses or diseases affecting
			active ingredients of veterinary		only animals that have or may have a
			medicinal products may be		major impact on human health, or where
			useful to address the public		the use of active ingredients of veterinary medicinal products may be useful to
			health emergency or the major event, or otherwise whenever		address the public health emergency or
			necessary, the Medicines		the major event, or otherwise whenever
			Steering Group may liaise with		necessary.
			the Committee for Medicinal		necessury.
			Products for Veterinary Use.		

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
64	Article 6	Article 6		Article 6	
		Lists of critical medicinal		Lists of critical medicinal	
		products and information to be		products and information to be	
		provided		provided	
	Article 6 –			0. Without prejudice to	Without prejudice to paragraph 2, the
	paragraph 0			paragraph 2, the Medicines	Medicines Shortages Steering Group
	(new)			Shortages Steering Group shall	shall identify and establish a list with the
				define the main therapeutic	main therapeutic groups of medicinal
				groups of medicinal products,	products for ensuring emergency care,
				for ensuring emergency care,	surgeries and intensive care which may
				surgeries and intensive care	be adapted as necessary, with a view to
				which may be adapted as	inform the preparation of the critical
				necessary, with a view to	medicines lists as defined in Article 6(1)
				respond to a public health	and Art 6(2), to respond to a public
				emergency or major event.	health emergency or major event. <i>The list</i> shall be established six months after the
					entry into force of the Regulation and
					updated annually.
					updated annually.

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 – paragraph 1		Amendment 63		
continued		1. Following a request for assistance referred to in Article 4(3) and after consultation of its working party, the Medicines Steering Group shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the major event ('the major event critical medicines list'). The list shall be updated whenever necessary until the major event has been sufficiently addressed.	1. Following a request for assistance referred to in Article 4(3) and after consultation of its working party, the Medicines Steering Group shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the major event ('the major event critical medicines list'). The list shall be updated whenever necessary until the major event has been sufficiently addressed and it has been confirmed that the assistance of the Medicines Steering Group is no longer needed as referred to in Article 4(4) of this Regulation.	1. Following a request for assistance referred to in Article 4(3) and after consultation of its working party, the Medicines <i>Shortages</i> 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 <i>Shortages</i> 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 <i>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</i> .

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
			_		comments
64 continued	Article 6 – paragraph 2	2. Immediately following	Amendment 64 2. Immediately following	2. Immediately following	2. Immediately following the
		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 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.	the recognition of a public health emergency and after consultation of its working party, the Medicines <u>Shortages</u> 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.	recognition of a public health emergency and after consultation of its working party, the Medicines <u>Shortages</u> 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.

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	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	Amendment 65 3. The Medicines Steering Group shall adopt a set of information <i>and actions</i> necessary to monitor the supply and demand of medicinal products included on the lists	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	3. The Medicines <i>Shortages</i> Steering Group shall adopt, <i>and make publically available</i> 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
		1 and 2 ('the critical medicines lists') and inform its working party thereof.	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.	1 and 2 ('the critical medicines lists') and inform its working party thereof.	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.	THY.	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 webportal referred to in Article 26 of Regulation (EC) No 726/2004.

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	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:		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		(a) trade name and international non- proprietary name;
			name; (b) indication;		(b) indication;
			(b) indication;		
			(c) reason for the shortage;		(c) reason for the shortage;
			(d) start and end dates;		(d) start and end dates;
			(e) Member States affected;		(e) Member States affected;
			(f) information for healthcare professionals and patients, including information on alternative treatments.		(f) information for healthcare professionals and patients, including if alternative treatments are available.

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and comments
65	Article 7	Article 7		Article 7	
	Article 7 –	Monitoring shortages of medicinal products on the critical medicines lists	Amendment 67	Monitoring shortages of medicinal products on the critical medicines lists	
	paragraph 1				
		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.	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.	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.

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

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
66	Article 8 –		Amendment 69		
66	paragraph 2				
continued		2. Where requested by the	2. Where requested by the	2. Where requested by the	2. Where requested by the
		Commission or the sub-network	Commission, one or more	Commission or the sub-network	Commission, one or more national
		referred to in Article 9(2), the	national competent authorities	referred to in Article 9(2), the	<i>competent authorities</i> or the sub-network
		Medicines Steering Group shall	or the sub-network referred to in	Medicines Shortages Steering	referred to in Article 9(2), the Medicines
		provide aggregated data and forecasts of demand to	Article 9(2), the Medicines	Group shall provide aggregated data and forecasts of demand to	Shortages Steering Group shall provide
		substantiate its findings. In that	Steering Group shall provide aggregated data and forecasts of	substantiate its findings. In that	aggregated data and forecasts of demand to substantiate its findings. In that regard,
		regard, the Medicines Steering	demand to substantiate its	regard, the Medicines Shortages	the Medicines Shortages Steering Group
		Group shall liaise with the	findings. In that regard, the	Steering Group shall liaise with	shall [use data from the database
		European Centre for Disease	Medicines Steering Group shall	the European Centre for Disease	established in accordance with Article
		Prevention and Control to obtain	use data from the database	Prevention and Control to obtain	12a, once fully functional, and shall
		epidemiological data to help	established in accordance with	epidemiological data to help	[[comment: for later] liaise with the
		forecast medicinal product needs,	Article 12a, once fully	forecast medicinal product	European Centre for Disease Prevention
		and with the Executive Steering	functional, and shall liaise with	needs, and with the Executive	and Control to obtain epidemiological
		Group on Shortages of Medical	the European Centre for Disease	Steering Group on Shortages of	data, models and development scenarios
		Devices referred to in Article 19	Prevention and Control to	Medical Devices referred to in	to help forecast medicinal product needs,
		where medicinal products included on the critical	obtain epidemiological data,	Article 19 where medicinal products included on the critical	and with the Executive Steering Group on Shortages of Medical Devices referred
		medicines lists are administered	models and development scenarios to help forecast	medicines lists are administered	to in Article 19 where medicinal products
		with a medical device.	medicinal product needs, and	with a medical device.	included on the critical medicines lists
		With a medical device.	with the Executive Steering	With a medical device.	are administered with a medical device.
			Group on Shortages of Medical		The aggregated data and forecasts of
			Devices referred to in Article 19		demand may also be made available to
			where medicinal products		other actors in the pharmaceutical supply
			included on the critical		chain, where relevant, and in accordance
			medicines lists are administered		with competition rules with a view to
			with a medical device. <i>The</i>		better prevent or mitigate potential or
			aggregated data and forecasts		actual shortages. The aggregated data
			of demand may also be made available to other actors in the		and forecasts of demand may also be made available to other actors in the
1	1	1	available to other actors in the		made available to other actors in the

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

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					comments
66	Article 8 – paragraph 4		Amendment 71		
continued	Article 8 –	4. The Medicines Steering Group may, on its own initiative or upon request from the Commission, provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities to ensure preparedness to deal with potential or actual shortages of medicinal products caused by public health emergencies or major events.	4. The Medicines Steering Group may, on its own initiative or upon request from the Commission, provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders, representatives of healthcare professionals and other entities to ensure preparedness to deal with potential or actual shortages of medicinal products caused by public health emergencies or major events. Amendment 72	4. The Medicines <u>Shortages</u> Steering Group may, on its own initiative or upon request from the Commission <u>or Member</u> <u>States</u> , 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.	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.
	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.	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 <u>Shortages</u> 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.	Group may upon request from the Commission coordinate measures, where relevant, between the national competent authorities, the marketing authorisation holders and other entities, <i>including representatives of healthcare professionals and patient organisations</i> to prevent or mitigate potential or actual shortages in the context of a major event or public health emergency.

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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:	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:

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	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	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	(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 Article 9 –	(b) specify the methods of and criteria for the monitoring, data collection and reporting provided for in Articles 4, 7 and 8;	patients; 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; Amendment 76	(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;
	paragraph 1 – point c	(c) develop streamlined electronic monitoring and reporting systems;	(c) develop streamlined electronic monitoring and reporting systems in coordination with the national competent authorities until the database provided for in Article 12a is fully functional, based on harmonised data fields across Member States;	(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.

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			-		comments
67 continued	Article 9 – paragraph 1 – point d Article 9 –	(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; (e) establish and maintain a		(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; (e) establish and maintain a	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 (e) establish and maintain a list of
	paragraph 1 – point e	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;		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;	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)(1) of Regulation 726/2004;
67	Article 9 –	(f) specify the methods for		(f) specify the methods for	(f) specify the methods for the
	paragraph 1 –	the provision of		the provision of	provision of recommendations, advice
continued	point f	recommendations, advice and coordination of measures provided for in Articles 5 and 8.		recommendations, advice and coordination of measures provided for in Articles 5 and 8.	and coordination of measures provided for in Articles 5 and 8.
	Article 9 – paragraph 1 –		Amendment 77		
	point f a (new)		(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:

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
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					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 subnetwork 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 –		Amendment 78		
	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;	(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 –		Amendement 79		
	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.	(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 <i>Shortages</i> 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 <i>Shortages</i> Steering Group and set a deadline for its submission, if that information is not available in the database provided for in Article 12a.

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			-		comments
67	Article 9 –	3. The information referred		3. The information referred	3. The information referred to in
	paragraph 3	to in point (b) of paragraph 2		to in point (b) of paragraph 2	point (b) of paragraph 2 shall include at
continued		shall include at least:		shall include at least:	least:
	Article 9 –	(a) the name of the marketing		(a) the name of the marketing	(a) the name of the marketing
	paragraph 3 –	authorisation holder;		authorisation holder;	authorisation holder;
	point a	(1) (1) (1) (1) (1) (1) (1) (1)		(1) (1) (1) (1)	(b) (b) (b) (c) (c) (c) (c) (c) (c) (c) (c) (c) (c
	Article 9 –	(b) the name of the medicinal		(b) the name of the medicinal	(b) the name of the medicinal
	paragraph 3 – point b	product;		product;	product;
	Article 9 –			(ba) Identification of active	(ba) Identification of active
	paragraph 3 –			manufacturing sites of finished	manufacturing sites of finished products
	point ba (new)			products and active substances;	and active substances
	Article 9 –	(c) the country of		(c) the country of	
	paragraph 3 –	authorisation and marketing		authorisation and marketing	
	point c	status in each Member State;		status in each Member State;	
	Article 9 –		Amendment 80		
	paragraph 3 –				
	point d	(d) details of the potential or	(d) details of the potential or	(d) details of the potential or	(d) details of the potential or actual
		actual shortage such as actual or	actual shortage such as actual or	actual shortage such as actual or	shortage such as actual or estimated start
		estimated start and end dates and	estimated start and end dates	estimated start and end dates and	and end dates and suspected or known
		suspected or known cause;	and suspected or known cause	suspected or known cause;	cause as well as information on
			as well as information on		potential vulnerability in the supply
			potential bottlenecks in the		chain;
			supply chain;		

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67 continued	Article 9 – paragraph 3 – point e	(e) sales and market share data;		(e) <u>Data on stock levels,</u> sales and market share-data;	(e) sales and market share data;
	Article 9 – paragraph 3 –		Amendement 81		
	point e a (new) Article 9 – paragraph 3 –		(ea) available stocks; Amendment 82		(ea) available stocks;
	point e b (new)		(eb) quantities already delivered;		(eb) quantities already delivered;
	Article 9 – paragraph 3 –		Amendement 83		
	point e c (new) Article 9 – paragraph 3 – point f	(f) details of available alternative medicinal products;	(ec) projected deliveries;	(f) details of available alternative medicinal products;	(ec) projected deliveries; (f) details of available alternative medicinal products;

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67 continued	Article 9 – paragraph 3 – point g Article 9 – paragraph 3 –	(g) mitigation plans including production and supply capacity;	(g) prevention and mitigation plans including information on production and supply capacity, production sites of the finished pharmaceutical product and of active pharmaceutical ingredients, potential alternative production sites or minimum stock levels, with a view to guarantee continued supply and prevent shortages of medicinal products included on the critical medicines lists. Amendment 85	(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.
	point h	(h) information from the wholesale distributors and legal person entitled to supply the medicinal product to the public	deleted	(h) information from the wholesale distributors and legal person entitled to supply the medicinal product to the public.	(h) information from the wholesale distributors and legal person entitled to supply the medicinal product to the public. Comment: Council: information from wholesalers valuable, but understand cannot go through holders so can accept AM 85 but would like to add a general reporting requirement from wholesalers to national authorities by adding "wholesalers" in Art 9(1)(e) and Art 9(2)(a) Check point 3 and Art. 10. COM: need to make sure any links will not block system or be misinterpreted.

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
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68	Article 10	Article 10		Article 10	Article 10
		Obligations on marketing		Obligations on marketing	Obligations on marketing authorisation
		authorisation holders		authorisation holders	<u>holders</u>
	Article 10 –	1. In order to facilitate the		1. In order to facilitate the	1. In order to facilitate the
	paragraph 1	monitoring referred to in Article		monitoring referred to in Article	monitoring referred to in Article 7 and
		7 and following a request from		7 and following a request from	following a request from the Agency,
		the Agency, marketing		the Agency, marketing	marketing authorisation holders for
		authorisation holders for		authorisation holders for	medicinal products included on the
		medicinal products included on		medicinal products included on	critical medicines lists shall submit the
		the critical medicines lists shall		the critical medicines lists shall	information referred to in Article 9(3) by
		submit the information referred		submit the information referred	the deadline set by the Agency. They
		to in Article 9(3) by the deadline		to in Article 9(3) by the deadline	shall submit the information through the
		set by the Agency. They shall		set by the Agency. They shall	points of contact designated in
		submit the information through		submit the information through	accordance with Article 9(2) and using
		the points of contact designated		the points of contact designated	the reporting methods and system
		in accordance with Article 9(2)		in accordance with Article 9(2)	established pursuant to Article 9(1). They
		and using the reporting methods		and using the reporting methods	shall provide updates where necessary.
		and system established pursuant		and system established pursuant	
		to Article 9(1). They shall		to Article 9(1). They shall	
		provide updates where necessary.		provide updates where	
				necessary.	

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
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					comments
68	Article 10 – paragraph 2		Amendement 86		
continued		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)(1) of Regulation (EC) No 726/2004. Those marketing authorisation holders shall update their submission wherever necessary.	2. Marketing authorisation holders of medicinal products authorised in the Union shall, within 6 months from the date of application of this Regulation, provide the information required pursuant to Article 9(1)(e) in the form of an electronic submission in the database referred to in Article 57(1)(l) of Regulation (EC) No 726/2004 and in compliance with the standards developed by the International Organization for Standardization (ISO) for the identification of medicinal products for human use (IDMP). Those marketing authorisation holders shall update their submission	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.	wherever necessary.	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.

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
68	Article 10 –		Amendment 87		
continued	paragraph 4	4 377 1 4	4 777	4 337 1 4	4 331 1 (1 1 1
Continued		4. Where marketing authorisation holders for	4. Where marketing authorisation holders for	4. Where marketing authorisation holders for	4. Where marketing authorisation holders for medicinal products included
		medicinal products included on	medicinal products included on	medicinal products included on	on the critical medicines lists indicate
		the critical medicines lists	the critical medicines lists	the critical medicines lists	that the submitted information requested
		indicate that the submitted	indicate that the submitted	indicate that the submitted	by the Agency or the national competent
		information contains information	information requested by the	information contains information	authorities contains information of a
		of a commercially confidential nature, they shall identify the	Agency or the national competent authorities contains	of a commercially confidential nature, they shall identify the	commercially confidential nature, they shall identify the relevant parts and
		relevant parts and clarify the	information of a commercially	relevant parts and clarify the	clarify the reasons for such an indication.
		reasons for such an indication.	confidential nature, they shall	reasons for such an indication.	The Agency shall assess the merits of
		The Agency shall assess the	identify the relevant parts and	The Agency shall assess the	each request and protect commercially
		merits of each request and	clarify the reasons for such an	merits of each request and	confidential information against
		protect commercially confidential information against	indication. The Agency shall assess the merits of each request	protect commercially confidential information against	unjustified disclosure.
		unjustified disclosure.	and protect commercially	unjustified disclosure.	
			confidential information against	a gaza ca a a ca a ca	
			unjustified disclosure.		
	Article 10 –		Amendement 88		
	paragraph 5	5. Where marketing	5. Where marketing	5. Where marketing	5. Where marketing authorisation
		authorisation holders for	authorisation holders for	authorisation holders for	holders for medicinal products included
		medicinal products included on	medicinal products included on	medicinal products included on	on the critical medicines lists <i>or other</i>
		the critical medicines lists are in	the critical medicines lists	the critical medicines lists are in	relevant actors in the pharmaceutical
		possession of any additional	and/or other relevant actors in	possession of any additional	supply chain are in possession of any
		information, which provides evidence of a potential or actual	the pharmaceutical supply chain are in possession of any	information, which provides evidence of a potential or actual	additional information, which provides evidence of a potential or actual shortage
		shortage they shall immediately	additional information, which	shortage they shall immediately	they shall immediately provide such
		provide such information to the	provides evidence of a potential	provide such information to the	information to the Agency.
		Agency.	or actual shortage they shall	Agency.	
			immediately provide such		
1			information to the Agency.		

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
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					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: (a) provide any comments they have to the Agency:		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: (a) provide any comments they have to the Agency:	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: (a) provide any comments they have to the Agency.
	paragraph 6 – point a Article 10 – paragraph 6 – point b Article 10 –	they have to the Agency; (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;	Amendment 89	they have to the Agency; (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;	to the Agency; (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;
	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.	(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 <u>Shortages</u> 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 <u>Shortages</u> Steering Group of any measures taken and report on the <i>monitoring and</i> results of those measures, including information on the resolution of the potential or actual shortage.

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					comments
68	Article 10 –		Amendement 90		
continued	paragraph 6 a		Con Townston to prompt on and		
Continued	(new)		6a. In order to supplement the shortage prevention and		6a. In order to supplement the shortage prevention and mitigation
			mitigation plans of critical		plans of critical medicinal products, the
			medicinal products, the Agency		Agency and national competent
			and national competent		authorities may request additional
			authorities may request additional information from		information from wholesale distributors and other relevant actors regarding any
			wholesale distributors and		logistical challenges incurred by the
			other relevant actors regarding		wholesale supply chain.
			any logistical challenges		
			incurred by the wholesale supply chain.		
69	Article 11	Article 11	supply chain.	Article 11	Article 11
09					
		Obligations on Member States in		Obligations on Role of Member	Obligations on Role of Member States in
		the monitoring and mitigation of		States in the monitoring and	the monitoring and mitigation of
		shortages of medicinal products		mitigation of shortages of medicinal products	shortages of medicinal products
	Article 11 –		Amendment 91	meatemat products	
	paragraph 1				
		1. In order to facilitate the			
		monitoring referred to in Article 7 and following a request from	monitoring referred to in Article 7 and following a request from	monitoring referred to in Article 7 and following a request from	monitoring referred to in Article 7 and following a request from the Agency,
		the Agency, Member States	the Agency, Member States	the Agency, Member States	Member States shall, by the deadline set
		shall, by the deadline set by the	shall, by the deadline set by the	shall, by the deadline set by the	by the Agency, submit the following
		Agency:	Agency, submit the following	Agency:	information provided that it is not
			information provided that it is not available in the database		available in the database established in Article 12a:
			established in Article 12a:		rifucie 12d.

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	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		(a) submit the set of information requested by the Agency including available andor estimated data on volume of demand, through its designated point of contact and using the reporting methods and system established pursuant to	(a) submit the set of information requested by the Agency including available <i>and</i> 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	9(1); (b) indicate the existence of any commercially confidential information and clarify the reasons for such an indication;		Article 9(1); (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.

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.	2. Where necessary to fulfil their reporting obligations set out in paragraph 1, Member States, with the support of the Agency, shall gather <i>relevant</i> information and data, <i>including</i> on stock levels, from wholesale distributors and other legal entities <i>and persons authorised</i> 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. 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 shall provide relevant information and data, including on stock levels, where necessary for Member States to fulfil their reporting obligations set out in paragraph 1, 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.

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
69	Article 11 –	3. Where Member States are		3. Where Member States are	3. Where Member States are in
	paragraph 3	in possession of any additional		in possession of any additional	possession of any additional information
continued		information on volume of sales		information on volume of sales	on volume of sales and volumes of
		and volumes of prescriptions,		and volumes of prescriptions,	prescriptions, including data based on
		including data based on Article		including data based on Article	Article 23a of Directive 2001/83/EC,
		23a of Directive 2001/83/EC,		23a of Directive 2001/83/EC,	which provides evidence of a potential or
		which provides evidence of a		which provides evidence of a	actual shortage of a medicinal product
		potential or actual shortage of a		potential or actual shortage of a	included on the critical medicines lists,
		medicinal product included on		medicinal product included on	they shall immediately provide such
		the critical medicines lists, they		the critical medicines lists, they	information to the Medicines Shortages
		shall immediately provide such		shall immediately provide such	Steering Group through their designated
		information to the Medicines		information to the Medicines	points of contact.
		Steering Group through their		Shortages Steering Group	
		designated points of contact.		through their designated points	
				of contact.	
	Article 11 –	4. Following the reporting		4. Following the reporting	4. Following the reporting on the
	paragraph 4	on the results of the monitoring		on the results of the monitoring	results of the monitoring and any
		and any recommendations on		and any recommendations on	recommendations on preventive or
		preventive or mitigating		preventive or mitigating	mitigating measures in accordance with
		measures in accordance with		measures in accordance with	Article 8, Member States shall:
		Article 8, Member States shall:		Article 8, Member States shall:	
	Article 11 –	(a) take into account any		(a) take into account consider	(a) take into account <u>consider</u> any
	paragraph 4 –	recommendations and guidelines		any recommendations and,	recommendations-and, guidelines and
	point a	and comply with any measures		guidelines and comply with any	comply with any measures taken at
		taken at Union-level pursuant to		measures taken at Union-level	Union-level pursuant to Article 12;(a).
		Article 12;		pursuant to Article 12;(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
69 continued	Article 11 – paragraph 4 – point a Article 11 – Article 11 –	(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.	Amendment 93	(b) inform the Medicines <u>Shortages</u> 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.
	paragraph 4a (new)		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.		4a. National competent authorities for medicinal products shall facilitate online data collection on the impact of medicine shortages on patients and consumers. Where 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.

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

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

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	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.	(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	(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.
			Medicines Steering Group.		

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

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
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. 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.		comments (d) to enable the Commission, the Agency and the national competent authorities to carry out their tasks in accordance with this Regulation on a well-informed basis and to enhance the cooperation between them. The EUMSD, which shall be functional not only during public health emergencies and major events but also under normal circumstances, shall function as an interoperable and digital database at Union level, based on the data reported through the national electronic platforms established pursuant to paragraph 2. The database shall allow the Agency and the national competent authorities to simultaneously access and share the information provided in the database.

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			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		2. Each Member State shall develop an electronic platform with a view to establishing real-time monitoring of the supply of medicinal products, capable of determining the volume of supply of each medicinal product existing at any given moment, and detecting, predicting and preventing shortages of medicinal products. Those platforms, which shall be managed by the national competent authorities, shall be fully operational at Member State level by [30 months after the date of entry into force of this Regulation].
			into force of this Regulation]. Data on supply and demand shall be reported at Member State level by the following entities: (a) marketing authorisation holders (b) wholesale distributors (c) community and hospital pharmacies.		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.

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

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		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.
			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.		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.

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	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		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].
			[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.		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.

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.		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 Communication on the Medicines Steering Group	Section of the sectio	Article 13 Communication on the Medicines <u>Shortages</u> Steering	Article 13 Communication on the Medicines Shortages Steering Group
	Article 13 – paragraph 1	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 webportal 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.	Group The Agency shall, via its webportal 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.	The Agency shall, via <i>a dedicated space on</i> its web-portal and other appropriate means, in conjunction with national competent authorities, inform the public and interest groups <i>in a timely manner</i> with regard to the work of the Medicines <i>Shortages</i> Steering Group, <i>and respond to disinformation targeting the work of the Medicines Shortage Steering Group as appropriate</i> .

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		Chapter III	
		Medicinal Products with the potential to address public health emergencies		Medicinal Products with the potential to address public health emergencies	

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
74	Article 14	Article 14		Article 14	Article 14
		The Emergency Task Force		The Emergency Task Force	The Emergency Task Force
	Article 14 – paragraph 1		Amendement 100		
		1. The Emergency Task Force is hereby established as part of the Agency. It shall be convened during public health emergencies, either in person or remotely. The Agency shall provide its secretariat.	1. The Emergency Task Force is hereby established as part of the Agency. It shall be convened <i>in preparation for</i> and during public health emergencies, either in person or remotely. The Agency shall provide its secretariat.	1. The Emergency Task Force is hereby established as part of the Agency. It shall be convened 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 <i>in preparation for and</i> during public health emergencies, either in person or remotely. The Agency shall provide its secretariat.

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
			3		comments
7.4	Article 14 –	2. During public health		2. During public health	2. During public health emergencies,
74	paragraph 2	emergencies, the Emergency		emergencies, the Emergency	the Emergency Task Force shall
continued	paragrapa 2	Task Force shall undertake the		Task Force shall undertake the	undertake the following tasks:
		following tasks:		following tasks:	undertune die zeite Hing weite.
	Article 14 –	(a) providing scientific		(a) in liaison with the	(a) in liaison with the scientific
	paragraph 2 –	advice and reviewing the		scientific committees, working	committees, working parties, and
	point a	available scientific data on		parties, and scientific advisory	scientific advisory groups of the Agency,
		medicinal products with the		groups of the Agency, providing	providing scientific advice and reviewing
		potential to address the public		scientific advice and reviewing	the available scientific data on medicinal
		health emergency, including		the available scientific data on	products with the potential to address the
		requesting data from developers		medicinal products with the	public health emergency, including
		and engaging with them in		potential to address the public	requesting data from developers and
		preliminary discussions;		health emergency, including	engaging with them in preliminary
				requesting data from developers	discussions;
				and engaging with them in	
				preliminary discussions;	
	Article 14 –	(b) reviewing clinical trial		(b) reviewing providing	(b) reviewing providing advice on the
	paragraph 2 –	protocols and providing advice to		advice on the main aspects of	main aspects of clinical trial protocols;
	point b	developers on clinical trials to be		clinical trial protocols; and	and providing advice to developers on
		conducted in the Union for		providing advice to developers	clinical trials to be conducted in the
		medicinal products intended to		on clinical trials to be conducted	Union for medicinal products intended to
		treat, prevent, or diagnose the		in the Union for medicinal	treat, prevent, or diagnose the disease
		disease causing the public health		products intended to treat,	causing the public health emergency, in
		emergency, in accordance with		prevent, or diagnose the disease	accordance with Article 15 without
		Article 15;		causing the public health	prejudice to the tasks of the Member
				emergency, in accordance with Article 15 <i>without prejudice to</i>	States as regards assessment of submitted clinical trial applications to be
				the tasks of the Member States	conducted on their territories in
				as regards assessment of	accordance with Regulation (EU) No
				submitted clinical trial	536/2014;
				applications to be conducted on	330/2017.
				their territories in accordance	
				with Article 6 of Regulation	
				(EU) No 536/2014;	
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entatively agreed text, empromise proposals and emments
cooperating with <i>national mpetent authorities</i> , Union bodies and encies, the World Health Organization, and countries, and international ientific organisations on scientific and chnical issues relating to the public alth emergency and to medicinal oducts which may have the potential to dress public health emergencies, as cessary.
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Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
			, and the second		comments
74	Article 14 –		Amendment 102		
-	paragraph 3				
continued		3. The Emergency Task	3. The Emergency Task	3. The Emergency Task	3. The Emergency Task Force shall
		Force shall be composed of	Force shall be composed of	Force shall be composed of	be composed of representatives,
		representatives of the scientific	representatives of the scientific	representatives <i>nominated by the</i>	nominated by the scientific committees,
		committees, working parties, and	committees, working parties,	scientific committees, working	working parties, including (vice) Chairs
		staff members of the Agency, the	including representatives of the	parties, including (vice)Chairs	of the scientific committees, working
		coordination group established in	PCWP and the HCPWP , and	of the scientific committees,	parties, including representatives of the
		accordance with Article 27 of	staff members of the Agency,	working parties, and staff	PCWP and the HCPWP , and staff
		Directive 2001/83/EC, and the	the coordination group	members of the Agency, the	members of the Agency, the coordination
		Clinical Trials Coordination and	established in accordance with	coordination group established in	group established in accordance with
		Advisory Group established in	Article 27 of Directive	accordance with Article 27 of	Article 27 of Directive 2001/83/EC, and
		accordance with Article 85 of	2001/83/EC, and the Clinical Trials Coordination and	Directive 2001/83/EC, and the Clinical Trials Coordination and	the Clinical Trials Coordination and Advisory Group established in
		Regulation (EU) 536/2014. External experts may be	Advisory Group established in	Advisory Group established in	accordance with Article 85 of Regulation
		appointed and representatives of	accordance with Article 85 of	accordance with Article 85 of	(EU) 536/2014. sas well as other clinical
		other Union bodies and agencies	Regulation (EU) 536/2014. ²¹	Regulation (EU) 536/2014- as	trial experts representing competent
		be invited on an ad hoc basis, as	External experts may be	well as other clinical trial	authorities of the Member States.
		necessary. It shall be chaired by	appointed and representatives of	experts representing competent	External experts may be appointed and
		the Agency.	other Union bodies and agencies	authorities of the Member	representatives of other Union bodies and
		ine rigeney.	be invited on an ad hoc basis, as	States. External experts may be	agencies <i>shall</i> be invited on an ad hoc
			necessary. It shall be chaired by	appointed and representatives of	basis, as necessary, especially in cases of
			the Agency.	other Union bodies and agencies	public health emergencies which affect
				shall be invited on an ad hoc	also the veterinary medicinal products
				basis, as necessary., especially in	field. It shall be chaired by the Agency
				cases of public health	and co-
				emergencies which affect also	
				the veterinary medicinal	
				products field. It shall be chaired	
				by the Agency <u>and co-</u>	

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 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.		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. 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.	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. 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.

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
74	Article 14 – paragraph 5		Amendment 103		
continued		5. The Chair may invite representatives of Member States, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, and interest groups representing patients and healthcare professionals to attend its meetings.	5. The Chair may invite representatives of Member States, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, <i>independent clinical trial experts and researchers</i> , 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.	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 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.

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	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	on / July 2021	7. The Emergency Task Force shall perform its tasks as aan 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	7. The Emergency Task Force shall perform its tasks as 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 shall take account of any scientific opinion issued by those committees in accordance with Regulation (EC) No 726/2004 and Directive 2001/83/EC.		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.	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.

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
74	Article 14 – paragraph 8		Amendment 104		
continued	paragraph o	8. Article 63 of Regulation (EC) No 726/2004 shall apply to the Emergency Task Force as regards transparency and the independence of its members.	8. Article 63 of Regulation (EC) No 726/2004 shall apply to the Emergency Task Force as regards transparency and the independence of its members. Members of the Emergency Task Force shall update the annual declaration of their financial interests provided for in Article 63 of Regulation (EC) No 726/2004 whenever a relevant change occurs.	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.	recount change occurs.	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.

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
75	Article 15	Article 15		Article 15	
/ 3					
		Advice on clinical trials		Advice on clinical trials	
	Article 15 –	1. During a public health		1. During a public health	1. During a public health emergency,
	paragraph 1	emergency, the Emergency Task		emergency, the Emergency Task	the Emergency Task Force shall
		Force shall review clinical trial		Force shall review provide advice	reviewprovide advice on main aspects of
		protocols submitted or intended		on main aspects of clinical trial	clinical trial protocols submitted or
		to be submitted in a clinical trial		protocols submitted or intended	intended to be submitted in a clinical trial
		application by developers of		to be submitted in a clinical trial	application, without prejudice of the
		medicinal products as part of an		application, without prejudice of	responsibility of the Member State(s)
		accelerated scientific advice		the responsibility of the Member	according to Regulation (EU) 536/2014,
		process.		State(s) according to Regulation	by developers of medicinal products as
				(EU) 536/2014, by developers of	part of an accelerated scientific advice
				medicinal products as part of an accelerated scientific advice	process.
				process.	
	Article 15 –	2. Where a developer		2. Where a developer	
	paragraph 2	engages in an accelerated		engages in an accelerated	
	paragraph 2	scientific advice process, the		scientific advice process, the	
		Emergency Task force shall		Emergency Task force shall	
		provide such advice free of		provide such advice free of	
		charge at the latest 20 days		charge at the latest 20 days	
		following the submission to the		following the submission to the	
		Agency of a complete set of		Agency of a complete set of	
		requested information and data		requested information and data	
		by the developer. The advice		by the developer. The advice	
		shall be endorsed by the		shall be endorsed by the	
		Committee for Medicinal		Committee for Medicinal	
		Products for Human Use.		Products for Human Use.	

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
75	Article 15 – paragraph 3		Amendement 105		
continued	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.	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.	 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. 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.

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 takeconsider 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 Article 15 – paragraph 7	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. 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.		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. 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.	

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
76	Article 15 a		Amendment 107		
	(new)		Article 15a		Article 15a
			Public information about		Public information about clinical trials
			clinical trials and marketing		and marketing authorisation decisions
			authorisation decisions		
			1. For the duration of a		1. For the duration of a public
			public health emergency, the		health emergency, the sponsors of
			sponsors of clinical trials		clinical trials conducted in the Union
			conducted in the Union shall:		shall, in particular:
			(a) publish the study		(a) publish the study protocol at the
			protocol at the start of the trial through the EU clinical trials		start of the trial through the EU clinical trials register;
			register;		trius register,
			(b) publish the summary of		(b) publish the summary of the
			the results through the EU		results through the EU clinical trials
			clinical trials register within a		register within a timeline set by the
			timeline set by the Agency that		Agency that is shorter than the timeline
			is shorter than the timeline laid		laid down in Article 37 of Regulation
			down in Article 37 of		(EU) No 536/2014.
			Regulation (EU) No 536/2014.		2 111
			2. Where a medicinal		2. Where a medicinal product
			product receives a marketing		receives a marketing authorisation, the Agency shall publish, in particular:
			authorisation, the Agency shall publish:		Agency shau puousn, in particular.
			(a) the product information		(a) the product information with
			with details of the conditions of		details of the conditions of use at the
			use at the time of marketing		time of marketing authorisation;
			authorisation;		

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

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and comments
77	Article 16	Article 16		Article 16	
		Review of medicinal products and recommendations on their		Review of medicinal products and recommendations on their	
		use		use	
	Article 16 – paragraph 1		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.	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.	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.

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

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
			-		comments
77 continued	Article 16 – paragraph 3 – point b Article 16 –	 (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 		 (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 	4. Following receipt of the
	paragraph 4	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.		recommendation, the Committee for Medicinal Products for Human Use shall adopt an <i>independent and scientifically based</i> opinion on the conditions for use, the conditions for distribution and the patients targeted. The opinion shall be updated where necessary.	recommendation, the Committee for Medicinal Products for Human Use shall adopt <i>its</i> opinion on the conditions for use, the conditions for distribution and the patients targeted. The opinion shall be updated where necessary.
	Article 16 – paragraph 5	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.		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.	

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

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
100111	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
78	Article 17	Article 17		Article 17	
		Communication on the		Communication on the	
		Emergency Task Force		Emergency Task Force	
	Article 17 – paragraph 1		Amendment 111		
		The Agency shall, via its web- portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Emergency Task Force.	The Agency shall, via a dedicated space on its web-portal and other appropriate means and, in conjunction with national competent authorities, inform without delay the public and relevant interest groups with regard to the work of the Emergency Task Force, and respond to disinformation targeting the work of the Emergency Task Force as appropriate.	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 <i>a dedicated space</i> 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.

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	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 webportal.		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."

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 IT tools and data To prepare for and support the work of the Emergency Task Force during public health emergencies, the Agency shall:		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:	To prepare for and support the work of the Emergency Task Force during public health emergencies, the Agency shall:
	Article 18 – paragraph 1 – point a	(a) develop and maintain electronic tools for the submission of information and data, including electronic health data generated outside the scope of clinical studies;	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;	(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;	(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;

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

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

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 theira 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 <u>Shortages</u> Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one <u>senior</u> appointed representative per Member State. Each Member State shall appoint <u>a</u> representative <u>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.</u>

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

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
81	Article 19 –	4. The Medical Devices		4. The Medical Devices	4. The Medical Devices <i>Shortages</i>
continued	paragraph 4	Steering Group shall establish its		Shortages Steering Group shall	Steering Group shall establish its rules of
continued		rules of procedure including		establish its rules of procedure	procedure including procedures relating
		procedures relating to the		including procedures relating to	to the working party referred to in
		working party referred to in		the working party referred to in	paragraph 5, and on the adoption of lists,
		paragraph 5, and on the adoption		paragraph 5, and on the adoption	sets of information and
		of lists, sets of information and		of lists, sets of information and	recommendations. The rules of
		recommendations. The rules of		recommendations. The rules of	procedures shall enter into force after
		procedures shall enter into force		procedures shall enter into force	receiving a favourable opinion from the
		after receiving a favourable		after receiving a favourable	Commission and the Management Board
		opinion from the Commission		opinion from the Commission	of the Agency.
		and the Management Board of		and the Management Board of	
	A 4: 1 10	the Agency.		the Agency.	
	Article 19 –	5. The Medical Devices		5. The Medical Devices	5. The Medical Devices Shortages
	paragraph 5	Steering Group shall be		Shortages Steering Group shall	Steering Group shall be supported in its
		supported in its work by a		be supported in its work by a	work by a working party comprised of
		working party comprised of		working party comprised of	single points of contact from national
		single points of contact from		single points of contact from	competent authorities for responsible for
		national competent authorities for medical devices established		national competent authorities	shortage monitoring and management
		in accordance with Article 23(1).		for responsible for shortage monitoring and management	of medical devices and in vitro diagnostic medical devices established in
		in accordance with Article 25(1).		for medical devices and in vitro	accordance with Article 23(1).
				diagnostic medical devices	accordance with Article 25(1).
				established in accordance with	
				Article 23(1).	
	Article 19 –	6. The Medical Devices		6. The Medical Devices	6. The Medical Devices Shortages
	paragraph 6	Steering Group shall be		Shortages Steering Group shall	Steering Group shall be responsible for
	paragraph	responsible for fulfilling the		be responsible for fulfilling the	fulfilling the tasks referred to in Articles
		tasks referred to in Articles 20,		tasks referred to in Articles 20,	20, 21, and 22.
		21, and 22.		21, and 22.	20, 21, unu 22.
I	1	21, and 22.	l	21, and 22.	I

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.		

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

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
	Number	(2020/0321 (COD))	Oil / July 2021	011 13 June 2021	comments
82	Article 20 – paragraph 2		Amendment 120		
continued		2. The Medical Devices Steering Group shall adopt a set of information necessary to monitor the supply and demand of medical devices included on the public health emergency critical devices list and inform its working party thereof.	2. The Medical Devices Steering Group shall adopt a set of information necessary to monitor the supply and demand of medical devices included on the public health emergency critical devices list and inform its working party thereof. Union or national entities that are engaged in stockpiling of medical devices shall be informed accordingly.	2. The Medical Devices Shortages Steering Group shall adoptpursuant 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 <u>Shortages</u> Steering Group shall adopt and make publically available a set of information necessary to monitor the supply and demand of <u>medical devices and in vitro diagnostic</u> medical devices included on the public health emergency critical devices list and inform its working party thereof.
	Article 20 – paragraph 3	2 The Assessment of the blish	Amendment 121	2 The Assessment of the blish	2 The Array de Health de
	Article 20 –	3. The Agency shall publish the public health emergency critical devices list and any updates to that list on its webportal.	3. The Agency shall publish the public health emergency critical devices list and any updates to that list on <i>a dedicated space on</i> its webportal. Amendment 122	3. The Agency shall publish the public health emergency critical devices list and any updates to that list on its webportal.	3. The Agency shall publish the public health emergency critical devices list and any updates to that list on <i>a dedicated space on</i> its web-portal.
	paragraph 3 a (new)		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).

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
			, and the second		comments
0.2	Article 21	Article 21		Article 21	Comments
83	Tittlete 21	11/11/01/02/1		Tittlette 21	
		Monitoring shortages of medical		Monitoring shortages of medical	
		devices on the public health		devices on the public health	
		emergency critical devices list		emergency critical devices list	
	Article 21 –	1. On the basis of the public		1. On During the basis	1. On <u>During</u> the basis recognition
	paragraph 1	health emergency critical devices		<u>recognition</u> of the <u>a</u> public	of the <u>a</u> public health emergency, <u>and on</u>
		list and the information and data		health emergency, and on the	the basis of the critical medical devices
		provided in accordance with		basis of the critical medical	and in vitro diagnostic medical devices
		Articles 24 and 25, the Medical		devices and in vitro diagnostic	list and the information and data
		Devices Steering Group shall		medical devices list and the	provided in accordance with Articles 24
		monitor supply and demand of		information and data provided in	and 25, the Medical Devices Shortages
		medical devices included on that		accordance with Articles 24 and	Steering Group shall monitor supply and
		list with a view to identifying		25, the Medical Devices	demand of medical devices and in vitro
		any potential or actual shortages		Shortages Steering Group shall	diagnostic medical devices included on
		of those medical devices. As part		monitor supply and demand of	that list with a view to identifying any
		of that monitoring, the Medical		medical devices and in vitro	potential or actual shortages of those
		Devices Steering Group shall		<u>diagnostic</u> medical devices	medical devices. As part of that
		liaise, where relevant, with the		included on that list with a view	monitoring, the Medical Devices
		Health Security Committee		to identifying any potential or	Shortages Steering Group shall-liaise,
		established in Article 4 of		actual shortages of those medical	where relevant, with <u>the MDCG</u> , the
		Regulation (EU) 2020/[] and		devices. As part of that	Health Security Committee established in
		the Advisory Committee on		monitoring, the Medical Devices	Article 4 of Regulation (EU) 2020/[]
		public health emergencies		<u>Shortages</u> Steering Group shall	and the Advisory Committee on public
		established pursuant to Article 24		liaise, where relevant, with <u>the</u>	health emergencies established pursuant
		of that Regulation.		MDCG the Health Security	to Article 24 of that Regulation.
				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.	

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 <u>Shortages</u> 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 <u>Shortages</u> Steering Group <u>shallmay</u> 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 <u>Shortages</u> 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 <u>Shortages</u> Steering Group shall <u>may</u> 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 –	Article 22 Reporting and recommendations on shortages of medical devices	Amendment 123	Article 22 Reporting and recommendations on shortages of medical devices	
	paragraph 1	1. For the duration of the public health emergency, the Medical Devices Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article 23(1)(b), and, in particular, signal any potential or actual shortages of medical devices included on the public health emergency critical devices list.	1. For the duration of the public health emergency, the Medical Devices Steering Group shall regularly report the results of its monitoring to the Commission and the subnetwork 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.	1. For the duration of the public health emergency, the Medical Devices <u>Shortages</u> Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article 23(1)(b2)(a), and, in particular, signal any potential or actual shortages of <u>medical</u> <u>devices and in vitro diagnostic</u> 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.

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	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
			, and the second		comments
0.1	Article 22 –		Amendment 124		
84	paragraph 2				
continued	1 0 1	2. Where requested by the	2. Where requested by the	2. Where requested by the	2. Where requested by the
		Commission or the sub-network	Commission, one or more	Commission or the sub-network	Commission, Member States or the sub-
		referred to in Article 23(2)(b),	national competent authorities,	referred to in Article 23(2)(b),	network referred to in Article 23(2)(a),
		the Medical Devices Steering	or the sub-network referred to in	the Medical Devices Steering	the Medical Devices Shortages Steering
		Group shall provide aggregated	Article 23(2)(a), the Medical	Group Shortages shall provide	Group shall provide aggregated data and
		data and forecasts of demand to	Devices Steering Group shall	aggregated data and forecasts of	forecasts of demand to support its
		support its findings. In that	provide aggregated data and	demand to support its findings.	findings. In that regard, the Medical
		regard, the Steering Group shall	forecasts of demand to support	In that regard, the Steering	Devices Shortages Steering Group shall
		liaise with the European Centre	its findings. In that regard, the	Group shall liaise with the	liaise with the European Centre for
		for Disease Prevention and	Steering Group shall liaise with	European Centre for Disease	Disease Prevention and Control to obtain
		Control to obtain	the European Centre for Disease	Prevention and Control to obtain	epidemiological data to help forecast
		epidemiological data to help	Prevention and Control to	epidemiological data to help	medical device needs, and with the
		forecast medical device needs,	obtain epidemiological data to	forecast medical device needs, and with the Medicines	Medicines Shortages Steering Group
		and with the Medicines Steering Group referred to in Article 3	help forecast medical device needs, and with the Medicines	Shortages Steering Group	referred to in Article 3 where medical devices <i>and in vitro diagnostic medical</i>
		where medical devices included	Steering Group referred to in	referred to in Article 3 where	devices included on the public health
		on the public health emergency	Article 3 where medical devices	medical devices <i>and in vitro</i>	emergency critical devices list are used to
		critical devices list are used to	included on the public health	diagnostic medical devices	jointly with a medicinal product. <i>The</i>
		jointly with a medicinal product.	emergency critical devices list	included on the public health	findings and conclusions of the Medical
		Jointly with a medicinal product.	are used to jointly with a	emergency critical devices list	Devices Shortages Steering Group may
			medicinal product. <i>The Medical</i>	are used to jointly with a	also be made available to other actors in
			Devices Steering Group shall	medicinal product.	the medical device and in vitro medical
			also share its findings and	r	device sectors, where relevant, and in
			conclusions with Union and		accordance with relevant competition
			national actors engaged with		rules.
			stockpiling of medicinal		
			products and medical devices.		

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
		(===;,)			comments
0.4	Article 22 –	3. As part of the reporting		3. As part of the reporting	3. As part of the reporting referred to in
84	paragraph 3	referred to in paragraphs 1 and 2,		referred to in paragraphs 1 and 2,	paragraphs 1 and 2, the Medical Devices
continued	paragraph 5	the Medical Devices Steering		the Medical Devices Shortages	Shortages Steering Group may also
Continued		Group may also provide		Steering Group may also provide	provide recommendations on measures,
		recommendations on measures,		recommendations on measures,	which may be taken by the Commission,
		which may be taken by the		which may be taken by the	Member States, medical device
		Commission, Member States,		Commission, Member States,	manufacturers, notified bodies and other
		medical device manufacturers,		medical device manufacturers,	entities to prevent or mitigate potential or
		notified bodies and other entities		notified bodies and other entities	actual shortages. In that regard the Group
		to prevent or mitigate potential or		to prevent or mitigate potential	shall liaise, where relevant, with the
		actual shortages. In that regard		or actual shortages. In that regard	MDCG, the Health Security Committee
		the Group shall liaise, where		the Group shall liaise, where	and the Advisory Committee on public
		relevant, with the Health Security		relevant, with the <i>MDCG</i> , the	health emergencies.
		Committee and the Advisory		Health Security Committee and	
		Committee on public health		the Advisory Committee on	
		emergencies.		public health emergencies.	
	Article 22 –	4. The Medical Devices		4. The Medical Devices	4. The Medical Devices Shortages
	paragraph 4	Steering Group may, on its own		Shortages Steering Group may,	Steering Group may, on its own initiative
		initiative or upon request from		on its own initiative or upon	or upon request from the Commission,
		the Commission, provide		request from the Commission,	provide recommendations on measures
		recommendations on measures		provide recommendations on	which may be taken by the Commission,
		which may be taken by the		measures which may be taken by	Member States, medical device
		Commission, Member States,		the Commission, Member States,	manufacturers, notified bodies and other
		medical device manufacturers,		medical device manufacturers,	entities to ensure preparedness to deal
		notified bodies and other entities		notified bodies and other entities	with potential or actual shortages of
		to ensure preparedness to deal		to ensure preparedness to deal	medical devices and <u>in vitro diagnostic</u>
		with potential or actual shortages		with potential or actual shortages	medical devices caused by public health
		of medical devices caused by		of medical devices <u>and in vitro</u>	emergencies.
		public health emergencies.		diagnostic medical devices	
				caused by public health	
				emergencies.	

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
	1 (dillot)	(2020/0321 (202))	011 / 0413/ 2021	on 10 vane 2021	comments
0.4	Article 22 –	5. The Medical Devices		5. The Medical Devices	5. <i>Where relevant</i> , the Medical
84	paragraph 5	Steering Group may, upon		Shortages Steering Group may,	Devices Shortages Steering Group may,
continued		request from the Commission		upon request from the	upon request from the Commission
		coordinate measures, where		Commission coordinate	coordinate measures [] between the
		relevant, between the national		measures, where relevant,	national competent authorities,
		competent authorities, manufacturers of medical		between the national competent authorities, manufacturers of	manufacturers of medical devices, notified bodies, and other entities to
		devices, notified bodies, and		medical devices, notified bodies,	prevent or mitigate potential or actual
		other entities to prevent or		and other entities to prevent or	shortages in the context of a public health
		mitigate potential or actual		mitigate potential or actual	emergency.
		shortages in the context of a		shortages in the context of a	
	4 : 1 22	public health emergency.		public health emergency.	
	Article 22 –		Amendment 125		
	paragraph 5 a (new)		5a. Where the		
	(new)		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.		
85	Article 23	Article 23		Article 23	
		Working methods and provision		Working methods and provision	
		of information on medical		of information on medical	
	A 4: 1 22	devices		devices	1 1 1 0 0 0 1 5 1 1
	Article 23 –	1. In order to prepare for fulfilling the tooks referred to in		1. In order to prepare for	1. In order to prepare for fulfilling the tasks referred to in Articles 20, 21,
	paragraph 1	fulfilling the tasks referred to in Articles 20, 21, and 22, the		fulfilling the tasks referred to in Articles 20, 21, and 22, the	and 22, the Agency shall:
		Agency shall:		Agency <i>in liaison with MDCG</i> ,	and 22, the regency shall.
				as appropriate, shall:	

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
85	Article 23 –		Amendment 126		
continued	paragraph 1 – point a Article 23 –	(a) specify the procedures for establishing the public health emergency critical devices list;	(a) specify the procedures and criteria for establishing and reviewing the public health emergency critical devices list, ensuring adequate consultation with manufacturers and other relevant actors in the medical devices supply chain as well as with healthcare professionals, consumers and patients; Amendment 127	(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.
	paragraph 1 – point b	(b) dayslan straamlined	(b) dayalan atraamlinad	(b) develop streamlined	(b) develop streamlined electronic
	point b	(b) develop streamlined electronic monitoring and	(b) develop streamlined electronic monitoring and	(b) develop streamlined electronic monitoring and	monitoring and reporting systems, in
		reporting systems;	reporting systems in	reporting systems, facilitating	coordination with the national competent
			coordination with the national	interoperability with existing electronic tools, namely	authorities, facilitate interoperability
			competent authorities;	EUDAMED and providing the	with existing electronic tools, namely EUDAMED and provide the adequate
				adequate support to Members	support to Members States' competent
				States' competent authorities	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;		for monitoring and reporting; (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;

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
			-		comments
85 continued	Article 23 – paragraph 1 – point d	(d) establish and maintain a list of single points of contact from medical device manufacturers, authorised representatives and notified bodies;	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;	(d) establish and maintain a list of single points of contact from medical device manufacturers, authorised representatives, <i>importers</i> , <i>if appropriate</i> , and notified bodies, through EU or national databases, including Eudamed, or stakeholder associations representing the medical societies.
	Article 23 – paragraph 1 – point e	(e) specify the methods for the provision of recommendations and coordination of measures provided for in Article 22.		(e) specify the methods for the provision of recommendations and coordination of measures provided for in Article 22.	RECITAL: Additional recital ◊ In order to ensure the completeness of information and data obtained by the Agency and considering the specific characteristics of the medical device sector, the points of contact for monitoring the shortage of medical devices may be composed by stakeholder associations representing the medical societies at EU or national level with an interest in medical devices and in vitro medical devices, including national public and private hospital and healthcare associations and hospital, health and social care services owners, pharmacies and other relevant nongovernmental organisations in the field of health.
	Article 23 – paragraph 2	2. Following the recognition of a public health emergency the Agency shall:		2. Following the recognition of a public health emergency the Agency shall:	

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	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					1 1 1
85 continued	Article 23 – paragraph 2 – point c Article 23 – paragraph 2 – point ca (new) Article 23 – paragraph 3 Article 23 – paragraph 3 – point a	(2020/0321 (COD)) (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. 3. The information referred to in point (b) of paragraph 2 shall include at least: (a) the name of the manufacturer and, if applicable, the name of the authorised	on 7 July 2021	(c) request <u>relevant</u> 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 <u>Shortages</u> Steering Group and set a deadline for its submission. (ca) other sources, including existing databases and databases in development, may also be used to gather part of the information required under paragraph 3. 3. The information referred to in point (b) of paragraph 2 shall include at least: (a) the name of the manufacturer and, if applicable, the name of the authorised	compromise proposals and comments (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 (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 – point b	representative; (b) identification of the medical device and the intended purpose;		representative; (b) identification of the medical device and the intended purpose <i>and if applicable specific characteristics</i> ;	(b) identification of the medical device and in vitro diagnostic medical device and the intended purpose and where necessary, specific characteristics;

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10111	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
	Transcr	(2020/0321 (COD))	011 7 3 tally 2021	011 13 34110 2021	1 1 1
85 continued	Article 23 – paragraph 3 – point c Article 23 – paragraph 3 – point d Article 23 – paragraph 3 – point e Article 23 – paragraph 3 – point ea (new) Article 23 – paragraph 3 – point ea (new) Article 23 – paragraph 3 – point eb (new)	(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;	Amendment 130 (ea) available stocks; Amendment 131 (eb) quantities already delivered;	(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;	(ea) available stocks (eb) quantities already delivered
	Article 23 – paragraph 3 – point ec (new) Article 23 – paragraph 3 – point f	(f) mitigation plans including production and supply capacity;	(ec) projected deliveries; 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;	(ec) projected deliveries (f) prevention and mitigation plans at least including information on production and supply capacity;

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			,		comments
85 continued	Article 23 – paragraph 3 – point g Article 23 – paragraph 3 – point h	(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; (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;		(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; (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;	(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; (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; (h) emergency critical devices list and relevant conformity assessment procedures;

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85	Article 23 –	(i) where conformity		(i) where conformity	(i) where conformity assessments are
continued	paragraph 3 –	assessments are on-going, the		assessments are on-going, the	on-going, the status of the conformity
Continued	point i	status of the conformity		status of the conformity	assessment by the concerned notified
		assessment by the concerned		assessment by the concerned	bodies in relation to medical devices and
		notified bodies in relation to		notified bodies in relation to	<u>in vitro diagnostic medical devices</u>
		medical devices included in the		medical devices and in vitro	included in the public health emergency
		public health emergency critical		diagnostic medical devices	critical devices list and possible critical
		devices list and possible issues		included in the public health	issues that have impact and which need
		which need to be resolved in		emergency critical devices list	to be resolved considered in order to
		order to complete the conformity		and possible <i>critical</i> issues <i>that</i>	complete the conformity assessment
		assessment process.		have impact and which need to	process.
				be resolved considered in order	
				to complete the conformity	
				assessment process.	
86	Article 24	Article 24		Article 24	
		Obligations on medical device		Obligations on medical device	Obligations on medical device
		manufacturers, authorised		manufacturers, authorised	manufacturers, authorised
		representatives, and notified		representatives, importers,	representatives, importers, distributors
		bodies		distributors and notified bodies	and notified bodies

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		(//			comments
0.6	Article 24 –	In order to facilitate the		In order to facilitate the	In order to facilitate the
86	paragraph 1	monitoring referred to in Article		monitoring referred to in Article	monitoring referred to in Article 21 and
continued	paragrapiri	21 and following a request from		21 and following a request from	following a request from the Agency,
Continued		the Agency, medical device		the Agency, medical device	medical device manufacturers, of the
		manufacturers of the medical		manufacturers of the medical	medical devices or their authorised
		devices included on the public		devices or their authorised	representatives, as applicable, and, if
		health emergency critical devices		representatives, as applicable,	appropriate, importers and distributors
		list and, where necessary,		and, if appropriate, importers,	of medical devices included on the
		concerned notified bodies, shall		distributors, included on the	public health emergency critical devices
		submit the information requested		public health emergency critical	list and, where necessary, concerned
		by the deadline set by the		devices list and, where	notified bodies, shall submit the
		Agency. They shall submit the		necessary, concerned notified	information requested by the deadline
		information requested through		bodies, shall submit the	set by the Agency. They shall submit
		the points of contact designated		information requested by the	the information requested through the
		in accordance with Article 23(2)		deadline set by the Agency. They	points of contact designated in
		and using the reporting methods		shall submit the information	accordance with Article 23(2) and using
		and system established pursuant		requested through the points of	the reporting methods and system
		to Article 23(1). They shall		contact designated in accordance	established pursuant to Article 23(1).
		provide updates wherever		with Article 23(2) and using the	They shall provide updates wherever
		necessary.		reporting methods and system	necessary.
		necessary.		established pursuant to Article	necessary.
				23(1). They shall provide	
				updates wherever necessary.	
	Article 24 –	2. Medical device		2. Medical device	2. Medical device manufacturers
	paragraph 2	manufacturers and notified		manufacturers and or their	andor their authorised representatives,
	paragraph 2	bodies shall justify the absence		authorised representatives, as	as applicable, notified bodies and, if
		of any requested information and		applicable, notified bodies and,	appropriate, importers and distributors
		any delays in providing it by the		if appropriate, importers and	of medical devices shall justify the
		deadline set by the Agency.		distributors shall justify the	absence of any requested information
		armania set of the rigonof.		absence of any requested	and any delays in providing it by the
				information and any delays in	deadline set by the Agency.
				providing it by the deadline set	serial development igency.
				by the Agency.	
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	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
0.6	Article 24 –	3. Where manufacturers of		3. Where manufacturers-of,	3. Where manufacturers-of, <i>or their</i>
86	paragraph 3	medical devices included on the		or their authorised	authorised representatives and, if
continued	F 18- 11- 1	public health emergency critical		representatives and, if	appropriate, importers and distributors
		devices list and concerned		apropriate, importers and	of medical devices and in vitro
		notified bodies indicate that the		distributors of medical devices	diagnostic medical devices included on
		submitted information contains		and in vitro diagnostic medical	the public health emergency critical
		information of a commercially		devices included on the public	devices list and concerned notified bodies
		confidential nature, they shall		health emergency critical devices	indicate that the submitted information
		identify the relevant parts and		list and concerned notified	contains information of a commercially
		clarify the reasons for such an		bodies indicate that the	confidential nature, they shall identify the
		indication. The Agency shall		submitted information contains	relevant parts and clarify the reasons for
		assess the merits of each request		information of a commercially	such an indication. The Agency shall
		and protect such commercially confidential information against		confidential nature, they shall identify the relevant parts and	assess the merits of each request and protect such commercially confidential
		unjustified disclosure.		clarify the reasons for such an	information against unjustified
		unjustified disclosure.		indication. The Agency shall	disclosure.
				assess the merits of each request	disclosure.
				and protect such commercially	
				confidential information against	
				unjustified disclosure.	
	Article 24 –	4. Where manufacturers of		4. Where manufacturers <u>or</u>	4. Where manufacturers or their
	paragraph 4	medical devices included on the		their authorised representatives	authorised representatives and, if
		public health emergency critical		and, if apropriate, importers	appropriate, importers and distributors
		devices list and concerned		and distributors of medical	of <i>medical devices and in vitro</i>
		notified bodies are in possession		devices and in vitro diagnostic	diagnostic medical devices included on
		of any additional information,		medical devices included on the	the public health emergency critical
		which provides evidence of a		public health emergency critical	devices list and concerned notified
		potential or actual shortage, they		devices list and concerned	bodies are in possession of any
		shall immediately provide such		notified bodies are in possession	additional information, which provides
		information to the Agency.		of any additional information,	evidence of a potential or actual
				which provides evidence of a potential or actual shortage, they	shortage, they shall immediately provide such information to the Agency.
				shall immediately provide such	provide such information to the Agency.
				information to the Agency.	
		1		imormation to the Agency.	

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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: (a) provide any comments		5. Following the reporting on the results of the monitoring and any recommendations on preventive or mitigating measures in accordance with Article 22, manufacturers ofor 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: (a) provide any comments	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:
	paragraph 5 – point a Article 24 – paragraph 5 – point b Article 24 – paragraph 5 – point c	they have to the Agency; (b) (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;		they have to the Agency; (b) (<u>b</u>) 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.		(dc) 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.	(dc) 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.

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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 <u>and in vitro</u> <u>diagnostic medical devices</u> 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	devices and in vitro diagnostic 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.
				distributors.	
87	Article 25	Article 25		Article 25	Article 25
	Article 25 – paragraph 1	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:		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:	Obligations on Role of Member States in the monitoring and mitigation of shortages of medical devices

87 continued 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 (a) submit the set of information requested by the Agency, including available information about needs related to the information about needs related to the medical devices and in vitro diagnostic medical devices included in the public health critical devices	ise proposals and s mit the set of information by the Agency, including
87 continued 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 (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 critical devices	S nit the set of information
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 (a) submit the set of information requested by the Agency, including available information about needs related to the witro diagnostic medical devices included in the public health critical devices	mit the set of information
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 demand, through its designated 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); (b) indicate the existence of any commercially confidential information, and, clarify the demand, through its designated 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); (b) indicate the existence of any commercially confidential information, and, clarify the	information about needs the medical devices and in ostic medical devices the public health emergency ices list, and available and lata on the volume of rough its designated point of lusing the reporting methods in established pursuant to

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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	Amendment 134 2. Where necessary to fulfil their reporting obligations set out in paragraph 1, Member States shall gather information from manufacturers, importers, distributors, <i>healthcare professionals</i> and notified	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 <i>and in vitro</i>	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
		the public health emergency critical devices list.	bodies on medical devices included on the public health emergency critical devices list.	diagnostic medical devices included on the public health emergency critical devices list.	bodies on medical devices <u>and in vitro</u> <u>diagnostic medical devices</u> 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 <i>Shortages</i> 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:	

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87 continued	Article 25 – paragraph 4 – point a	(b) consider the need to	Amendment 135 (a) consider the need to	$(\underline{b}\underline{a})$ consider the need to	(\underline{ba}) consider the need to provide for
		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;	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;	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 <u>and in vitro diagnostic medical</u> <u>devices</u> included on the public health emergency critical devices list;	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;		(e) take into account(<u>b</u>) <u>consider</u> any recommendations and, guidelines and comply with any measures taken at Union-level pursuant to Article 26 (<u>a</u>);	(c) take into account(<u>b</u>) <u>consider</u> any recommendations and guidelines and comply with any measures taken at Union-level pursuant to Article 26 (a);

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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.		(dc) 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.	(dc) 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 webportal as referred to in Article 13. (dc) 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.

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0.0	Article 26	Article 26		Article 26	
88					
		Role of the Commission in the		Role Obligations of the	Role of the Commission in the
		monitoring and mitigation of		Commission in the monitoring	monitoring and mitigation of shortages
		shortages of medical devices		and mitigation of shortages of	of medicinal products
				medical devices	
	Article 26 –	The Commission shall take into		The Commission shall take into	The Commission shall take into account
	paragraph 1	account the information from and		account the information from	the information from and
		recommendations of the Medical		and recommendations of the	recommendations of the Medical Devices
		Devices Steering Group and		Medical Devices Shortages	Shortages Steering Group and shall:
		shall:		Steering Group and shall:	
	Article 26 –		Amendment136		
	paragraph 1 –				
	point a	(a) take all necessary action	(a) take all necessary action	(a) take all necessary action	(a) take all necessary action within
		within the limits of the powers	within the limits of the powers	within the limits of the powers	the limits of the powers conferred on it,
		conferred on it, with a view to	conferred on it, with a view to	conferred on it, with a view to	with a view to mitigating potential or
		mitigating potential or actual	mitigating potential or actual	mitigating potential or actual	actual shortages of medical devices and
		shortages of medical devices	shortages of medical devices	shortages of medical devices <u>and</u>	in vitro diagnostic medical devices
		included on the public health	included on the public health	in vitro diagnostic medical	included on the public health
		emergency critical devices list,	emergency critical devices list,	<u>devices</u> included on the public	emergency critical devices list,
		including, where necessary,	including, where necessary,	health emergency critical devices	including, where necessary, granting
		granting temporary exemptions	granting temporary exemptions	list, including, where necessary,	temporary exemptions at Union level
		at Union level pursuant to Article	at Union level pursuant to	granting temporary exemptions	pursuant to Article 59(3) of Regulation
		59(3) of Regulation (EU)	Article 59(3) of Regulation	at Union level pursuant to	(EU) 2017/745 or Article 54(3) of
		2017/745 or Article 54(3) of	(EU) 2017/745 or Article 54(3)	Article 59(3) of Regulation (EU)	Regulation (EU) 2017/746, while
		Regulation (EU) 2017/746;	of Regulation (EU) 2017/746	2017/745 or Article 54(3) of	respecting the conditions set in those
			while at the same time ensuring	Regulation (EU) 2017/746, while	articles and at the same time seeking to
			both patient and product safety;	respecting the conditions set in	ensure both patient and product safety;
				those articles;	

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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	(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 Article 26 – paragraph 1 – point d	(c) request the Medical Devices Steering Group to provide recommendations or coordinate measures pursuant to Article 22(3), (4) and (5); (d) consider the need for medical countermeasures in accordance with Articles 12 and 25(b) of Regulation (EU) 2020/[];	necessary;	(c) request the Medical Devices <i>Shortages</i> Steering Group to provide recommendations or coordinate measures pursuant to Article 22(3), (4) and (5); (d) consider the need for medical countermeasures in accordance with Articles 12 and 25(b) of Regulation (EU) 2020/[];	(c) request the Medical Devices Shortages Steering Group to provide recommendations or coordinate measures pursuant to Article 22(3), (4) and (5);

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					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.	(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 <u>and in vitro diagnostic medical devices</u> 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.

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89	Article 27	Article 27		Article 27	
		Communication on the Medical		Communication on the Medical	Communication on the Medical Devices
		Devices Steering Group		Devices <u>Shortages</u> Steering	Shortages Steering Group
	A :::1- 27		A 1 120	Group	
	Article 27 – paragraph 1		Amendment 139		
	paragraph	The Agency shall, via its web-	The Agency shall, via <i>a</i>	The Agency shall, via its web-	The Agency shall, via a dedicated space
		portal and other appropriate	dedicated space in its web-	portal and other appropriate	in its web-portal and other appropriate
		means and, in conjunction with national competent authorities,	portal and other appropriate means and, in conjunction with	means and, in conjunction with national competent authorities,	means and, in conjunction with national competent authorities, inform the public
		inform the public and relevant	national competent authorities,	inform the public and relevant	and relevant interest groups <i>in a timely</i>
		interest groups with regard to the	inform the public and relevant	interest groups with regard to the	manner with regard to the work of the
		work of the Medical Devices	interest groups in a timely	work of the Medical Devices	Medical Devices Shortages Steering
		Steering Group.	<i>manner</i> with regard to the work of the Medical Devices Steering	Shortages Steering Group.	Group and respond to disinformation targeting the work of the Medical
			Group and respond to		Devices Shortages Steering Group as
			disinformation targeting the		appropriate.
			work of the Medical Devices Steering Group as appropriate.		
	Article 27 –		Amendment 140		
	paragraph 1a				Amendment 140 is linked to AM 99
	(new)		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.		

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
90	Article 28	Article 28		Article 28	Article 28
		Support for the expert panels on medical devices		Support for the expert panels on medical devices	Support for the expert panels on medical devices
			Amendment 141		
		The Agency shall, on behalf of the Commission, <i>from 1 March 2022 onwards</i> , 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:	I. 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) 2019/13962017/745 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	The Agency shall, on behalf of the Commission, <i>from 1 March 2022 onward</i> , provide the secretariat of the expert panels designated in accordance with <i>Implementing Decision</i> (EU) 2019/13962017/745 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:
	Article 28 –		Amendment 142	Agency shall:	
	paragraph 1 – point a Article 28 – paragraph 1 –	 (a) provide administrative and technical support to the expert panels for the provision of scientific opinions, views and advice; (b) facilitate and manage remote and physical meetings of 	(a) provide administrative, <i>scientific</i> 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; (b) facilitate and manage remote and physical meetings of 	(a) provide administrative and technical support to the expert panels for the provision of scientific opinions, views and advice;
	point b	the expert panels;		the expert panels;	

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	,
		(====, ==== (=== //			1 1
90 continued	Article 28 – paragraph 1 – point c Article 28 – paragraph 1 – point d	(2020/0321 (COD)) (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; (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	on 7 July 2021	(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 establishwith 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; (d) maintain and regularly update a web-page for the expert panels and make publicly available on the web-page all information necessary not	compromise proposals and comments (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 establishwith 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; (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
		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;		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;	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;

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
90	Article 28 – paragraph 1 –	(e) publish the scientific opinions, views, and advice of		(e) publish, on behalf of the Commission, the scientific	(e) publish the scientific opinions, views, and advice of the panels while
continued	point e	the panels while ensuring		opinions, views, and advice of	ensuring confidentiality in accordance
		confidentiality in accordance		the panels while ensuring	with Article 106(12) second
		with Article106(12) second		confidentiality in accordance	subparagraph and Article 109 of
		subparagraph and Article 109 of		with Article106(12) second	Regulation (EU) 2017/745;
		Regulation (EU) 2017/745;		subparagraph and Article 109 of	
	Article 28 –	(f) ensure that remuneration		Regulation (EU) 2017/745; (f) ensure that remuneration	(f) ensure that remuneration and
	paragraph 1 –	and expenses are provided to the		and expenses are provided to the	(f) ensure that remuneration and expenses are provided to the experts in
	point f	experts in accordance with		experts in accordance with	accordance with <i>implementing acts</i>
	point 1	Article 11 of Implementing		implementing acts adopted by	adopted by the Commission pursuant to
		Decision (EU) 2019/1396;		the Commission pursuant to	Article 11106(1) of Implementing
				Article 11106(1) of	Decision Regulation (EU)
				Implementing	2019/13962017/745 ;
				Decision Regulation (EU)	
				2019/1396 2017/745 ;	
	Article 28 –	(g) monitor compliance with		(g) monitor compliance with	(g) monitor compliance with the
	paragraph 1 –	the panels' common rules of		the panels' common rules of	panels' common rules of procedure and
	point g	procedure and available		procedure and available	available guidelines and methodologies
		guidelines and methodologies		guidelines and methodologies	relevant to the functioning of the panels;
		relevant to the functioning of the		relevant to the functioning of the	
	4 1 20	panels;		panels;	
	Article 28 –	(h) provide annual reports to		(h) provide annual reports to	(h) provide annual reports to the
	paragraph 1 –	the Commission on the work		the Commission and the MDCG	Commission <i>and the MDCG</i> on the work
	point h	undertaken by the expert panels,		on the work undertaken by the	undertaken by the expert panels,
		including the number of		expert panels, including the	including the number of opinions, views
		opinions, views and advice delivered.		number of opinions, views and advice delivered.	and advice delivered.
Į	1	denvered.	I	advice delivered.	

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
	rumoer	(2020/0321 (202))	011 / 3413/2021	011 13 04110 2021	comments
0.0	Article 28 –			2. In order to perform the	Comments
90	paragraph 2			Agency's tasks, as described	
continued	(new)			under the previous paragraph,	
	(new)			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.	
	Article 28 –			3. The Agency should	
	paragraph 3			periodically, at least twice a	
	(new)			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	
0.1	Chapter V	Chapter V		<u>strategy defined in point 2.</u> Chapter V	
91	Chapter v	Chapter v		Chapter v	
		Final Provisions		Final Provisions	
92	Article 29	Article 29		Article 29	Article 29
		Cooperation between Steering		Cooperation between Steering	Cooperation between Steering Groups,
		Groups		Groups, Emergency Task Force	Emergency Task Force and the expert
		Groups		and the expert panels	panels
	Article 29 –	1. The Agency shall ensure		1. The Agency shall ensure	1. The Agency shall ensure
	paragraph 1	cooperation between the		cooperation between the	cooperation between the Medicines and
		Medicines and Medical Devices		Medicines and Medical Devices	Medical Devices Shortages Steering
		Steering Groups in relation to		Shortages Steering Groups in	Groups in relation to measures to address
		measures to address major events		relation to measures to address	major events and public health
		and public health emergencies.		major events and public health	emergencies.
				emergencies.	

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
92 continued	Article 29 – paragraph 2	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.		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	2. Members of the Medicines and Medical Devices <i>Shortages</i> 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.
	Article 29 – paragraph 3	3. In agreement with the Chairs, joint meetings of the Medicines and Medical Devices Steering Groups may be held.		and opinions. 3. In agreement with the (Co-) Chairs, joint meetings of the Medicines and Medical Devices Steering Groups Shortages Group may be held.	3. In agreement with the <u>(Co-)</u> Chairs, joint meetings of the Medicines and Medical Devices Steering <u>Groups Shortages Group</u> may be held.
	Article 29 – paragraph 4 (new)			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.	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.

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)		Article 29a Protection against cyberattacks 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.

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)		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.		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.

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
95	Article 30	Article 30		Article 30	Article 30
		Confidentiality		Confidentiality	Confidentiality
				Commercially confidential	
	A 4: 1 20			<u>information</u>	1 11 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
	Article 30 – paragraph 1		Amendment 145		1. Unless otherwise provided for in this Regulation and without prejudice to
	paragraph	1. Unless otherwise	1. Unless otherwise	1. Unless otherwise	Regulation (EC) No 1049/201 ²⁴ and
		provided for in this Regulation	provided for in this Regulation	provided for in this Regulation	Directive (EU) 2019/1937 of the
		and without prejudice to	and without prejudice to	and without prejudice to	European Parliament and of the
		Regulation (EC) No 1049/2001	Regulation (EC) No 1049/201 ²⁴ and Directive (EU) 2019/1937	Regulation (EC) No 1049/2001	Council ^{24a} , and existing national
		and existing national provisions and practices in the Member	of the European Parliament	and existing national provisions and practices in the Member	provisions and practices in the Member States on confidentiality, all parties
		States on confidentiality, all	and of the Council ^{24a} , and	States on confidentiality, all	involved in the application of this
		parties involved in the	existing national provisions and	parties involved in the	Regulation shall respect the
		application of this Regulation	practices in the Member States	application of this Regulation	confidentiality of information and data
		shall respect the confidentiality of information and data obtained	on confidentiality, all parties involved in the application of	shall respect the confidentiality of information and data obtained	obtained in carrying out their tasks in order to protect
		in carrying out their tasks in	this Regulation shall respect the	in carrying out their tasks in	order to protect
		order to protect the following:	confidentiality of information	order to protect the following:	
			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).		

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

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
	1 (0,1110 01	(2020,0021 (002))	011 / 0411/ = 0=1		comments
0.5	Article 30 –	2. All parties involved in the		2. Without prejudice to	2. Without prejudice to paragraph
95	paragraph 2	application of this Regulation		paragraph 1, Aall parties	1, Aall parties involved in the application
continued	paragraph 2	shall ensure that no		involved in the application of	of this Regulation shall ensure that no
		commercially confidential		this Regulation shall ensure that	commercially confidential information is
		information is shared in a way		no commercially confidential	shared in a way which has the potential
		which has the potential to enable		information is shared in a way	to enable undertakings to restrict or
		undertakings to restrict or distort		which has the potential to enable	distort competition in the meaning of
		competition in the meaning of		undertakings to restrict or distort	Article 101 TFEU.
		Article 101 TFEU.		competition in the meaning of	
				Article 101 TFEU.	
	Article 30 –	3. Without prejudice to		3. Without prejudice to	3. Without prejudice to paragraph 1,
	paragraph 3	paragraph 1, information		paragraph 1, information	information exchanged on a confidential
		exchanged on a confidential		exchanged on a confidential	basis between competent authorities and
		basis between competent		basis between competent	between competent authorities and the
		authorities and between		authorities and between	Commission and the Agency shall not be
		competent authorities and the		competent authorities and the	disclosed without the prior agreement of
		Commission and the Agency		Commission and the Agency	the authority from which that information
		shall not be disclosed without the		shall not be disclosed without the	originates.
		prior agreement of the authority		prior agreement of the authority	
		from which that information		from which that information	
	Article 30 –	originates.		originates.	4. Paragraphs 1, 2, and 3 shall not
		4. Paragraphs 1, 2, and 3 shall not affect the rights and		4. Paragraphs 1, 2, and 3 shall not affect the rights and	affect the rights and obligations of the
	paragraph 4	obligations of the Commission,		obligations of the Commission,	Commission, the Agency,
		the Agency, Member States and		the Agency, Member-States and	Member-States and other actors
		other actors identified in this		other actors identified in this	identified in this Regulation with regard
		Regulation with regard to the		Regulation with regard to the	to the exchange of information and the
		exchange of information and the		exchange of information and the	dissemination of warnings, nor the
		dissemination of warnings, nor		dissemination of warnings, nor	obligations of the persons concerned to
		the obligations of the persons		the obligations of the persons	provide information under criminal law.
		concerned to provide information		concerned to provide	
		under criminal law.		information under criminal law.	

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.

Item	Article	Commission text	EP amendments voted	Text approved by Council	Tentatively agreed text,
	Number	(2020/0321 (COD))	on 7 July 2021	on 15 June 2021	compromise proposals and
					comments
96			2. For transfers of	2. In the absence of an	2. For transfers of personal data to a
			personal data to a third	adequacy decision, or of	third country, in the absence of an
continued			country, in the absence of an	appropriate safeguards, as	adequacy decision, or of appropriate
			adequacy decision, or of	referred to in Article 49(1) of	safeguards, as referred to in Article 46 of
			appropriate safeguards, as	Regulation (EU) 2016/679 and	Regulation (EU) 2016/679 and Article 48
			referred to in Article 49(1) of	Article 50(1) of Regulation (EU)	of Regulation (EU) 2018/1725, the
			Regulation (EU) 2016/679 and	2018/1725, the Commission, the	Commission, the Agency, and Member
			Article 50(1) of Regulation	Agency, and Member States	States may exchange personal data with
			(EU) 2018/1725, the	may exchange personal data	regulatory authorities of third countries
			Commission, the Agency, and	with regulatory authorities of	with which they have put in place
			Member States may exchange	third countries where necessary	confidentiality arrangements where it is
			personal data with regulatory	for the prevention of or	necessary for important reasons of public
			authorities of third countries	response to a serious threat to	interest, such as to protect public health,
			with which they have	public health of a Member State	in conformity with Article 49 of
			concluded bilateral or	or a third country.	Regulation (EU) 2016/679 and Article 50
			multilateral confidentiality		of Regulation (EU) 2018/1725.
			arrangements where it is		
			necessary for important		
			reasons of public interest, such		
			as to protect public health.		

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		Amendment 150	Article 30c	Article 30c
	(EP) Article 30c (Council) (new)		Article 30b		
			Review	Evaluation and Reporting	Evaluation and Reporting
			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.	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.	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"

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
98	Article 30b (Council) (new)	(2020/0321 (COD))	on 7 July 2021	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.	

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				2. The Agency shall remunerate the activities of the	2. The Agency shall remunerate the activities of the Members States'
continued				Members States' representatives	representatives and experts in relation to
				and experts in relation to the	the Emergency Task Force under this
				Emergency Task Force under	Regulation and reimburse the costs of
				this Regulation and reimburse	the Member States' representatives and
				the costs of the Member States'	experts related to the meetings of the
				representatives and experts	Medicines Shortages and Medical
				related to the meetings of the	Devices Shortages Steering Groups, the
				Medicines Shortages and	Emergency Task Force and their
				Medical Devices Shortages	working parties, in accordance with
				Steering Groups, the Emergency Task Force and	financial arrangements established by the Management Board. Such
				their working parties, in	remuneration shall be paid to national
				accordance with financial	competent authorities.
				arrangements established by the	competent authorness.
				Management Board. Such	<u>OR</u>
				remuneration shall be paid to	
				national competent authorities.	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
	1				

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

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

Presidency suggestions for alternatives on the database

The EP has proposed to introduce a European Medicines Supply Database that would consist of two parts. In the first part the database would enable monitoring supply and demand and managing shortages and enabling stakeholders included in the Regulation, to comply with their requirements. In the second part the EP proposes to mandate the MS to create national databases that would enable real-time tracking of supply of medicinal products.

The Proposals from the Presidency are the following:

1. For the proposed European Medicines Supply database, the Council could be able to accept the proposal, if the database would be built by updating the existing database referred to in article 57(1)i of Regulation 726/2004. This database should be updated with a dataset enabling high level reporting of status of supply, demand and shortages of medicinal products at Union and MS level. The data should be provided directly by Marketing Authorisation Holders (MAH) and wholesalers (WS), the data shall be validated by National Competent Authorities (NCA). The NCA should be able to use this information for high level market monitoring and general identification of potential issues with supply and demand. Additionally, pharmacists and other entities or persons entitled or authorised to supply public with medicines, shall report on shortages through the database, but only if the shortage is not already entered in the database. Furthermore, the general dataset in the database should be updated to reflect the reporting requirements set out in this Regulation (e.g. art 9). The database shall be functional not only during Public Health Emergency or major event, but also under normal circumstances, as the MAH already have the requirement to report on marketing status. The proposal would extend this requirement to WS. The database shall be interoperable with already existent national systems or shall have the option for member states (MS) to enter data directly into the database.

2. For the proposed national databases used for real time monitoring, the proposal of the EP is unacceptable. Real time monitoring is already established with the Falsified medicines database. The database contains a lot of useful information, but is not structured appropriately for high level analysis and reporting. Additionally, NCAs lack the legal authority to access that data in order to manage or prevent shortages, as this activity is not listed in art 39 of Falsified Medicines Directive (FMD). The Council can propose to the EP to discuss needed changes to art 39 of FMD and reporting from Falsified medicines database, but establishing an additional system to serve this purpose is unacceptable.

Summary of the Presidency proposal:

- 1. Using already established infrastructure (Art 57 database and PMS/SPOR), additional information may also be provided from the falsified medicines database.
- 2. The dataset should be updated to take into account attributes for describing supply, demand and shortages as well as for reporting requirements in the Regulation.
- 3. MAH, WS, NCA and other stakeholders should enter, review and monitor the information directly in the database.
- 4. The database should ease communication between stakeholders
- 5. For scope outside of crisis: The requirement for MAH to submit information regarding marketing status should be provided through the database.
- 6. Not a lot of additional workload on MS.
- 7. Interoperable with existing systems on MS level, or offer MS the opportunity to enter data directly into the database.
- 8. Real time monitoring is not acceptable, but the Presidency is prepared to discuss Article 39 of the Falsified Medicines Directive and report from that database.