European Parliament
2019-2024

Committee on the Environment, Public Health and Food Safety

2020/0321(COD)

17.6.2021

COMPROMISE AMENDMENTS 1 - 32

Draft report
◄Nicolás González Casares►
(PE680.818v02-00)

A reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

Proposal for a regulation
(COM(2020)0725 – C9-0365/2020 – 2020/0321(COD))

Amendment 1 (SUBJECT MATTER)
EPP, S&D, RE, Greens/EFA, ID, ECR, The Left
Compromise amendment replacing Amendments: Article 1 (25-27, 241-255, ITRE48)

Proposal for a regulation
Article 1

Text proposed by the Commission	*Amendment*
Subject Matter	*Subject Matter*
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:
(a) prepare for and manage the impact of major events on medicinal products for human use and of public health emergencies on medicinal products for human use and on medical devices;	(a) ***prevent,*** prepare for, ***coordinate*** and manage ***at Union level*** the impact of major events on medicinal products for human use and of public health emergencies on medicinal products for human use and on medical devices;
(b) monitor and report on shortages of medicinal products for human use and medical devices;	(b) ***prevent,*** monitor and report on shortages of medicinal products for human use and ***critical*** medical devices;
	(b a) set up an interoperable and digital database at Union level to monitor and report on shortages of medicinal products;
(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;
(d) provide support for the expert panels designated in accordance with Implementing Decision (EU) 2019/1396.	(d) provide support for the expert panels designated in accordance with Implementing Decision (EU) 2019/1396.

Amendment 2 (DEFINITIONS)
EPP, S&D, RE, Greens/EFA, ID, The Left
Compromise amendment replacing Amendments: Article 2 (28-32; 256-290, 292-306, ITRE49-51) + Recital 4 (5-6, 133-136, 234, 237, 239) + Recital 5 (7, 138-142, ITRE6)

Proposal for a regulation
Article 2

Text proposed by the Commission	*Amendment*
Definitions	*Definitions*
For the purposes of this Regulation, the following definitions shall apply:	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];	(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/[…][2];
(b) *'medicinal product'* means a medicinal product as defined in point (2) of Article 1 of Directive 2001/83/EC of the European Parliament and of the Council;	(b) *'medicinal product'* means a medicinal product as defined in point (2) of Article 1 of Directive 2001/83/EC of the European Parliament and of the Council;
	(b a) '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];
(c) *'medical device'* means both a medical device as defined in point (1) of Article 2 of Regulation (EU) 2017/745, read in conjunction with point (a) of Article 1(6) of that Regulation, and an *in vitro* diagnostic medical device as defined in point (2) of Article 2 of Regulation (EU) 2017/746;	(c) *'medical device'* means both a medical device as defined in point (1) of Article 2 of Regulation (EU) 2017/745, read in conjunction with point (a) of Article 1(6) of that Regulation, and an *in vitro* diagnostic medical device as defined in point (2) of Article 2 of Regulation (EU) 2017/746;
	(c a) 'supply' refers to the total volume of stock of an individual medicinal product or medical device that is placed on the market by a marketing authorisation holder or a manufacturer;
	(c b) '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

[1] [*insert reference to the Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU]* OJ C […], […], p. […].
[2] [*insert reference to the Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU]* OJ C […], […], p. […].

	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;
(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) 's*hortage*' 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***;
(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;
(f) *'major event'* means an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State. Such an event concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin or incident that can affect the supply or quality, safety, and efficacy of medicinal products. Such an event may lead to shortages of medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection.	(f) *'major event'* means an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State. Such an event concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin or incident that can affect the ***manufacturing,*** supply***, demand*** or quality, safety, and efficacy of medicinal products. Such an event may lead to shortages of medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection. ***Recurrent problems of supply of medicinal products are excluded from the scope of this definition.***

Or. en

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) ***Dealing with the issue of*** shortages of medicinal products has been a long-standing priority for the Member States and European Parliament as illustrated by several reports from the European Parliament[3] as well as discussions under recent Presidencies of the Council of the European Union.	(4) ***Addressing the*** shortages of medicinal products has been a long-standing priority***, but unresolved,*** for the Member States and European Parliament as illustrated by several reports from the European Parliament[4] as well as discussions under recent Presidencies of the Council of the European Union.

Proposal for a regulation
Recital 4 a (new)

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

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

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

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) The COVID-19 pandemic has exacerbated the problem of shortages for certain medicinal products considered as critical in addressing the pandemic, and has highlighted the structural limitations in the Union's ability to rapidly and effectively react to such challenges during public health crises.	(5) The COVID-19 pandemic has exacerbated the ***already existing*** problem of shortages for certain medicinal products considered as critical in addressing the pandemic, and has highlighted ***the Union's external dependence in terms of domestic production of medicinal products and medical devices, the lack of coordination and*** the structural limitations in the Union's ***and Member States'*** ability to rapidly and effectively react to such challenges during public health crises***, the need to support and strengthen the industrial fabric through appropriate policies, as well as the need for a more active and extended involvement of the Union institutions, bodies, offices and agencies addressing the health of the Union citizens***.

Amendment 3 (THE EXECUTIVE STEERING GROUP ON MEDICINES)
EPP, S&D, RE, Greens/EFA, ECR, The Left
Compromise amendment replacing Amendments: Article 3 (33-35; 308-331; 335-344, ITRE53-58)

Proposal for a regulation
Article 3

Text proposed by the Commission	*Amendment*
The Executive Steering Group On Shortages And Safety Of Medicinal Products	*The Executive Steering Group On Shortages And Safety Of Medicinal Products*
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 p erson or remotely,	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

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.	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.
2. The Medicines Steering Group shall be composed of a representative of the Agency, a representative of the Commission ~~***and***~~ one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields.	2. The Medicines Steering Group shall be composed of a representative of the Agency, a representative of the Commission ***and*** one ***authorised*** senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields. ***The Medicines Steering Group shall also include a representative of the Agency's Patients' and Consumers' Working Party (PCWP) and a representative of the Agency's Healthcare Professionals' Working Party (HCPWP) as observers. The list of the members of the Medicines Steering Group shall be transparent and made public on the Agency's web-portal.***
3. The Medicines Steering Group shall be chaired by the Agency. ***The*** Chair ***may*** invite third parties, including representatives of medicinal product interest groups and marketing authorisation holders to attend its meetings.	3. The Medicines Steering Group shall be chaired by the Agency. ***Any member of the Medicines Steering Group may propose to the*** Chair ***to*** invite third parties, including representatives of medicinal product interest groups***,*** marketing authorisation holders***, wholesale distributors, or any other appropriate actor in the pharmaceutical supply chain, representatives of healthcare professionals, patients and consumers*** to attend its meetings ***when their contribution may inform the discussions of the Steering Group***.
	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.
4. The Medicines Steering Group shall establish its rules of procedure including procedures relating to the working party referred to the paragraph 5 and on the adoption of lists, sets of information, and recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.	4. The Medicines Steering Group shall establish its rules of procedure including procedures relating to the working party referred to the paragraph 5 and on the adoption of lists, sets of information, and recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.
5. The Medicines Steering Group shall be supported in its work by a working party comprised of single points of contact related to shortages from national competent authorities for medicinal products established in accordance with Article 9(1).	5. The Medicines Steering Group shall be 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).
6. The Medicines Steering Group shall be responsible for fulfilling the tasks referred to in Article 4(4) and Articles 5 to 8.	6. The Medicines Steering Group shall be responsible for fulfilling the tasks referred to in Article ***4(3),*** 4(4) and Articles 5 to 8.
	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.
	6 b. Members of the Medicines Steering Group shall not have financial or other interests in the pharmaceutical industry that could affect their impartiality. They shall act in the public interest and in an independent manner and make an annual declaration of their financial interests and update it whenever a relevant change occurs. All indirect interests which could relate to the pharmaceutical industry shall be entered in a register held by the Agency and upon

request shall be accessible to the public. The declaration of interests shall be made publicly available on the Agency's web-portal.

Or. en

Amendment 4 (MONITORING OF EVENTS AND PREPAREDNESS)
EPP, S&D, RE, Greens/EFA, ID, The Left
Compromise amendment replacing Amendments: Article 4 (36-39, 345-365, ITRE46, ITRE59-62)

Proposal for a regulation
Article 4

Text proposed by the Commission	*Amendment*
Monitoring of events and preparedness for major events and public health emergencies	*Monitoring of events and preparedness for major events and public health emergencies*
1. The Agency shall continuously monitor any event that is likely to lead to a major event or a public health emergency.	1. The Agency shall continuously monitor any event that is likely to lead to a major event or a public health emergency ***in coordination with the national competent authorities. In that regard, the Agency shall cooperate closely with the European Centre for Disease Prevention and Control (ECDC) and other Union agencies, where relevant.***
2. To facilitate the monitoring task referred to in paragraph 1, the national competent authorities, through the single points of contact referred to in Article 3(5), shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report to the Agency on any event, including a shortage of a medicinal product in a given Member State, that is likely to lead to a major event or a public health emergency. Where a national competent authority informs the Agency of a shortage	2. To facilitate the monitoring task referred to in paragraph 1, the national competent authorities, through the single points of contact referred to in Article 3(5) ***or the database referred to in Article 12a once fully functional***, shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report ***without delay*** to the Agency on any event, including a shortage of a medicinal product in a given Member State, that is likely to lead to a major event or a public health

of a medicinal product in a given Member State, it shall provide the Agency with any information received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC. Based on a report of an event from a national competent authority and in order to understand the impact of the event in other Member States, the Agency may request information from the national competent authorities, through the working party referred to in Article 3(5).

emergency. Where a national competent authority informs the Agency of a shortage of a medicinal product in a given Member State, it shall provide the Agency with any information received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC. Based on a report of an event from a national competent authority and in order to understand the impact of the event in other Member States, the Agency may request information from the national competent authorities, through the working party referred to in Article 3(5).

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

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

4. The Medicines Steering Group shall inform the Commission and the Executive Director of the Agency, once it considers that the major event has been sufficiently addressed. On the basis of that information or on its own initiative, the Commission or the Executive Director may confirm that the assistance of the Medicines Steering Group is no longer needed.

4. The Medicines Steering Group shall inform the Commission and the Executive Director of the Agency, once it considers that the major event has been sufficiently addressed. On the basis of that information or on its own initiative, the Commission or the Executive Director may confirm that the assistance of the Medicines Steering Group is no longer needed.

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:

(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;

(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.

Or. en

Amendment 5 (EVALUATION OF INFORMATION)
EPP, S&D, RE, Greens/EFA, ID, ECR, The Left
Compromise amendment replacing Amendments: Article 5 (40- 44, 366-370, ITRE63-64)

Proposal for a regulation
Article 5

Text proposed by the Commission	*Amendment*
Evaluation of information and the provision of advice on action in relation to the safety, quality, and efficacy of medicinal products related to public health emergencies and major events	*Evaluation of information and the provision of advice on action in relation to the safety, quality, and efficacy of medicinal products related to public health emergencies and major events*
Following the recognition of a public health emergency or a request for assistance referred to in Article 4(3), the Medicines Steering Group shall evaluate the information related to the major event or the public health emergency and consider the need for urgent and coordinated action with regard to the safety, quality, and efficacy of the medicinal products concerned.	Following the recognition of a public health emergency or a request for assistance referred to in Article 4(3), the Medicines Steering Group shall evaluate the information related to the major event or the public health emergency and consider the need for urgent and coordinated action with regard to the safety, quality, and efficacy of the medicinal products concerned.
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.[5]	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.[6]
	The Commission and Member States shall provide a substantiated justification in the

[5] Regulation (EC) No 726/2004
[6] Regulation (EC) No 726/2004

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.

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

Or. en

Amendment 6 (LISTS OF CRITICAL MEDICINAL PRODUCTS)
EPP, S&D, RE, Greens/EFA, ID, The Left
Compromise amendment replacing Amendments: Article 6 (45- 47, 371-392, ITRE65-69) + Recital 15 (15, 16, 189-194, ITRE26)

Proposal for a regulation
Article 6

Text proposed by the Commission	*Amendment*
Lists of critical medicinal products and information to be provided	*Lists of critical medicinal products and information to be provided*
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	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.	(‘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***.
2. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medicines Steering Group shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the public health emergency (‘the public health emergency critical medicines list’). The list shall be updated whenever necessary until the termination of the recognition of the public health emergency.	2. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medicines Steering Group shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the public health emergency (‘the public health emergency critical medicines list’). The list shall be updated whenever necessary until the termination of the recognition of the public health emergency. ***The list may be updated in accordance with the outcomes of the review process under Article 16 of this Regulation, where appropriate, for which the Medicines Steering Group shall liaise with the Emergency Task Force.***
3. The Medicines Steering Group shall adopt a set of information necessary to monitor the supply and demand of medicinal products included on the lists referred to in paragraphs 1 and 2 (‘the critical medicines lists’) and inform its working party thereof.	3. The Medicines Steering Group shall adopt a set of information ***and actions*** necessary to monitor the supply and demand of medicinal products included on the lists referred to in paragraphs 1 and 2 (‘the critical medicines lists’) and inform its working party thereof. ***Union or national entities that are engaged in stockpiling of medicinal products shall be informed accordingly. The Medicines Steering Group shall report to the Agency and to the Commission in due time on the monitoring and shall notify immediately on any major event or shortage in the supply.***
4. The Agency shall immediately publish the critical medicines lists and any updates to those lists on its web-portal referred to in Article 26 of Regulation (EC) No 726/2004.	4. The Agency shall immediately publish the critical medicines lists and any updates to those lists on its web-portal referred to in Article 26 of Regulation (EC) No 726/2004.
	4a. The Agency shall establish a publicly accessible webpage with information on

actual shortages of critical medicinal products. Reference to national registries on medicinal products shortages shall also be included. The webpage shall contain information on, but not limited to:

(a) Trade name and international non-proprietary name;

(b) Indication;

(c) Reason for the shortage;

(d) Start and end dates;

(e) Member States affected;

(e)Information for healthcare professionals and patients, including information on alternative treatments.

Or. en

Proposal for a regulation
Recital 15

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

Amendment 7 (MONITORING SHORTAGES OF CRITICAL MEDICINES)
EPP, S&D, RE, Greens/EFA, ID, ECR, The Left
Compromise amendment replacing Amendments: Article 7 (48, 399- 408, ITRE70)

Proposal for a regulation
Article 7

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

Or. en

Amendment 8 (REPORTING ON SHORTAGES)
EPP, S&D, RE, Greens/EFA, ID, ECR, The Left
Compromise amendment replacing Amendments: Article 8 (49, 50, 409-440, ITRE71-75)

Proposal for a regulation
Article 8

Text proposed by the Commission	*Amendment*
Reporting and recommendations on shortages of medicinal products	*Reporting and recommendations on shortages of medicinal products*
1. For the duration of a public health emergency or following a request for	1. For the duration of a public health emergency or following a request for

assistance referred to in Article 4(3) and until its closure, the Medicines Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article 9(2), and, in particular, signal any potential or actual shortages of medicinal products included on the critical medicines lists.	assistance referred to in Article 4(3) and until its closure, the Medicines Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article 9(2), and, in particular, signal any potential or actual shortages of medicinal products included on the critical medicines lists. ***Those reports may also be made available to other actors in the pharmaceutical supply chain, where relevant.***
2. Where requested by the Commission or the sub-network referred to in Article 9(2), the Medicines Steering Group shall provide aggregated data and forecasts of demand to substantiate its findings. In that regard, the Medicines Steering Group shall liaise with the European Centre for Disease Prevention and Control to obtain epidemiological data to help forecast medicinal product needs, and with the Executive Steering Group on Shortages of Medical Devices referred to in Article 19 where medicinal products included on the critical medicines lists are administered with a medical device.	2. Where requested by the Commission, ***one or more national competent authorities*** or the sub-network referred to in Article 9(2), the Medicines Steering Group shall provide aggregated data and forecasts of demand to substantiate its findings. In that regard, the Medicines Steering Group ***shall use data from the database established in accordance with Article 12a once fully functional and*** shall liaise with the European Centre for Disease Prevention and Control to obtain epidemiological data***, models and development scenarios*** to help forecast medicinal product needs, and with the Executive Steering Group on Shortages of Medical Devices referred to in Article 19 where medicinal products included on the critical medicines lists are administered with a medical device. ***The aggregated data and forecasts of demand may also be made available to other actors in the pharmaceutical supply chain, where relevant, with a view to better prevent or mitigate potential or actual shortages. The Medicine Steering Group shall also share its findings and conclusions with Union and national actors engaged with stockpiling of medicinal products and medical devices.***
3. As part of that reporting, the Medicines Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, as relevant, with the	3. As part of that reporting, the Medicines Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities, ***including representatives of healthcare professionals and patient organisations,*** to prevent or mitigate

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

Or. en

Amendment 9 (WORKING METHODS)
EPP, S&D, RE, ID, The Left
Compromise amendment replacing Amendments: Article 9 (51-63, 441-495, ITRE76-87)

Proposal for a regulation
Article 9

Text proposed by the Commission	*Amendment*
Working methods and provision of information on medicinal products	*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:	1. In order to prepare for fulfilling the tasks referred to in Articles 4 to 8, the Agency shall:
(a) specify the procedures for establishing the critical medicines lists;	(a) specify the procedures ***and criteria*** for establishing ***and reviewing*** the critical medicines lists***, ensuring adequate consultation with marketing authorisation holders and other relevant actors in the pharmaceutical supply chain as well as with healthcare professionals, consumers and patients***;
(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***;
(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***;
(d) establish and maintain membership of the working party referred to in Article 3(5) comprised of single points of contacts from national competent authorities for medicinal products;	(d) establish and maintain membership of the working party referred to in Article 3(5) comprised of single points of contacts from national competent authorities for medicinal products;
(e) establish and maintain a list of single points of contact from marketing authorisation holders for all medicinal products for human use authorised in the Union, through the database provided for in Article 57(1)(l) of Regulation 726/2004;	(e) establish and maintain a list of single points of contact from marketing authorisation holders for all medicinal products for human use authorised in the Union, through the database provided for in Article 57(1)(l) of Regulation 726/2004;
(f) specify the methods for the provision of recommendations, advice and coordination of measures provided for in	(f) specify the methods for the provision of recommendations, advice and coordination of measures provided for in

Articles 5 and 8.	Articles 5 and 8.
	(f a) publish information referred to in points (a), (b) and (f) of paragraph 1 on its web-portal.
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:
(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;
(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***;
(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***.
3. The information referred to in point (b) of paragraph 2 shall include at least:	3. The information referred to in point (b) of paragraph 2 shall include at least:
(a) the name of the marketing authorisation holder;	(a) the name of the marketing authorisation holder;
(b) the name of the medicinal product;	(b) the name of the medicinal product;
(c) the country of authorisation and marketing status in each Member State;	(c) the country of authorisation and marketing status in each Member State;
(d) details of the potential or actual shortage such as actual or estimated start and end dates and suspected or known	(d) details of the potential or actual shortage such as actual or estimated start and end dates and suspected or known cause ***as well as information on potential***

cause;	***bottlenecks in the supply chain***;
(e) sales and market share data;	(e) sales and market share data;
	(ea) available stocks;
	(eb) quantities already delivered;
	(ec) projected deliveries;
(f) details of available alternative medicinal products;	(f) details of available alternative medicinal products;
(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;***
(h) information from the wholesale distributors and legal person entitled to supply the medicinal product to the public.	***deleted***

Or. en

Amendment 10 (OBLIGATIONS ON MAHs)
EPP, S&D, RE, Greens/EFA, ID, The Left
Compromise amendment replacing Amendments: Article 10 (64-70, 496-516, ITRE88-91)

Proposal for a regulation
Article 10

Text proposed by the Commission	*Amendment*
Obligations on marketing authorisation holders	*Obligations on marketing authorisation holders*
1. In order to facilitate the monitoring referred to in Article 7 and following a	1. In order to facilitate the monitoring referred to in Article 7 and following a

request from the Agency, marketing authorisation holders for medicinal products included on the critical medicines lists shall submit the information referred to in Article 9(3) by the deadline set by the Agency. They shall submit the information through the points of contact designated in accordance with Article 9(2) and using the reporting methods and system established pursuant to Article 9(1). They shall provide updates where necessary.

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.

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.

4. Where marketing authorisation holders for medicinal products included on the critical medicines lists indicate that the submitted information contains information of a commercially confidential nature, they shall identify the relevant parts and clarify the reasons for such an indication. The Agency shall assess the merits of each request and protect commercially confidential information against unjustified disclosure.

5. Where marketing authorisation holders for medicinal products included on the critical medicines lists are in possession of any additional information, which

request from the Agency, marketing authorisation holders for medicinal products included on the critical medicines lists shall submit the information referred to in Article 9(3) by the deadline set by the Agency. They shall submit the information through the points of contact designated in accordance with Article 9(2) and using the reporting methods and system established pursuant to Article 9(1). They shall provide updates where necessary.

2. Marketing authorisation holders of medicinal products authorised in the Union shall, within 6 months from the date of application of this Regulation, provide the information required pursuant to Article 9(1)(e) in the form of an electronic submission in the database referred to in Article 57(1)(l) of Regulation (EC) No 726/2004 ***and in compliance with the standards developed by the International Organization for Standardization (ISO) for the identification of medicinal products for human use (IDMP)***. Those marketing authorisation holders shall update their submission wherever necessary.

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.

4. Where marketing authorisation holders for medicinal products included on the critical medicines lists indicate that the submitted information ***requested by the Agency or the national competent authorities*** contains information of a commercially confidential nature, they shall identify the relevant parts and clarify the reasons for such an indication. The Agency shall assess the merits of each request and protect commercially confidential information against unjustified disclosure.

5. Where marketing authorisation holders for medicinal products included on the critical medicines lists ***and/or other relevant actors in the pharmaceutical***

provides evidence of a potential or actual shortage they shall immediately provide such information to the Agency.	***supply chain*** are in possession of any additional information, which provides evidence of a potential or actual shortage they shall immediately provide such information to the Agency.
6. Following the reporting on the results of the monitoring and any recommendations on preventive or mitigating measures in accordance with Article 8, marketing authorisation holders for medicinal products included on the critical medicines list shall:	6. Following the reporting on the results of the monitoring and any recommendations on preventive or mitigating measures in accordance with Article 8, marketing authorisation holders for medicinal products included on the critical medicines list shall:
(a) provide any comments they have to the Agency;	(a) provide any comments 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;	(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;
(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.
	6 a. In order to supplement the shortage prevention and mitigation plans of critical medicinal products, the Agency and national competent authorities may request additional information from wholesale distributors and other relevant actors regarding any logistical challenges incurred by the wholesale supply chain.

Or. en

Amendment 11 (OBLIGATIONS ON MSs)
EPP, S&D, RE, Greens/EFA, ID, The Left
Compromise amendment replacing Amendments: Article 11 (71, 72, 520-535, ITRE92-93)

Proposal for a regulation
Article 11

Text proposed by the Commission	*Amendment*
Obligations on Member States in the monitoring and mitigation of shortages of medicinal products	*Obligations on Member States in the monitoring and mitigation of shortages of medicinal products*
1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, Member States shall, by the deadline set by the Agency:	1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, Member States shall, by the deadline set by the Agency, ***submit the following information provided that it is not available in the database established in Article 12a***:
(a) submit the set of information requested by the Agency including available and estimated data on volume of demand, through its designated point of contact and using the reporting methods and system established pursuant to Article 9(1);	(a) submit the set of information requested by the Agency including available and 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);
(b) indicate the existence of any commercially confidential information and clarify the reasons for such an indication;	(b) indicate the existence of any commercially confidential information and clarify the reasons for such an indication;
(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.
2. Where necessary to fulfil their reporting obligations set out in paragraph 1, Member States, with the support of the Agency, shall gather information and data on stock levels from wholesale distributors and other legal entities entitled to supply the public with medicinal products included on the critical medicines lists.	2. Where necessary to fulfil their reporting obligations set out in paragraph 1, Member States, with the support of the Agency, shall gather ***relevant*** information and data***, including*** on stock levels***,*** from wholesale distributors and other legal entities and ***persons authorised or*** entitled to supply the public with medicinal products included on the critical medicines lists.
3. Where Member States are in possession of any additional information on volume of sales and volumes of prescriptions, including data based on Article 23a of Directive 2001/83/EC, which provides evidence of a potential or actual shortage of a medicinal product	3. Where Member States are in possession of any additional information on volume of sales and volumes of prescriptions, including data based on Article 23a of Directive 2001/83/EC, which provides evidence of a potential or actual shortage of a medicinal product

included on the critical medicines lists, they shall immediately provide such information to the Medicines Steering Group through their designated points of contact.	included on the critical medicines lists, they shall immediately provide such information to the Medicines Steering Group through their designated points of contact.
4. Following the reporting on the results of the monitoring and any recommendations on preventive or mitigating measures in accordance with Article 8, Member States shall:	4. Following the reporting on the results of the monitoring and any recommendations on preventive or mitigating measures in accordance with Article 8, Member States shall:
(a) take into account any recommendations and guidelines and comply with any measures taken at Union-level pursuant to Article 12;	(a) take into account any recommendations and guidelines and comply with any measures taken at Union-level pursuant to Article 12;
(b) inform the Medicines Steering Group of any measures taken and report on the results of those measures, including information on the resolution of the potential or actual shortage.	(b) inform the Medicines 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.
	4 a. 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 these 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.

Or. en

Amendment 12 (ROLE of COM)
EPP, S&D, RE, Greens/EFA, ID, ECR, The Left
Compromise amendment replacing Amendments: 12 (73, 536-549, 552, ITRE47, ITRE94-96)

Proposal for a regulation
Article 12

Text proposed by the Commission	*Amendment*
Role of the Commission in the monitoring and mitigation of shortages of medicinal products	*Role of the Commission in the monitoring and mitigation of shortages of medicinal products*

The Commission shall take into account the information from and recommendations of the Medicines Steering Group and shall:	The Commission shall take into account the information from and recommendations of the Medicines Steering Group and shall:
(a) take all necessary action within the limits of the powers conferred on it, with a view to mitigating potential or actual shortages of medicinal products included on the critical medicines lists;	(a) take all necessary action within the limits of the powers conferred on it, with a view to mitigating potential or actual shortages of medicinal products included on the critical medicines lists;
	(a a) facilitate the coordination between manufacturers and other relevant stakeholders to address demand surges;
(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities;	(b) consider the need for guidelines ***and recommendations*** addressed to Member States, marketing authorisation holders, and other entities***, including from the pharmaceutical supply chain as well as healthcare professionals, to support them in their work and in the communication with patients***;
(c) inform the Medicines Steering Group of any measures taken and report on the results;	(c) inform the Medicines Steering Group of any measures taken and report on the results;
(d) request the Medicines Steering Group to provide recommendations or coordinate measures as provided for in Article 8(3), (4) and (5);	(d) request the Medicines Steering Group to provide recommendations or coordinate measures as provided for in Article 8(3), (4) and (5);
(e) consider the need for medical countermeasures in accordance with Articles 12 and 25(b) of Regulation (EU) 2020/[…];[7]	(e) consider the need for medical countermeasures in accordance with Articles 12 and 25(b) of Regulation (EU) 2020/[…];[8]
(f) liaise with third countries and relevant international organisations, as appropriate, to mitigate potential or actual shortages of medicinal products included on the critical medicines list or their active pharmaceutical ingredients, where those products or ingredients are imported into the Union and where such potential or actual shortages have international implications.	(f) liaise with third countries and relevant international organisations, as appropriate, to mitigate potential or actual shortages of medicinal products included on the critical medicines list or their active pharmaceutical ingredients, where those products or ingredients are imported into the Union and where such potential or actual shortages have international implications***, and report those actions as well as the results obtained to the Medicines Steering Group***.

[7] [*insert reference to adopted text referred to in footnote 4]*
[8] [*insert reference to adopted text referred to in footnote 4]*

Amendment 13 (EU DATABASE)
S&D, RE, Greens/EFA, ID, The Left
Compromise amendment replacing Amendments: Article 12a (75, 307, 393-398, 530, 550, 553) + Recital 13a (15, 175, 177, 186, 187, 196, 197, 229, 230, 235, ITRE39-41)

Proposal for a regulation
Article 12 a (new)

Text proposed by the Commission	*Amendment*
	Article 12 a
	European Medicines Supply Database
	1. The Agency shall, in collaboration with the Commission and Member States, set up, maintain and manage the European medicines supply database (EUMSD) for the following purposes:
	(a) to enable the monitoring of supply and demand of medicinal products at Union and Member State level;
	(b) to enable the monitoring and reporting of shortages of medicinal products at Union and Member State level;
	(c) to enable marketing authorisation holders and wholesale distributors to comply with the information obligations laid down in Article 10;
	(d) to enable the Commission, the Agency and the national competent authorities to carry out their tasks in accordance with this Regulation on a well-informed basis and to enhance the cooperation between them.
	The EUMSD, which shall be functional not only during public health emergencies and major events but also under normal circumstances, shall function as an interoperable and digital database at

Union level, based on the data reported through the national electronic platforms established pursuant to paragraph 2. The database shall allow the Agency and the national competent authorities to simultaneously access and share the information provided in the database.

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

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

(a) marketing authorisation holders

(b) wholesale distributors

(c) community and hospital pharmacies

3. In addition to paragraph 2, the electronic platforms shall provide the national competent authorities with real-time access to information on unmet demands from wholesale distributors, community pharmacies and hospital pharmacies at national level. Those platforms shall also allow marketing authorisation holders to report any medicinal products supply problems, including manufacturing problems.

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

Article 9(2).

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

6. The data submitted shall be compliant with the standards developed by the International Organization for Standardization (ISO) for the identification and description of medicinal products for human use (IDMP) and be based on the four domains of master data in pharmaceutical regulatory processes: substance, product, organisation and referential data.

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

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

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

Or. en

Proposal for a regulation
Recital 13 a (new)

Text proposed by the Commission	*Amendment*
	(13a) In order to facilitate the prevention, monitoring and reporting of shortages of medicinal products, it would be necessary for the Union and Member States to set up an electronic platform capable of determining the volume of stocks existing at any given moment, and detecting, predicting and preventing shortages of medicinal products. To facilitate the development of such a system, lessons could be learnt from projects such as CISMED, funded by the Union through Horizon Europe. The platform should provide the national competent authorities with real-time access to information on unmet demands from wholesale distributors, community pharmacies and hospital pharmacies, providing accurate data in order to understand the functioning of the supply chain and anticipate potential shortages of medicinal products. The platform should also act as the sole portal for marketing authorisation holders and wholesale distributors to provide the information required during major events and public health emergencies once fully implemented, with a view to increasing efficiency, predictability during crises, and accelerate the decision-making process while avoiding duplication of

	efforts and an unjustified burden on all stakeholders. In order to facilitate the coordination role of the Agency, Member States' supply monitoring platforms should be interoperable and replicate their information in the Union database managed by the Agency. To accelerate the implementation of the system at Union and national level, its development and implementation should be supported by Union funding from, inter alia, the EU4Health Programme or the Recovery and Resilience Facility established by Regulation (EU) 2021/241 of the European Parliament and of the Council1a.

Amendment 14 (OBLIGATIONS ON MSs)
EPP, S&D, RE, Greens/EFA, ID, ECR, The Left
Compromise amendment replacing Amendments: Article 13 (76, 77, 332- 334, 554-559, ITRE97-98)

Proposal for a regulation
Article 13

Text proposed by the Commission	*Amendment*
Communication on the Medicines Steering Group	*Communication on the Medicines Steering Group*
The Agency shall, via its web-portal and other appropriate means, in conjunction with national competent authorities, inform the public and interest groups with regard to the work of the Medicines Steering Group.	The Agency shall, via ***a dedicated space on*** its web-portal and other appropriate means, in conjunction with national competent authorities, inform the public and interest groups ***in a timely manner*** with regard to the work of the Medicines Steering Group***, and respond to disinformation targeting the work of the Medicines Steering Group as appropriate***. ***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.

Or. en

Amendment 15 (EMERGENCY TAK FORCE)
EPP, S&D, RE, Greens/EFA, ID, ECR, The Left
Compromise amendment replacing Amendments: Article 14 (78, 79, 80, 560-587, ITRE99-100) + Recital 17 (198, 199, 200, ITRE29) + Recital 18 (18, 201, 202, ITRE30) + Recital 19 (203, ITRE31)

Proposal for a regulation
Article 14

Text proposed by the Commission	*Amendment*
The Emergency Task Force	*The Emergency Task Force*
1. The Emergency Task Force is hereby established as part of the Agency. It shall be convened during public health emergencies, either in person or remotely. The Agency shall provide its secretariat.	1. The Emergency Task Force is hereby established as part of the Agency. It shall be convened ***in preparation for and*** during public health emergencies, either in person or remotely. The Agency shall provide its secretariat.
2. During public health emergencies, the Emergency Task Force shall undertake the following tasks:	2. During public health emergencies, the Emergency Task Force shall undertake the following tasks:
(a) providing scientific advice and reviewing the available scientific data on medicinal products with the potential to address the public health emergency, including requesting data from developers and engaging with them in preliminary discussions;	(a) providing scientific advice and reviewing the available scientific data on medicinal products with the potential to address the public health emergency, including requesting data from developers and engaging with them in preliminary discussions;
(b) reviewing clinical trial protocols and providing advice to developers on clinical trials to be conducted in the Union for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency, in accordance with Article 15;	(b) reviewing clinical trial protocols and providing advice to developers on clinical trials to be conducted in the Union for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency, in accordance with Article 15;
(c) providing scientific support to	(c) providing scientific support to

facilitate clinical trials to be conducted in the Union for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency. Such support shall include advice to sponsors of similar or linked planned clinical trials on the establishment, in their place, of joint clinical trials and may include advice on establishing agreements to act as a sponsor or as co-sponsor in accordance with Articles 2(14) and 72 of Regulation (EU) 536/2014;

(d) contributing to the work of the scientific committees, working parties and scientific advisory groups of the Agency;

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

(f) cooperating with Union bodies and agencies, the World Health Organization, third countries, and international scientific organisations on scientific and technical issues relating to the public health emergency and to medicinal products which may have the potential to address public health emergencies, as necessary.

3. The Emergency Task Force shall be composed of representatives of the scientific committees, working parties, and staff members of the Agency, the coordination group established in accordance with Article 27 of Directive 2001/83/EC, and the Clinical Trials Coordination and Advisory Group established in accordance with Article 85 of Regulation (EU) 536/2014. External experts may be appointed and representatives of other Union bodies and agencies be invited on an ad hoc basis, as necessary. It shall be chaired by the Agency.

facilitate clinical trials to be conducted in the Union for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency. Such support shall include advice to sponsors of similar or linked planned clinical trials on the establishment, in their place, of joint clinical trials and may include advice on establishing agreements to act as a sponsor or as co-sponsor in accordance with Articles 2(14) and 72 of Regulation (EU) 536/2014;

(d) contributing to the work of the scientific committees, working parties and scientific advisory groups of the Agency;

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

(f) cooperating ***with national competent authorities,*** Union bodies and agencies, the World Health Organization, third countries, and international scientific organisations on scientific and technical issues relating to the public health emergency and to medicinal products which may have the potential to address public health emergencies, as necessary.

3. The Emergency Task Force shall be composed of representatives of the scientific committees, working parties, ***including representatives of the Patients' and Consumers' Working Party and the Healthcare Professionals' Working Party***, and staff members of the Agency, the coordination group established in accordance with Article 27 of Directive 2001/83/EC, and the Clinical Trials Coordination and Advisory Group established in accordance with Article 85 of Regulation (EU) 536/2014. External experts may be appointed and representatives of other Union bodies and agencies be invited on an ad hoc basis, as necessary. It shall be chaired by the Agency.

4. The composition of the Emergency Task Force shall be approved by the Management Board of the Agency. The Executive Director of the Agency or their representative and representatives of the Commission shall be entitled to attend all meetings.	4. The composition of the Emergency Task Force shall be approved by the Management Board of the Agency. The Executive Director of the Agency or their representative and representatives of the Commission shall be entitled to attend all 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, and interest groups representing patients and healthcare professionals to attend its meetings.	5. The Chair may invite representatives of Member States, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, ***independent clinical trial experts and researchers,*** and interest groups representing patients and healthcare professionals to attend its meetings.
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.
7. The Emergency Task Force shall perform its tasks as a body separate from, and without prejudice to the tasks of the scientific committees of the Agency as regards the authorisation, supervision and pharmacovigilance of the concerned medicinal products and related regulatory actions to ensure the quality, safety and efficacy of those medicinal products. The Emergency Task Force shall take account of any scientific opinion issued by those committees in accordance with Regulation (EC) No 726/2004 and Directive 2001/83/EC.	7. The Emergency Task Force shall perform its tasks as a body separate from, and without prejudice to the tasks of the scientific committees of the Agency as regards the authorisation, supervision and pharmacovigilance of the concerned medicinal products and related regulatory actions to ensure the quality, safety and efficacy of those medicinal products. The Emergency Task Force shall take account of any scientific opinion issued by those committees in accordance with Regulation (EC) No 726/2004 and Directive 2001/83/EC.
8. Article 63 of Regulation (EC) No 726/2004 shall apply to the Emergency Task Force as regards transparency and the	8. Article 63 of Regulation (EC) No 726/2004 shall apply to the Emergency Task Force as regards transparency and the

independence of its members.	independence of its members. ***Members of the Emergency Task Force shall update the annual declaration of their financial interests provided for in Article 63 of Regulation (EC) No 726/2004 whenever a relevant change occurs.***
9. The Agency shall publish information about the medicinal products that the Emergency Task Force considers may have the potential to address public health emergencies and any updates on its web-portal.	9. The Agency shall publish information about the medicinal products that the Emergency Task Force considers may have the potential to address public health emergencies and any updates on its web-portal.

Or. en

Proposal for a regulation
Recital 17

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

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) The work of the Emergency Task Force should be separate from the work of the scientific committees of the Agency and should be carried out without prejudice to the scientific assessments of those committees. The Emergency Task Force should provide recommendations with regard to the use of medicinal products in the fight against the disease that is responsible for the public health crisis. The Committee for Medicinal Products for Human Use should be able to use those recommendations when preparing scientific opinions on compassionate or other early use of a medicinal product prior to marketing authorisation.	(18) The work of the Emergency Task Force should be separate from the work of the scientific committees of the Agency and should be carried out without prejudice to the scientific assessments of those committees. The Emergency Task Force should provide recommendations with regard to the use of medicinal products in the fight ***to overcome*** the public health crisis. The Committee for Medicinal Products for Human Use should be able to use those recommendations when preparing scientific opinions on compassionate or other early use of a medicinal product prior to marketing authorisation. ***The Executive Steering Group on Shortages and Safety of Medicinal Products could also draw on the work of the Emergency Task Force when developing the critical medicines lists.***

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(19) The establishment of the Emergency Task Force should build on the support provided by the Agency during the COVID-19 pandemic, notably as regards scientific advice on clinical trials design and product development as well as the 'rolling' review i.e. on an on-going basis, of emerging evidence to allow a more efficient assessment of medicinal products including vaccines during public health emergencies.	(19) The establishment of the Emergency Task Force should build on the support provided by the Agency during the COVID-19 pandemic, notably as regards scientific advice on clinical trials design and product development as well as the 'rolling' review i.e. on an on-going basis, of emerging evidence to allow a more efficient assessment of medicinal products including vaccines during public health emergencies***, while guranteeing a high level of human health protection***.

Amendment 16 (ADVICE ON CTs)
EPP, S&D, RE, Greens/EFA, ID, The Left
Compromise amendment replacing Amendments: Article 15 (81, 82, 588-591, ITRE110-115) + Recital 8 (8, 156, ITRE15) + Recitals 19a and 19b (19, 157-160, 204, ITRE36, ITRE37); Recital 20 (20, 205, 206, ITRE32)

Proposal for a regulation
Article 15

Text proposed by the Commission	*Amendment*
Advice on clinical trials	*Advice on clinical trials*
1. During a public health emergency, the Emergency Task Force shall review clinical trial protocols submitted or intended to be submitted in a clinical trial application by developers of medicinal products as part of an accelerated scientific advice process.	1. During a public health emergency, the Emergency Task Force shall review clinical trial protocols submitted or intended to be submitted in a clinical trial application by developers of medicinal products as part of an accelerated scientific advice process.
2. Where a developer engages in an accelerated scientific advice process, the Emergency Task force shall provide such advice free of charge at the latest 20 days following the submission to the Agency of a complete set of requested information and data by the developer. The advice shall be endorsed by the Committee for Medicinal Products for Human Use.	2. Where a developer engages in an accelerated scientific advice process, the Emergency Task force shall provide such advice free of charge at the latest 20 days following the submission to the Agency of a complete set of requested information and data by the developer. The advice shall be endorsed by the Committee for Medicinal Products for Human Use.
3. The Emergency Task Force shall establish procedures for the request and submission of the set of information and data required, including information on the Member State or States where an application for authorisation of a clinical trial is submitted or is intended to be submitted.	3. The Emergency Task Force shall establish procedures ***and guidance*** for the request and submission of the set of information and data required, including information on the Member State or States where an application for authorisation of a clinical trial is submitted or is intended to be submitted.
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.	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.
5. When authorising a clinical trial application for which scientific advice has been given, Member States shall take that advice duly into account.	5. When authorising a clinical trial application for which scientific advice has been given, Member States shall take that advice duly into account. ***The scientific***

	advice provided by the Emergency Task Force shall be without prejudice to the ethical review provided for in Regulation (EU) No 536/2014.
6. Where a developer is the recipient of scientific advice, the developer shall subsequently submit the data resulting from clinical trials to the Agency following a request made pursuant to Article 16.	6. Where a developer is the recipient of scientific advice, the developer shall subsequently submit the data resulting from clinical trials to the Agency following a request made pursuant to Article 16.
7. Without prejudice to the provisions of this Article, the scientific advice shall otherwise be provided to those developers in accordance with the procedures established pursuant to Article 57 of Regulation EC (No) 726/2004.	7. Without prejudice to the provisions of this Article, the scientific advice shall otherwise be provided to those developers in accordance with the procedures established pursuant to Article 57 of Regulation EC (No) 726/2004.

Or. en

Proposal for a regulation
Recital 8

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

Proposal for a regulation
Recital 19 a

Text proposed by the Commission	*Amendment*
	(19 a) 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.

Proposal for a regulation
Recital 19 b

Text proposed by the Commission	*Amendment*
	(19 b) 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 is fully applied, in particular as regards the launch of a functioning clinical trials information system.

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(20) Individual research entities may agree together, or with another party, to act	(20) Individual research entities may agree together, or with another party, to act

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

as a sponsor in order to prepare one harmonised Union-wide clinical trial protocol, yet experience during the COVID-19 pandemic has shown that initiatives to set up large multinational trials struggle to materialise due to the lack of a single entity that can undertake all the responsibilities and activities of a sponsor within the Union, while interacting with multiple Member States. ***In that regard, a new Union wide and Union funded vaccine trial network called VACCELERATE was launched in light of the Commission communication of 17 February 2021 entitled "HERA Incubator: Anticipating together the threat of COVID-19 variants". The Emergency Task Force should build on that trial network and other established networks such as the Heads of Medicines Agencies (HMA, the Clinical Trials Facilitation and Coordination Group (CTFG) and the European Clinical Research Infraestructure Network (ECRIN) to ensure that adequate data on new medicinal products in light of a possible public health emergency is expediently generated.*** It is therefore ***imperative*** for the Agency to identify and facilitate such initiatives by giving advice on the possibilities to act as a sponsor or, where applicable, to define respective responsibilities as co-sponsors in accordance with Article 72 of Regulation (EU) 536/2014 ***and coordinate the development of clinical trial protocols. The Emergency Task Force should define the most clinically relevant performance targets for vaccines and treatments to be measured in clinical trials, so that they can meet the criteria for effective public health interventions.*** Such an approach would strengthen the research environment in the Union, and promote harmonisation and avoid subsequent delays in integrating the results of research to a marketing authorisation. A Union sponsor could benefit from Union research funding available at the time of the public health emergency as well as existing clinical trial

networks to facilitate the development, application, submission, and running of the trial. This may be particularly valuable for trials established by Union or international public health or research organisations.

Amendment 17 (INFO ON CLINICAL TRIALS)
EPP, S&D, RE, Greens/EFA, ID, ECR, The Left
Compromise amendment replacing Amendments: Article 15a (592, 593, 627, 628, 717)

Proposal for a regulation
Article 15 a (new)

Text proposed by the Commission	*Amendment*
	Article 15 a
	Public information about clinical trials and marketing authorisation decisions
	1. For the duration of a public health emergency, the sponsors of clinical trials conducted in the Union shall:
	(a) publish the study protocol at the start of the trial through the EU clinical trials register;
	(b) publish the summary of the results through the EU clinical trials register within a timeline set by the Agency that is shorter than the timeline laid down in Article 37 of Regulation (EU) No 536/2014.
	2. Where a medicinal product receives a marketing authorisation, the Agency shall publish:
	(a) the product information with details of the conditions of use at the time of marketing authorisation;

	(b) the European public assessment reports as soon as possible and, where possible, within seven days of marketing authorisation;
	(c) the clinical data submitted to the Agency in support of the application where possible within two months of authorisation by the Commission, and after personal data have been anonymised and commercially confidential information redacted;
	(d) the full body of the Risk Management Plan and any updated versions.

Amendment 18 (REVIEW OF MEDICINES AND RECOMMENDATIONS)
EPP, S&D, RE, Greens/EFA, ID, The Left
Compromise amendment replacing Amendments: Article 16 (83, 594-603, ITRE116-121)

Proposal for a regulation
Article 16

Text proposed by the Commission	*Amendment*
Review of medicinal products and recommendations on their use	*Review of medicinal products and recommendations on their use*
1. Following the recognition of a public health emergency, the Emergency Task Force shall undertake a review of the available scientific data on medicinal products, which may have the potential to be used to address the public health emergency. The review shall be regularly updated during the public health emergency.	1. Following the recognition of a public health emergency, the Emergency Task Force shall undertake a review of the available scientific data on medicinal products, which may have the potential to be used to address the public health emergency. The review shall be regularly updated 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.
2. In preparation of the review, the Emergency Task Force may request information and data from marketing authorisation holders and from developers and engage with them in preliminary discussions. The Emergency Task Force may also, where available, make use of observational studies of health data generated outside of clinical studies taking into account their reliability.	2. In preparation of the review, the Emergency Task Force may request information and data from marketing authorisation holders and from developers and engage with them in preliminary discussions. The Emergency Task Force may also, where available, make use of observational studies of health data generated outside of clinical studies taking into account their reliability. ***The Emergency Task Force may liaise with medicine agencies of third countries for additional information and data exchange.***
3. Based on a request from one or more Member States, or the Commission, the Emergency Task Force shall provide recommendations to the Committee for Medicinal Products for Human Use for an opinion in accordance with paragraph 4 on the following:	3. Based on a request from one or more Member States, or the Commission, the Emergency Task Force shall provide recommendations to the Committee for Medicinal Products for Human Use for an opinion in accordance with paragraph 4 on the following:
(a) the compassionate use of medicinal products falling under the scope of Directive 2001/83/EC or Regulation (EC) No 726/2004;	(a) the compassionate use of medicinal products falling under the scope of Directive 2001/83/EC or Regulation (EC) No 726/2004;
(b) the use and distribution of an unauthorised medicinal product in accordance with Article 5(2) of Directive 2001/83/EC.	(b) the use and distribution of an unauthorised medicinal product in accordance with Article 5(2) of Directive 2001/83/EC.
4. Following receipt of the recommendation, the Committee for Medicinal Products for Human Use shall adopt an opinion on the conditions for use, the conditions for distribution and the patients targeted. The opinion shall be updated where necessary.	4. Following receipt of the recommendation, the Committee for Medicinal Products for Human Use shall adopt an opinion on the conditions for use, the conditions for distribution and the patients targeted. The opinion shall be updated where necessary.
5. Member States shall take account of the opinions referred to in paragraph 4. Where Member States make use of such an opinion, Article 5(3) and (4) of Directive 2001/83/EC shall apply.	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.
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	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.	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 updates on its web-portal.***	***deleted***

Or. en

Amendment 19 (COMMUNICATION ON THE EMER TASK FORCE)
EPP, S&D, RE, Greens/EFA, ID, ECR, The Left
Compromise amendment replacing Amendments: Article 17 (84, 85, 604-608, ITRE122-127)

Proposal for a regulation
Article 17

Text proposed by the Commission	*Amendment*
Communication on the Emergency Task Force	*Communication on the Emergency Task Force*
The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Emergency Task Force.	The Agency shall, via ***a dedicated space on*** its web-portal and other appropriate means and, in conjunction with national competent authorities, inform ***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 list of the members of the Emergency Task Force, the rules of procedure, as well as the recommendations provided pursuant to Article 16 (3) and the opinions adopted pursuant to Article 16 (4) shall be published on the Agency's web-portal.***

Amendment 20 (IT TOOLS AND DATA)
EPP, S&D, RE, Greens/EFA, ID, ECR, The Left
Compromise amendment replacing Amendments: Article 18 (86, 609-626, ITRE 127, ITRE128)

Proposal for a regulation
Article 18

Text proposed by the Commission	*Amendment*
IT tools and data	*IT tools and data*
To prepare for and support 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:
(a) develop and maintain electronic tools for the submission of information and data, including electronic health data generated outside the scope of clinical studies;	(a) develop and maintain electronic tools***, including an interoperable and digitalized platform,*** for the submission of information and data, including electronic health data generated outside the scope of clinical studies;
(b) coordinate independent vaccine effectiveness and safety monitoring studies using relevant data held by public authorities. Such coordination shall be conducted jointly with the European Centre for Disease Prevention and Control and notably through a new vaccine monitoring platform;	(b) coordinate independent ***utilisation,*** effectiveness and safety monitoring studies ***of medicinal products intended to treat, prevent or diagnose a disease*** using relevant data held by public authorities***; for vaccines, s***uch coordination shall be conducted jointly with the European Centre for Disease Prevention and Control and notably through a new vaccine monitoring platform;
(c) as part of its regulatory tasks, make use of digital infrastructures or tools, to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of clinical studies, and the exchange of such data between Member States, the Agency, and other Union bodies;	(c) as part of its regulatory tasks, make use of digital infrastructures or tools, to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of ***interventional*** clinical studies, and the exchange of such data between Member States, the Agency, and other Union bodies;
(d) provide access to the Emergency Task Force to external sources of electronic health data including, health data generated outside the scope of clinical studies, to	(d) provide access to the Emergency Task Force to external sources of electronic health data including, health data generated outside the scope of clinical studies, to

which the Agency has access.	which the Agency has access.

Or. en

Amendment 21 (EXEC STEERING GROUP ON MDs)
EPP, S&D, RE, Greens/EFA, The Left
Compromise amendment replacing Amendments: Article 19 (87, 629-648, ITRE129-132) + Recital 6 (8, 145-151, ITRE10, ITRE12) + Recital 21 (21, 207, 208, ITRE27, ITRE33)

Proposal for a regulation
Article 19

Text proposed by the Commission	*Amendment*
The Executive Steering Group on Medical Devices	*The Executive Steering Group on Medical Devices*
1. The Executive Steering Group on Medical Devices ('the Medical Devices Steering Group') is hereby established as part of the Agency. It shall meet either in person or remotely, in preparation for or during a public health emergency. The Agency shall provide its secretariat.	1. The Executive Steering Group on Medical Devices ('the Medical Devices Steering Group') is hereby established as part of the Agency. It shall meet ***at regular intervals*** either in person or remotely, ***and whenever the situation requires,*** in preparation for or during a public health emergency. The Agency shall provide its secretariat.
2. The Medical Devices Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields.	2. The Medical Devices Steering Group shall be composed of a representative of the Agency, a representative of the Commission ***and*** one ***authorised*** senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields. ***The Medical Devices Steering Group shall also include a representative of the 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 members of the Medical Devices Steering Group shall be transparent and made***

	public on the Agency's web-portal.
3. The Medical Devices Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medical device interest groups to attend its meetings.	3. The Medical Devices Steering Group shall be chaired by the Agency. ***Any member of the Medical Devices Steering Group may propose to t***he Chair ***to*** invite third parties, including representatives of medical device interest groups***, such as representatives of manufacturers and notified bodies or any other actor in the medical devices supply chain, as well as representatives of healthcare professionals, patients and consumers*** to attend its meetings ***when their contribution may inform the discussions of the Medical Devices Steering Group***.
4. The Medical Devices Steering Group shall establish its rules of procedure including procedures relating to the working party referred to in paragraph 5, and on the adoption of lists, sets of information and recommendations. The rules of procedures shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.	4. The Medical Devices Steering Group shall establish its rules of procedure including procedures relating to the working party referred to in paragraph 5, and on the adoption of lists, sets of information and recommendations. The rules of procedures shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.
5. The Medical Devices Steering Group shall be supported in its work by a working party comprised of single points of contact from national competent authorities for medical devices established in accordance with Article 23(1).	5. The Medical Devices Steering Group shall be supported in its work by a working party comprised of single points of contact from national competent authorities for medical devices established in accordance with Article 23(1).
6. The Medical Devices Steering Group shall be responsible for fulfilling the tasks referred to in Articles 20, 21, and 22.	6. The Medical Devices Steering Group shall be responsible for fulfilling the tasks referred to in Articles 20, 21, and 22.
	6 a. 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.

Or. en

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(6) The rapid evolution of COVID-19 and the spread of the virus led to a sharp increase in demand for medical devices such as ventilators, surgical masks, and COVID-19 test kits while disruption of production or limited capacity to rapidly increase production and the complexity and global nature of the supply chain for medical devices, led to a negative impact on supply. Those issues resulted in new entities being involved in the production of those products, which subsequently resulted in bottlenecks in conformity assessment, as well as the prevalence of non-compliant, unsafe, and in some cases counterfeit products. It is therefore appropriate to establish long-term structures within an appropriate Union body to ensure monitoring of shortages of medical devices resulting from a public health emergency.	(6) The rapid evolution of COVID-19 and the spread of the virus led to a sharp increase in demand for medical devices such as ventilators, surgical masks, and COVID-19 test kits while disruption of production or limited capacity to rapidly increase production and the complexity and global nature of the supply chain for medical devices, led to ***severe*** supply ***difficulties and, at certain times, serious stock-outs***, ***and placed Member States in competition with each other to respond to the legitimate needs of their citizens, contributing to uncoordinated actions at national levels such as national hoarding and stockpiling.*** Those issues ***further*** resulted in new entities being involved in the ***rushed*** production of those products, which subsequently resulted in bottlenecks in conformity assessment, as well as the prevalence of ***over-priced,*** non-compliant, unsafe, and in some cases counterfeit products. It is therefore appropriate ***and urgent*** to establish long-term structures within an appropriate Union body to ensure ***a more solid and effective coordination and*** monitoring of shortages of medical devices ***that can occur during*** a public

	health emergency***, as well as increased and early dialogue with the medical devices industry and healthcare professionals to prevent and mitigate these shortages.***

Amendment 22 (LIST CRITICAL MEDICAL DEVICES)
EPP, S&D, RE, Greens/EFA, ID, ECR, The Left
Compromise amendment replacing Amendments: Article 20 (88, 89, 649-657, ITRE133-135)

Proposal for a regulation
Article 20

Text proposed by the Commission	*Amendment*
List of critical medical devices and information to be provided	*List of critical medical devices and information to be provided*
1. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medical Devices Steering Group shall adopt a list of medical devices which it considers as critical during the public health emergency ('the public health emergency critical devices list'). The list shall be updated whenever necessary until the termination of the recognition of the public health emergency.	1. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medical Devices Steering Group shall adopt a list of medical devices which it considers as critical during the public health emergency ('the public health emergency critical devices list'). The list shall be updated whenever necessary until the termination of the recognition of the public health emergency.
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.***
3. The Agency shall publish the public health emergency critical devices list and any updates to that list on its web-portal.	3. The Agency shall publish the public health emergency critical devices list and any updates to that list on ***a dedicated***

	space on its web-portal.
	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).

Or. en

Proposal for a regulation
Recital 21

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

Amendment 23 (REPORTING OF MDs SHORTAGES)
EPP, S&D, RE, Greens/EFA, ID, The Left
Compromise amendment replacing Amendments: Article 22 (90-92, 661-666, ITRE137-141)

Proposal for a regulation
Article 22

Text proposed by the Commission	*Amendment*
Reporting and recommendations on shortages of medical devices	*Reporting and recommendations on shortages of medical devices*
1. For the duration of the public health emergency, the Medical Devices Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article ***23(1)(b)***,	1. For the duration of the public health emergency, the Medical Devices Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article ***23(2)(a)***,

and, in particular, signal any potential or actual shortages of medical devices included on the public health emergency critical devices list.	and, in particular, signal any potential or actual shortages of medical devices included on the public health emergency critical devices list.
2. Where requested by the Commission or the sub-network referred to in Article 23***(2)(b)***, the Medical Devices Steering Group shall provide aggregated data and forecasts of demand to support its findings. In that regard, the Steering Group shall liaise with the European Centre for Disease Prevention and Control to obtain epidemiological data to help forecast medical device needs, and with the Medicines Steering Group referred to in Article 3 where medical devices included on the public health emergency critical devices list are used to jointly with a medicinal product.	2. Where requested by the Commission***, one or more national competent authorities,*** or the sub-network referred to in Article 23 ***(2)(a),*** the Medical Devices Steering Group shall provide aggregated data and forecasts of demand to support its findings. In that regard, the Steering Group shall liaise with the European Centre for Disease Prevention and Control to obtain epidemiological data to help forecast medical device needs, and with the Medicines Steering Group referred to in Article 3 where medical devices included on the public health emergency critical devices list are used to jointly with a medicinal product. ***The Medical Devices Steering Group shall also share its findings and conclusions with Union and national actors engaged with stockpiling of medicinal products and medical devices.***
3. As part of the reporting referred to in paragraphs 1 and 2, the Medical Devices Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, medical device manufacturers, notified bodies and other entities to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, where relevant, with the Health Security Committee and the Advisory Committee on public health emergencies.	3. As part of the reporting referred to in paragraphs 1 and 2, the Medical Devices Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, medical device manufacturers, notified bodies and other entities, to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, where relevant, with the Health Security Committee and the Advisory Committee on public health emergencies.
4. The Medical Devices Steering Group may, on its own initiative or upon request from the Commission, provide recommendations on measures which may be taken by the Commission, Member States, medical device manufacturers, notified bodies and other entities to ensure preparedness to deal with potential or actual shortages of medical devices caused by public health emergencies.	4. The Medical Devices Steering Group may, on its own initiative or upon request from the Commission, provide recommendations on measures which may be taken by the Commission, Member States, medical device manufacturers, notified bodies and other entities to ensure preparedness to deal with potential or actual shortages of medical devices caused by public health emergencies.

5. The Medical Devices Steering Group may, upon request from the Commission coordinate measures, where relevant, between the national competent authorities, manufacturers of medical devices, notified bodies, and other entities to prevent or mitigate potential or actual shortages in the context of a public health emergency.	5. The Medical Devices Steering Group may, upon request from the Commission coordinate measures, where relevant, between the national competent authorities, manufacturers of medical devices, notified bodies, and other entities, to prevent or mitigate potential or actual shortages in the context of a public health emergency. ***5a. Where the recommendations referred to in paragraphs 3 and 4 are not taken into account or are not implemented, the Commission, Member States, medical device manufacturers and notified bodies shall provide, where appropriate, a substantiated justification.***

Or. en

Amendment 24 (WORKING METHODS)
EPP, S&D, RE, ID, ECR, The Left
Compromise amendment replacing Amendments: Article 23 (93-99, 667-686, ITRE142-149)

Proposal for a regulation
Article 23

Text proposed by the Commission	*Amendment*
Working methods and provision of information on medical devices	*Working methods and provision of information on medical devices*
1. In order to prepare for fulfilling the tasks referred to in Articles 20, 21, and 22, the Agency shall:	1. In order to prepare for fulfilling the tasks referred to in Articles 20, 21, and 22, the Agency shall:
(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;
(b) develop streamlined electronic monitoring and reporting systems;	(b) develop streamlined electronic monitoring and reporting systems ***in coordination with the national competent authorities;***
(c) establish and maintain membership of the working party referred to in Article 19(5) comprised of single points of contact from Member States' national competent authorities for medical devices;	(c) establish and maintain membership of the working party referred to in Article 19(5) comprised of single points of contact from Member States' national competent authorities for medical devices;
(d) establish and maintain a list of single points of contact from medical device manufacturers, authorised representatives and notified bodies;	***deleted***
(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.
2. Following the recognition of a public health emergency the Agency shall:	2. Following the recognition of a public health emergency the Agency shall:
(a) establish and maintain for the duration of the public health emergency, a sub-network of single points of contact from medical device manufacturers and notified bodies based on the medical devices included on the public health emergency critical devices list;	(a) establish and maintain for the duration of the public health emergency, a sub-network of single points of contact from medical device manufacturers and notified bodies based on the medical devices included on the public health emergency critical devices list ***based on single points of contact to be included for all medical device manufacturers in the database referred to in Article 33 of Regulation (EU) 2017/745 and Article 30 of Regulation (EU) 2017/746***;
(b) request information from the points of contact included in the sub-network based on the set of information agreed on by the Medical Devices Steering Group and set a deadline for its submission;	(b) request information from the points of contact included in the sub-network based on the set of information agreed on by the Medical Devices Steering Group and set a deadline for its submission;
(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	(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.	deadline for its submission.
3. The information referred to in point (b) of paragraph 2 shall include at least:	3. The information referred to in point (b) of paragraph 2 shall include at least:
(a) the name of the manufacturer and, if applicable, the name of the authorised representative;	(a) the name of the manufacturer and, if applicable, the name of the authorised representative;
(b) identification of the medical device and the intended purpose;	(b) identification of the medical device and the intended purpose;
(c) if applicable, the name and number of the notified body and information on the relevant certificate or certificates	(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;	(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;	(e) sales and market share data;
	(ea) available stocks;
	(eb) quantities already delivered;
	(ec) projected deliveries;
(f) mitigation plans including production and supply capacity;	(f) ***prevention and*** mitigation plans including ***information on*** production and supply capacity ***with a view to guarantee continued supply and prevent shortages of medical devices included on the public health emergency critical devices list***;
(g) information from concerned notified bodies about their resource capacity to process applications and carry out and complete conformity assessments in relation to medical devices included in the public health emergency critical devices list;	(g) information from concerned notified bodies about their resource capacity to process applications and carry out and complete conformity assessments in relation to 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;	(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;
(i) where conformity assessments are on-going, the status of the conformity assessment by the concerned notified bodies in relation to medical devices included in the public health emergency critical devices list and possible issues	(i) where conformity assessments are on-going, the status of the conformity assessment by the concerned notified bodies in relation to medical devices included in the public health emergency critical devices list and possible issues

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

Or. en

Amendment 25 (COMMUNICATION ON THE MDs STEERING GROUP)
EPP, S&D, RE, Greens/EFA, ID, ECR, The Left
Compromise amendment replacing Amendments: Article 27 (101, 102, 705-710, ITRE159)

Proposal for a regulation
Article 27

Text proposed by the Commission	*Amendment*
Communication on the Medical Devices Steering Group	*Communication on the Medical Devices Steering Group*
The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Medical Devices Steering Group.	The Agency shall, via ***a dedicated space in*** its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups ***in a timely manner*** with regard to the work of the Medical Devices Steering Group ***and respond to disinformation targeting the work of the Medical Devices Steering Group as appropriate***. ***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.***

Or. en

Amendment 26 (CYBER ATTACKS)
EPP, S&D, RE, Greens/EFA, ID, The Left
Compromise amendment replacing Amendments: Article 29 a (104, 620, 624, 626, 718, ITRE45, ITRE128) + Recital 26 a (22)

Proposal for a regulation
Article 29 a (new)

Text proposed by the Commission	*Amendment*
	Article 29 a
	Protection against cyber-attacks
	The Agency shall be equipped with a high level of security controls and processes against cyber-attacks, cyber-espionage and human leaks 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.

Or. en

Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission	*Amendment*
	(26 a) 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 pandemic. The Agency itself has been the target of a cyber-attack that resulted in some of the unlawfully accessed documents related to COVID-19 medicines and vaccines belonging to third parties being leaked on the internet. There is therefore the need for the Agency to be

equipped with a high level of security against cyber-attacks to ensure the normal functioning of the Agency at all times and especially during public health emergencies. To that end, the Agency should establish a plan to prevent, detect, mitigate and respond to cyber-attacks so that its operation is secured at all times, while preventing any illegal access to documentation held by the Agency.

Amendment 27 (PENALTIES)
EPP, S&D, RE, Greens/EFA, The Left
Compromise amendment replacing Amendments: Article 29 b (105, 505, 512, 517, 518, 519, 551, 689, 690, 691, 714)

Proposal for a regulation
Article 29 b (new)

Text proposed by the Commission	*Amendment*
	Article 29 b
	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... [6 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.

Or. en

Amendment 28A (CONFIDENTIALITY)
EPP, S&D, RE, Greens/EFA, ID, ECR, The Left
Compromise amendment replacing Amendments: Article 30 (720, 721, 724, 725, 726, 730, 731, 732, ITRE161)

Proposal for a regulation
Article 30

Text proposed by the Commission	*Amendment*
Confidentiality	*Confidentiality*
1. Unless otherwise provided for in this Regulation and without prejudice to Regulation (EC) No 1049/2001[24] and existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:	1. Unless otherwise provided for in this Regulation and without prejudice to Regulation (EC) No 1049/2001[24] ***and Directive 2019/1937,*** and existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:
(a) ***personal data in accordance with Article 32***;	***deleted***
(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 2016/943, as well as other commercially confidential information and*** intellectual property right***s***;
(c) the effective implementation of this Regulation.	(c) the effective implementation of this Regulation.
2. All parties involved in the application of this Regulation shall ensure that no commercially confidential information is shared in a way which has the potential to enable undertakings to restrict or distort competition in the meaning of Article 101 TFEU.	2. All parties involved in the application of this Regulation shall ensure that no commercially confidential information is shared in a way which has the potential to enable undertakings to restrict or distort competition in the meaning of Article 101 TFEU.
3. Without prejudice to paragraph 1, information exchanged on a confidential basis between competent authorities and between competent authorities and the Commission and the Agency shall not be	3. Without prejudice to paragraph 1, information exchanged on a confidential basis between competent authorities and between competent authorities and the Commission and the Agency shall not be

disclosed without the prior agreement of the authority from which that information originates.	disclosed without the prior agreement of the authority from which that information originates.
4. Paragraphs 1, 2, and 3 shall not affect the rights and obligations of the Commission, the Agency, Member States and other actors identified in this Regulation with regard to the exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.	4. Paragraphs 1, 2, and 3 shall not affect the rights and obligations of the Commission, the Agency, Member States and other actors identified in this Regulation with regard to the exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.
5. The Commission, the Agency, and Member States may exchange commercially confidential information ***and, where necessary to protect public health, personal data,*** with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.	5. The Commission, the Agency, and Member States may exchange commercially confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

Amendment 28B (DATA PROTECTION)
EPP, S&D, RE, Greens/EFA, ID, ECR, The Left
Compromise amendment replacing Amendments: Article 30a (106, 107, 719, 722, 723, 727, 728, 729, 733, ITRE127, ITRE162, ITRE163) and Recital 26 a new (215, 216, 217, 219, ITRE44)

Proposal for a regulation
Article 30 a (new)

Text proposed by the Commission	*Amendment*
	Article 30 a
	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.
	2. For transfers of personal data to a third country, in the absence of an

adequacy decision, or of appropriate safeguards, as referred to in Article 49(1) of Regulation (EU) 2016/679 and Article 50(1) of Regulation (EU) 2018/1725, the Commission, the Agency, and Member States may exchange personal data with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements where it is necessary for important reasons of public interest, such as to protect public health.

Proposal for a regulation
Recital 26 a (new)

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

Amendment 29 (REVIEW)
EPP, S&D, RE, Greens/EFA, ECR, The Left
Compromise amendment replacing Amendments: Article 30b (108) + Recital 27 b (24)

Proposal for a regulation
Article 30 b (new)

Text proposed by the Commission	*Amendment*
	Article 30 b
	Review
	By 31 December 2026 the Commission shall submit to the European Parliament and to the Council an evaluation report on the functioning of this Regulation, accompanied, if appropriate, by a legislative proposal to amend it. This report shall specifically consider the possible extension of the scope to medicinal products for veterinary use.

Proposal for a regulation
Recital 27 b (new)

Text proposed by the Commission	*Amendment*
	(27 b) Taking into account that the COVID-19 pandemic has not come to an end, and that the duration and evolution of health crisis, 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, on the basis of which, if appropriate, it should be amended.

Amendment 30 (ENTRY INTO FORCE & APPLICATION)
EPP, S&D, RE, Greens/EFA, ID, ECR, The Left
Compromise amendment replacing Amendments: Article 31 (109-111, 734-737, ITRE164-165)

Proposal for a regulation
Article 31

Text proposed by the Commission	*Amendment*
Entry into Force	*Entry into Force* ***and date of application***
This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.	This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*. ***Chapter IV shall apply from... [date of entry into force + 12 months].***
This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in all Member States.

Amendment 31 (RECITALS 2+ 13)
EPP, S&D, RE, Greens/EFA, ID, ECR, The Left
Compromise amendment replacing Recital 2 (3, 114-121, 123, 124, 151, ITRE2, ITRE13) and Recital 13 (14, 181-185, ITRE21)

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(2) The unprecedented experience of the COVID-19 pandemic has demonstrated that the Union should be more effective in managing the availability of medicinal products and medical devices and in developing medical countermeasures to address the threats posed to public health. The Union's ability to do so has been severely impeded by the absence of a clearly defined legal framework for managing its response to the pandemic, and also by the limited degree of Union preparedness in case of a public health emergency impacting a majority of Member States.	(2) The unprecedented experience of the COVID-19 pandemic has ***also highlighted the difficulties of the Union and the Member States to cope with such a public health emergency and*** has demonstrated ***the need to strengthen the Union's role in order to*** be more effective in managing the availability of medicinal products and medical devices and in developing medical countermeasures to address the threats posed to public health ***from an early stage in a harmonised way ensuring cooperation and coordination between Union, national and regional competent authorities, industry and other actors of the pharmaceutical and medical devices supply chains, including healthcare professionals. The Union needs to give a higher priority to health, to ensure the continued provision of high quality healthcare services, and to be prepared to cope with epidemics and other health threats.*** The Union's ability to do so has been severely impeded by the absence of a clearly defined legal framework for managing its response to the pandemic, ***inadequate mandates and ressources 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.

Proposal for a regulation
Recital 13

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