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NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

With a view to the the informal videoconference of the members of the Working Party on Pharmaceuticals and Medical devices that will take place on 18 May, delegations will find attached a revised draft text as prepared by the Presidency.

Changes compared to document 8293/21 are marked in ***bold italics underlined*** and deletions in ~~strikethrough underlined.~~

Changes as in document 8293/21 are marked in ***bold italics*** and deletions in ~~strikethrough.~~

ANNEX

2020/0321 (COD)

Draft text

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

After consulting the European Economic and Social Committee[1],

After consulting the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Pursuant to Articles 9 and 168 of the Treaty on the Functioning of the European Union ('TFEU') and Article 35 of the Charter of Fundamental Rights of the European Union the Union is to ensure a high level of human health protection in the definition and implementation of all Union policies and activities.

[1] OJ C , , p. .
[2] OJ C , , p. .

(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.

(3) The often complex supply chains of medicinal products and medical devices, national export restrictions and bans, border closures impeding the free movement of those goods, and uncertainty related to their supply and demand in the context of the COVID-19 pandemic have led to significant impediments to the smooth functioning of the single market and to addressing the serious threats to public health across the Union.

(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.

(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.

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

(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.

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

(8) Safe and efficacious medicinal products that treat, prevent or diagnose diseases which cause public health emergencies, should be developed and made available within the Union as soon as possible during such emergencies. The COVID-19 pandemic has also highlighted ~~sub-optimal coordination~~ ***the need to coordinate assessments and conclusions on*** ~~and decision-making as regards~~ multinational clinical trials, ***in line with what is currently done on a voluntary basis by clinical experts of Member States,*** and Union-level advice on the use of medicinal products in national compassionate use programmes or outside of their authorised indications in the Union, causing delays in the adoption of research outcomes and in the development and availability of new or repurposed medicines.

(9) During the COVID-19 pandemic ad hoc solutions, including contingent arrangements between the Commission, the European Medicines Agency ('the Agency'), marketing authorisation holders, manufacturers and Member States, had to be found to achieve the objective of making available safe and efficacious medicinal products to treat COVID-19 or prevent its spread, and to facilitate and speed up the development and marketing authorisation of treatments and vaccines.

(10) In order to ensure a better functioning of the internal market of those products and contribute to a high level of human health protection, it is therefore appropriate to approximate the rules on monitoring of shortages of medicinal products and medical devices, and to facilitate the research and development of medicinal products, which may have the potential to treat, prevent, or diagnose diseases that cause public health crises.

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

(12) In order to improve crisis preparedness and management for medicinal products and medical devices and increase resilience and solidarity across the Union, the procedures and the respective roles and obligations of different concerned entities involved should be clarified. The framework should build on the ad hoc solutions identified so far in the response to the COVID-19 pandemic.

(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. ***This shouldn't affect the obligation of MAHs under article 23(a) of the Directive 2001/83/EC to notify Member States when the product ceases to be placed on the market of that Member State.***

(14) The operational phase of the work of the Steering Groups and Emergency Task Force provided for in this Regulation should be triggered by the recognition of a public health emergency in accordance with Regulation (EU) 2020/[…] on Cross-Border Health Threats and, as regards the Medicines ***Shortages*** Steering Group, the existence of a major event. Continuous monitoring of the risk to public health from major events, including manufacturing issues, natural disasters and bioterrorism with the potential to affect the quality, safety, efficacy or supply of medicinal products ***following One Health principles*** should also be ensured.

(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.

(16) The Executive Steering Group on Shortages and Safety of Medicinal Products should benefit from the Agency's extensive scientific expertise as regards the evaluation and supervision of medicinal products and should further develop the Agency's leading role in coordinating and supporting the response to shortages during the COVID-19 pandemic.

(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. ***All decisions on clinical trial applications should remain within the remit of the Member States*** ~~concerned~~ ***where the trials are to be conducted, in accordance with Regulation (EU) No 536/2014.***

(18) The work of the Emergency Task Force should be separate from the work of the scientific committees of the Agency and should be carried out without prejudice to the scientific assessments of those committees. The Emergency Task Force should provide ***advice and*** recommendations with regard to the use of medicinal products in the fight against the disease that is responsible for the public health crisis. The Committee for Medicinal Products for Human Use should be able to use those recommendations when preparing scientific opinions on compassionate or other early use of a medicinal product prior to marketing authorisation.

(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.

(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.

(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 bis) Considering that the Medical Device Coordination Group (MDCG), as established in Regulation (UE) 2017/745, is the formal forum to discuss key issues from medical devices sector, including Market Surveillance and in order to contribute with medical devices competence and experience necessary for the monitoring and mitigating of shortages of critical medical devices, a close liaison with MDCG should be established, between this group and the Executive Steering Group on Medical Devices. Effective coordination with the MDCG could be useful for the definition of the list of critical medical devices and information to be provided as well for the adoption of recommendations by the executive steering group on medical devices.

(22) This Regulation also provides the Agency with a role to support the expert panels on medical devices designated under Commission Implementing Decision (EU) 2019/1396[4] to provide independent scientific and technical assistance to the Member States, the Commission, ~~the Medical Device Coordination Group~~ MDCG~~)~~, notified bodies, manufacturers ***and authorised representatives***.

[4] Commission Implementing Decision (EU) 2019/1396 of 10 September 2019 laying down the rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the designation of expert panels in the field of medical devices OJ L 234, 11.9.2019, p. 23

(23) In addition to their role in clinical evaluation assessments and performance evaluations of certain high risk medical devices and *in vitro* diagnostic medical devices in accordance with Regulation (EU) 2017/745[5] and Regulation (EU) 2017/746[6] respectively, as well as providing opinions in response to consultation by manufacturers and notified bodies**.** ~~,~~ ~~the expert panels should play an essential role in the preparedness for and management of public health crises for medical devices, including those devices which have the potential to address public health emergencies~~. The panels are to provide scientific, technical, and clinical assistance to the Member States, the Commission, and the ~~Medical Device Coordination Group~~ ~~(~~MDCG~~)~~. In particular the panels are to contribute to the development of guidance on a number of points including clinical and performance aspects for specific devices, categories, or groups of devices or specific hazards related to a category or group of devices, develop clinical evaluation and performance evaluation guidance in line with the state of the art, and contribute to the identification of concerns and emerging issues on safety and performance. ***In this context, the expert panels together with MDCG and its technical groups could play a relevant role in the preparedness for and management of public health crises for medical devices, particularly those of high risk including those devices which have the potential to address public health emergencies without prejudice*** ~~its~~ ***to tasks and obligations under Regulation (EU) 2017/745 and Regulation (EU) 2017/746.***

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5 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC OJ L 117, 5.5.2017, p. 1.

6 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU OJ L 117, 5.5.2017, p. 176.

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

(24)bis ~~Until the date of application of this Regulation~~ To ensure a smooth transition to the Agency, the support to the expert panels should be provided ~~guaranteed~~ by the Commission, until the 1 March 2022.

(25) In order to facilitate the work and the exchange of information under this Regulation, provision should be made for the establishment and management of IT infrastructures and synergies with other existing IT systems ~~or~~ ***and*** systems under development, including the ***European data base on medical devices*** EUDAMED ~~IT platform for medical devices~~. ***In Eudamed, the European Medical Device Nomenclature (EMDN) system should help to gather relevant information on categorization of medical devices***.That work should also be facilitated by, where appropriate, emerging digital technologies such as computational models and simulations for clinical trials, as well as data from the EU Space Programme such as the Galileo geolocation services, and Copernicus earth observation data. ***Double or multiple registrations should be avoided to the extent possible.***

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

(27) During a public health emergency or in relation to a major event, the Agency should ensure cooperation with the European Centre for Disease Prevention and Control and other Union Agencies as appropriate. Such cooperation should include data sharing, including data on epidemiological forecasting, regular communication at an executive level, and invitations to representatives of the European Centre for Disease Prevention and Control and other Union Agencies to attend meetings of the Emergency Task Force, the Medicines ***Shortages*** Steering Group, and the Medical Devices Steering Group, as appropriate.

(28) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States alone due to the cross-border dimension of public health emergencies and major events and can, therefore, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(29) In order to ensure that sufficient resources are available for the work provided for under this Regulation, expenditure of the Agency should be covered by the contribution from the Union to the Agency's revenue. ***When considering the revision of Council regulation EC 297/95, provision should be made to accommodate the activities of monitoring shortages of medicines and medical devices and expert panels***.

(29 bis) Moreover, the EU4Health programme may provide additional support to national competent authorities in the area of shortages, namely the Joint Action to mitigate shortages of medicines and improve the security of supply, under the 2021 annual work programme. This could complement this proposal by supporting the national authorities to put in place the structure and the human resources to assess and report such shortages to EMA.

(30) The European Data Protection Supervisor has been consulted in accordance with Article 42(1) of Regulation (EU) No 2018/1725[7] and has adopted an opinion.[8]

(31) In accordance with Article 168(7) of the Treaty, this Regulation fully respects the responsibilities of the Member States for the definition of their public health policy and for the organisation and delivery of health services and medical care as well as the fundamental rights and principles recognised by the Charter of Fundamental Rights of the European Union including the protection of personal data,

HAVE ADOPTED THIS REGULATION:

Chapter I

General Provisions

Article 1

Subject Matter

This Regulation provides for, within the European Medicines Agency ('the Agency'), a framework for and the means to:

(a) prepare for and manage the impact of major events on medicinal products for human use and of public health emergencies on medicinal products for human use and on medical devices;

(b) monitor and report on shortages of medicinal products for human use, and medical devices;

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7 Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

8 *[insert reference once available]*

(c) provide advice on medicinal products for human use with the potential to address public health emergencies;

(d) provide ***administrative*** support for the expert panels designated in accordance with ~~Implementing Decision (EU) 2019/1396~~***Article 106(1) of Regulation (EU) 2017/745.***

Article 2

Definitions

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/[…][9];

(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;

(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) ***and accessory for a medical device in point (2) of Article 2*** of that Regulation~~; and an *in vitro* diagnostic medical device as defined in point (2) of Article 2 of Regulation (EU) 2017/746~~;

(ca) ***'in vitro diagnostic medical device' means an in vitro diagnostic medical device as defined in point (2) of Article 2 of Regulation (EU) 2017/746;***

(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;

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9 [*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. […].

(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.

Chapter II

Monitoring and mitigating shortages of critical medicinal products and management of major events

Article 3

"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 ***Shortages*** Steering Group') is hereby established as part of the Agency. It shall meet either in person or remotely, in preparation for or during a public health emergency or following a request for assistance referred to in Article 4(3). The Agency shall provide its secretariat.

2. The Medicines ***Shortages*** Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one ~~senior~~ representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields.

3. The Medicines ***Shortages*** Steering Group shall be ***Co***-chaired by the Agency ***and ~~co-chaired~~ by a representative of a Member State elected by and amongst its members***. The ***Co***-Chairs may invite ***representatives of national competent authorities for medicinal products for veterinary use and other*** third parties, including representatives of ~~medicinal product~~ interest groups and marketing authorisation holders ***for medicinal products for human and veterinary use*** to attend its meetings. ***The Members of the Medicines Shortages Steering Group may request the Chair to invite third parties to attend its meetings.***

4. The Medicines ***Shortages*** Steering Group shall establish its rules of procedure including procedures relating to the working party referred to ~~the~~ paragraph 5 and on the adoption of lists, sets of information, and recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.

5. The Medicines ***Shortages*** Steering Group shall be supported in its work by a working party comprised of single points of contact related to shortages from national competent authorities for medicinal products established in accordance with Article 9(1).

6. The Medicines ***Shortages*** Steering Group shall be responsible for fulfilling the tasks referred to in Article 4(4) and Articles 5 to 8.

Article 4

Monitoring of events and preparedness for major events and public health emergencies

1. The Agency**, *with the support of the ECDC and in collaboration with Member States,*** shall continuously monitor any event ***related to medicinal products*** that is likely to lead to a major event or a public health emergency.

2. To facilitate the monitoring task referred to in paragraph 1, the national competent authorities, through the single points of contact referred to in Article 3(5), shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report to the Agency on any event ***related to medicinal products***, including a shortage of a medicinal product in a given Member State, that is likely to lead to a major event or a public health emergency. Where a national competent authority informs the Agency of a shortage of a medicinal product 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 ***raise the issue of concern to*** ~~inform~~ the Commission and the Member States ~~thereof~~ ***for confirmation of the major event and trigger the actions foreseen in this Regulation***. The Commission, on its own initiative or following a request from one or more Member States, or the Executive Director of the Agency may request the assistance of the Medicines ***Shortages*** Steering Group ***or the Medical Devices Steering Group*** to address the major event.

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

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;

(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.

Article 5

Evaluation of information and the provision of advice on action in relation to the safety, quality, and efficacy of medicinal products related to public health emergencies and major events

Following the recognition of a public health emergency or a request for assistance referred to in Article 4(3), the Medicines ***Shortages*** Steering Group shall evaluate the information related to the major event or the public health emergency and consider the need for urgent and coordinated action with regard to the safety, quality, and efficacy of the medicinal products concerned.

The Medicines ***Shortages*** Steering Group shall provide advice to the Commission and Member States on any appropriate action it believes should be taken at Union level on the medicinal products concerned in accordance with the provisions of Directive 2001/83/EC or Regulation (EC) No 726/2004.[10]

Article 6

Lists of critical medicinal products and information to be provided

0. The Medicines Shortages Steering Group shall define the main therapeutic groups of medicinal products for ensuring emergency care, surgeries and intensive care to serve as a basis for the critical medicines lists referred to in paragraphs 1 and 2 and may be adapted if necessary.

[10] Regulation (EC) No 726/2004

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

2. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medicines ***Shortages*** Steering Group shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers as critical during the public health emergency ('the public health emergency critical medicines list'). The list shall be updated whenever necessary until the termination of the recognition of the public health emergency.

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.

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.

Article 7

Monitoring shortages of medicinal products on the critical medicines lists

Following the recognition of a public health emergency or a request for assistance referred to in Article 4(3,) ~~O~~on the basis of the critical medicines lists and the information and data provided in accordance with Articles 10 and 11, the Medicines ***Shortages*** Steering Group shall monitor supply and demand of medicinal products included on those lists with a view to identifying any potential or actual shortages of those medicinal products. As part of that monitoring, the Medicines Steering Group shall liaise, where relevant, with the Health Security Committee established in Article 4 of Regulation (EU) 2020/[…][11] and, in the case of a public health emergency, the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation.

Article 8

Reporting and recommendations on shortages of medicinal products

1. For the duration of a public health emergency or following a request for assistance referred to in Article 4(3) and until its closure, the Medicines ***Shortages*** Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article 9(2), and, in particular, signal any potential or actual shortages of medicinal products included on the critical medicines lists.

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

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

3. As part of that reporting, the Medicines ***Shortages*** Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities to prevent or mitigate potential or actual shortages. ***Member States may request the Medicines Shortages Steering Group to provide recommendations on measures.*** In that regard the Group shall liaise, as relevant, with the Health Security Committee and, in the case of a public health emergency, the Advisory Committee on public health emergencies.

4. The Medicines ***Shortages*** Steering Group may, on its own initiative or upon request from the Commission ***or Member States***, provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities to ensure preparedness to deal with potential or actual shortages of medicinal products caused by public health emergencies or major events.

5. The Medicines ***Shortages*** Steering Group may upon request from the Commission coordinate measures, where relevant, between the national competent authorities, the marketing authorisation holders and other entities to prevent or mitigate potential or actual shortages in the context of a major event or public health emergency.

Article 9

Working methods and provision of information on medicinal products

1. In order to prepare for fulfilling the tasks referred to in Articles 4 to 8, the Agency, ***together with Member States,*** shall:

   (a) specify the procedures for establishing the critical medicines lists**,**

   (b) specify the methods of and criteria for the monitoring, data collection and reporting provided for in Articles 4, 7 and 8**.**

(c) develop streamlined electronic monitoring and reporting systems ***~~ensuring~~*** ***facilitating the interoperability with other existing IT systems and systems under development***.

(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;

(f) specify the methods for the provision of recommendations, advice and coordination of measures provided for in Articles 5 and 8**.**

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;

(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;

(c) request information from the single points of contact from Member States' national competent authorities based on the set of information agreed on by the Medicines ***Shortages*** Steering Group and set a deadline for its submission.

3. The information referred to in point (b) of paragraph 2 shall include at least:

(a) the name of the marketing authorisation holder;

(b) the name of the medicinal product;

(ba) information on manufacturing sites;

(c) the country of authorisation and marketing status in each Member State;

(d) details of the potential or actual shortage such as actual or estimated start and end dates and suspected or known cause;

(e) sales and market share data;

(f) details of available alternative medicinal products;

(g) mitigation plans including production and supply capacity;

(h) information from the wholesale distributors and legal person entitled to supply the medicinal product to the public.

Article 10

Obligations on marketing authorisation holders

1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, marketing authorisation holders for medicinal products included on the critical medicines lists shall submit the information referred to in Article 9(3) by the deadline set by the Agency. They shall submit the information through the points of contact designated in accordance with Article 9(2) and using the reporting methods and system established pursuant to Article 9(1). They shall provide updates where necessary.

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 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:

   (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;

   (c) inform the Medicines ***Shortages*** Steering Group of any measures taken and report on the results of those measures, including information on the resolution of the potential or actual shortage.

Article 11

Obligations on Member States in the monitoring and mitigation of shortages of medicinal products

1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, Member States shall, by the deadline set by the Agency:

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

(b) indicate the existence of any commercially confidential information and clarify the reasons for such an indication, ***in accordance with article 10(4)***;

(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.

3. Where Member States are in possession of any additional information on volume of sales and volumes of prescriptions, including data based on Article 23a of Directive 2001/83/EC, which provides evidence of a potential or actual shortage of a medicinal product included on the critical medicines lists, they shall immediately provide such information to the Medicines ***Shortages*** Steering Group through their designated points of contact.

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~~ ***consider*** any recommendations, ~~and~~ guidelines and ~~comply with any~~ measures taken at Union-level pursuant to Article 12***(a).***

(b) inform the Medicines ***Shortages*** Steering Group of any measures taken and report on the results of those measures, including information on the resolution of the potential or actual shortage.

Article 12

Role of the Commission in the monitoring and mitigation of shortages of medicinal products

The Commission shall take into account the information from and recommendations of the Medicines ***Shortages*** Steering Group and shall:

(a) take all-necessary action within the limits of the powers conferred on it, with a view to mitigating potential or actual shortages of medicinal products included on the critical medicines lists;

(b) consider the need for guidelines addressed to Member States, marketing authorisation holders, and other entities;

(c) inform the Medicines ***Shortages*** Steering Group of any measures taken and report on the results;

(d) request the Medicines ***Shortages*** 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/[…];[12]

(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.

Article 13

*Communication on the Medicines **Shortages** Steering Group*

The Agency shall, via its web-portal and other appropriate means, in conjunction with national competent authorities, inform the public and interest groups with regard to the work of the Medicines ***Shortages*** Steering Group.

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

Chapter III

Medicinal Products with the potential to address public health emergencies

Article 14

The Emergency Task Force

1. The Emergency Task Force is hereby established as part of the Agency. It shall be convened during public health emergencies, either in person or remotely**,** ***and cease to be convened after termination of the recognition of a public health emergency pursuant to Article 23(2) of Regulation (EU) […/…].*** The Agency shall provide its secretariat.

2. During public health emergencies, the Emergency Task Force shall undertake the following tasks:

   (a) ***in liaison with the scientific committees, working parties, and scientific advisory groups of the Agency,*** providing scientific advice and reviewing the available scientific data on medicinal products with the potential to address the public health emergency, including requesting data from developers and engaging with them in preliminary discussions;

   (b) ***providing advice on*** ~~reviewing~~ ***the main aspects of*** clinical trial protocols ~~***without prejudice to the tasks of the Member States as regards assessment of submitted clinical trial applications to be conducted on their territories in accordance with Article 6 of Regulation (EU) No 536/2014***~~;~~and providing advice to developers on clinical trials to be conducted in the Union for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency, in accordance with Article 15 ***without prejudice to the tasks of the Member States as regards assessment of submitted clinical trial applications to be conducted on their territories in accordance with Article 6 of Regulation (EU) No 536/2014****;*

(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) ***in liaison with the scientific committees, working parties, and scientific advisory groups of the Agency,*** providing scientific recommendations with regard to the use of any medicinal product, which may have the potential to address public health emergencies, in accordance with Article 16;

(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 ***nominated by*** the scientific committees, working parties, ***including (vice)Chairs of the scientific committees*** 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~~.~~[13] ***as well as other clinical trial experts from the ~~European Medicines Regulatory Network representing clinical trial expertise~~ Competent Authorithies of Member States.*** 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 ***and co-chaired by the chair or vice-chair of the Committee for Medicinal Products for Human Use. The Emergency Task Force composition should be publicly available.***

4. The composition of the Emergency Task Force shall be approved by the Management Board of the Agency ***taking into account the specific expertise relevant for the therapeutic response to the public health emergency***. The Executive Director of the Agency or their representative and representatives of the Commission ***and of the Management Board of the Agency*** shall be entitled to attend all meetings.

5. The ***Co-c~~C~~hairs*** may invite ***other*** representatives of Member States, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, and interest groups representing patients and healthcare professionals to attend its meetings.

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.

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[13] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, OJ L 158, 27.5.2014, p. 1

7. The Emergency Task Force shall perform its tasks as ***an advisory and support~~ing~~*** body separate from, and without prejudice to the tasks of the scientific committees of the Agency as regards the authorisation, supervision and pharmacovigilance of the concerned medicinal products and related regulatory actions to ensure the quality, safety and efficacy of those medicinal products. ***The Committee for Medicinal Products for Human Use shall take into consider~~ation~~ the Emergency Task Force recommendation, when adopting ~~its~~ an independent and scientifically based opinion*.** The Emergency Task Force shall take account of any scientific opinion issued by those committees in accordance with Regulation (EC) No 726/2004 and Directive 2001/83/EC.

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.

9. The Agency shall ***inform Health Security Committee and national competent authorities as appropriate prior to*** publish***ing*** 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.

Article 15

Advice on clinical trials

1. During a public health emergency, the Emergency Task Force shall ***provide advice on main aspects of*** ~~review~~ clinical trial protocols submitted or intended to be submitted in a clinical trial application**,** ***without prejudice of the responsibility of the Member State(s) according to Regulation (EU) 536/2014*****,** by developers of medicinal products as part of an accelerated scientific advice process.

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.

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*** ~~***European Medicines Regulatory Network representing clinical trial expertise***~~ 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~~ ***consider*** that advice ~~duly into account~~.

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.

Article 16

Review of medicinal products and recommendations on their use

1. Following the recognition of a public health emergency, the Emergency Task Force shall undertake a review of the available scientific data on medicinal products, which may have the potential to be used to address the public health emergency. The review shall be updated during the public health emergency.

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.

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;

   (b) the use and distribution of an unauthorised medicinal product in accordance with Article 5(2) of Directive 2001/83/EC.

4. Following receipt of the recommendation, the Committee for Medicinal Products for Human Use shall adopt an ***independent and scientifically based*** opinion on the conditions for use, the conditions for distribution and the patients targeted. The opinion shall be updated where necessary.

5. Member States shall take account of the opinions referred to in paragraph 4. Where Member States make use of such an opinion, Article 5(3) and (4) of Directive 2001/83/EC shall apply.

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

7. The Agency shall publish the opinions adopted pursuant to paragraph 4 including any updates on its web-portal.

Article 17

Communication on the Emergency Task Force

The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Emergency Task Force.

Article 18

IT tools and data

To prepare for and support the ***decision making process and the*** work of the Emergency Task Force during public health emergencies, the Agency shall:

(a) develop and maintain electronic tools for the submission of information and data, including electronic health data generated outside the scope of clinical studies ***~~ensuring~~ facilitating interoperability with other existing electronic tools, and tools under development and providing the adequate support to Members States' competent authorities;***

(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;

(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;

(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.

Chapter IV

Monitoring and mitigating shortages of critical medical devices and support for expert panels

Article 19

The Executive Steering Group on Medical Devices

1. The Executive Steering Group on Medical Devices ('the Medical Devices Steering Group') is hereby established as part of the Agency. It shall meet either in person or remotely, in preparation for or during a public health emergency. The Agency shall provide its secretariat.

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~~ ***a*** representative ***with expertise in the field of medical devices and or in vitro diagnostic medical devices, as relevant. This representative may be the same as the one designated for MDCG where appropriate***. Members may be accompanied by experts in specific scientific or technical fields.

3. The Medical Devices Steering Group shall be ***Co-***chaired by the Agency ***and ~~co-chaired~~ by a representative of a Member State elected by and amongst its members***. The ***Co-***Chair***s*** may invite third parties, including representatives of medical device interest groups, ***of the industry, and of notified bodies*** to attend its meetings.

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 ***responsible for shortage monitoring and management*** for medical devices ***and in vitro diagnostic 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.

Article 20

List of critical medical devices and information to be provided

1. Immediately following the recognition of a public health emergency ***or at a request for assisstance referred to in article 4(3)*** and after consultation of its working party, the Medical Devices Steering Group shall adopt a list of ***categories of essential*** medical devices ***and in vitro diagnostic medical devices*** which it considers as critical during the public health emergency ('the public health emergency critical devices list'). ***To the extent possible, relevant ~~The~~ information on medical devices and in vitro diagnostics medical devices ~~caracterization and related~~ manufacturers shall be gathered from EUDAMED, when fully functional. Until then, available information may be gathered also from national databases or other available sources.*** The list shall be updated whenever necessary until the termination of the recognition of the public health emergency.

2. ***T***he Medical Devices Steering Group shall ***pursuant to article 23(3)*** ~~adopt~~ ***define*** a set of information necessary to monitor the supply and demand of medical devices ***and in vitro diagnostic medical devices*** included on the public health emergency critical devices list and inform its working party thereof.

~~***2(a) The set of information shall include as the minimum required information:***~~

~~***a) medical device category, and if applicable specific characteristics, such as design, performance, safety or other;***~~

~~***b) EU and non-EU manufacturers and respective legal representatives that can place the categories of medical device from the list on market;***~~

c) ~~***Notified bodies by designation codes applicable to medical device categories.***~~

3. The Agency shall publish the public health emergency critical devices list and any updates to that list on its web-portal.

Article 21

Monitoring shortages of medical devices on the public health emergency critical devices list

1. ***During the recognition of a public health emergency, or at a request for assistance referred to in article 4(3) and*** **o**~~O~~n the basis of the ~~public health emergency~~ critical ***medical*** devices ***and in vitro diagnostic medical devices*** list and the information and data provided in accordance with Articles 24 and 25, the Medical Devices Steering Group shall monitor supply and demand of medical devices ***and in vitro diagnostic medical devices*** included on that list with a view to identifying any potential or actual shortages of those medical devices. As part of that monitoring, the Medical Devices Steering Group shall liaise, where relevant, with ***the MDCG*** the Health Security Committee established in Article 4 of Regulation (EU) 2020/[…][14] and the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation.

2. As part of the monitoring, the Medical Devices Steering Group may also make use of data from device registries and databanks where such data is available to the Agency. In so doing, the Medical Devices Steering Group shall take into account the data generated pursuant to Article 108 of Regulation (EU) 2017/745 and Article 101 of Regulation (EU) 2017/746.

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

Article 22

Reporting and recommendations on shortages of medical devices

1. For the duration of the public health emergency, the Medical Devices Steering Group shall regularly report the results of its monitoring to the Commission and the sub-network referred to in Article 23(~~1~~***2***)(~~b~~***a***), and, in particular, signal any potential or actual shortages of medical devices ***and in vitro diagnostic medical devices*** included on the public health emergency critical devices list.

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 ***Shortages*** Steering Group referred to in Article 3 where medical devices ***and in vitro diagnostic medical devices*** included on the public health emergency critical devices list are used to jointly with a medicinal product.

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 MDCG,*** 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 ***and in vitro diagnostic 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.

Article 23

Working methods and provision of information on medical devices

1. In order to prepare for fulfilling the tasks referred to in Articles 20, 21, and 22, the Agency ***together with MDCG*** shall:

(a) specify the procedures for establishing the public health emergency critical devices list;

(b) develop streamlined electronic monitoring and reporting systems, ***~~including,~~ facilitating interoperability with existing electronic tools, namely EUDAMED and providing the adequate support to Members States' competent authorities for monitoring and reporting;***

c) establish and maintain membership of the working party referred to in Article 19(5) comprised of single points of contact from Member States' national competent authorities**;**

(d) establish and maintain a list of single points of contact from medical device manufacturers, authorised representatives and notified bodies***; ~~EUDAMED should be considered a relevant source of information;~~***

(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:

(a) establish and maintain for the duration of the public health emergency, a sub-network of single points of contact from medical device manufacturers, ***or their*** ***authorised representatives*** and notified bodies based on the medical devices ***and in vitro diagnostic medical devices*** included on the public health emergency critical devices list. ***EUDAMED should be considered as the relevant source of information for the establishment of the sub-network of single points of contact from medical device manufacturers, authorised representatives and notified bodies;***

(b) request ***relevant*** information from the points of contact included in the sub-network based on the set of information agreed on by the Medical Devices Steering Group and set a deadline for its submission**.**

(c) request ***relevant*** information from the single points of contact from Member States' national competent authorities based on the set of information agreed on by the Medical Devices Steering Group and set a deadline for its submission.

(d) other sources, including existing databases and databases in development, may also be used to gather part of the information required under paragraph 3.

3. The information referred to in point (b) of paragraph 2 shall include at least:

(a) the name of the manufacturer and, if applicable, the name of the authorised representative;

(b) identification of the medical device and the intended purpose ***and if applicable specific characteristics, such as design, performance or safety***;

(c) if applicable, the name and number of the notified body and information on the relevant certificate or certificates;

(d) details of the potential or actual shortage such as actual or estimated start and end dates, and the known or suspected cause;

(e) sales and market share data;

(f) mitigation plans including production and supply capacity;

(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 ***and in vitro diagnostic medical devices*** included in the public health emergency critical devices list;

(h) information on the number of applications received by concerned notified bodies in relation to medical devices ***and in vitro diagnostic medical devices*** included in the public health emergency critical devices list and relevant conformity assessment procedures;

(i) where conformity assessments are on-going, the status of the conformity assessment by the concerned notified bodies in relation to medical devices ***and in vitro diagnostic medical devices*** included in the public health emergency critical devices list and possible issues ***that have impact and*** which need to be ~~resolved~~ ***considered*** in order to complete the conformity assessment process.

Article 24

Obligations on medical device manufacturers, authorised representatives, and notified bodies

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

2. Medical device manufacturers ***or their authorised representatives, as applicable***, and notified bodies shall justify the absence of any requested information and any delays in providing it by the deadline set by the Agency.

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

4. Where manufacturers of medical devices ***and in vitro diagnostic medical devices*** included on the public health emergency critical devices list and concerned notified bodies are in possession of any additional information, which provides evidence of a potential or actual shortage, they shall immediately provide such information to the Agency.

5. Following the reporting on the results of the monitoring and any recommendations on preventive or mitigating measures in accordance with Article 22, manufacturers of medical devices ***and in vitro diagnostic medical devices*** included on the public health emergency critical devices list and concerned notified bodies shall:

(a) provide any comments they have to the Agency;

~~(b)~~

~~(c)~~ take into account any recommendations and guidelines and comply with any measures taken at Union and Member State-level pursuant to Articles 25 and 26;

~~(d)~~ inform the Medical Devices Steering Group of any measures taken and report on the results, including information on the resolution of the potential or actual shortage.

6. Where manufacturers of medical devices ***and in vitro diagnostic medical devices*** included on the public health emergency critical devices list are established outside the Union and are unable to provide the information required, in accordance with this Article, it shall be provided by the authorised representatives.

Article 25

~~Obligations on~~ ***Role of*** *Member States in the monitoring and mitigation of shortages of medical devices*

1. In order to facilitate the monitoring referred to in Article 21 and following a request from the Agency, Member States shall, by the deadline set by the Agency:

(a) submit the set of information requested by the Agency, including ***available*** information about needs related to the medical devices ***and in vitro diagnostic medical devices*** included in the public health emergency critical devices list, and available ~~and~~ ***or*** estimated data on the volume of demand, through its designated point of contact and using the reporting methods and system established pursuant to Article 23(1);

(b) indicate the existence of any commercially confidential information, and, clarify the reasons for such an indication, ***in accordance with ~~as per~~ article 24 (3)***;

(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 shall gather information from manufacturers, importers, distributors and notified bodies on medical devices ***and in vitro diagnostic medical devices*** included on the public health emergency critical devices list.

3. Where Member States are in possession of any additional information, which provides evidence of a potential or actual shortage, they shall immediately provide such information to the Medical Devices Steering Group through their designated points of contact.

4. Following the reporting on the results of the monitoring and any recommendations on preventive or mitigating measures in accordance with Article 22, Member States shall:

(a) consider the need to provide for temporary exemptions at Member State level pursuant to Article 59(1) of Regulation (EU) 2017/745 or Article 54(1) of Regulation (EU) 2017/746 with a view to mitigating potential or actual shortages of medical devices ***and in vitro diagnostic medical devices*** included on the public health emergency critical devices list;

(b) ~~take into account~~ ***consider*** any recommendations, ~~and~~ guidelines and ~~comply with any~~ measures taken at Union-level pursuant to Article 26;

(c) inform the Medical Devices Steering Group of any measures taken and report on the results of those measures, including information on the resolution of the potential or actual shortage.

Article 26

~~Role~~ Obligations *of the Commission in the monitoring and mitigation of shortages of medical devices*

The Commission shall take into account the information from and recommendations of the Medical Devices Steering Group and shall:

(a) take all necessary action within the limits of the powers conferred on it, with a view to mitigating potential or actual shortages of medical devices ***and in vitro diagnostic medical devices*** included on the public health emergency critical devices list, including, where necessary, granting temporary exemptions at Union level pursuant to Article 59(3) of Regulation (EU) 2017/745 or Article 54(3) of Regulation (EU) 2017/746, ***while respecting the conditions set in those articles***;

(b) consider the need for guidelines addressed to Member States, medical device manufacturers, notified bodies and other entities;

(c) request the Medical Devices Steering Group to provide recommendations or coordinate measures pursuant to Article 22(3), (4) and (5);

(d) consider the need for medical countermeasures in accordance with Articles 12 and 25(b) of Regulation (EU) 2020/[…];[15]

(e) liaise with third countries and relevant international organisations, as appropriate, to mitigate potential or actual shortages of medical devices ***and in vitro diagnostic medical devices*** included on the critical devices list or their component parts, where those devices or parts are imported into the Union, and where such potential or actual shortages have international implications.

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

Article 27

Communication on the Medical Devices Steering Group

The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Medical Devices Steering Group.

Article 28

Support for the expert panels on medical devices

1. The Agency shall, on behalf of the Commission, from 1 March 2022 onwards, provide the secretariat of the expert panels designated in accordance with ~~Implementing Decision (EU) 2019/1396~~ ***Article 106(1) of Regulation (EU) 2017/745*** and provide the support necessary to ensure that those panels can efficiently perform their tasks as set out in Article 106(9) and (10) of Regulation (EU) 2017/745. The Agency shall:

   (a) provide administrative and technical support to the expert panels for the provision of scientific opinions, views and advice;

   (b) facilitate and manage remote and physical meetings of the expert panels;

   (c) ensure that the work of the expert panels is carried out in an independent manner in accordance with Article 106(3), second subparagraph ***and Article 107*** of Regulation (EU) 2017/745 and ~~establish~~ ***with the*** systems and procedures ***established by the Commission*** to actively manage and prevent potential conflicts of interest in accordance with Article 106(3), third subparagraph ~~and Article 107~~ of that Regulation;

(d) maintain and regularly update a web-page for the expert panels and make publicly available on the web-page all information necessary ***not already publicly available in EUDAMED*** to ensure the transparency of the activities of the expert panels, including justifications of notified bodies where they did not follow the advice of the expert panels provided pursuant to Article 106(9) of Regulation (EU) 2017/745;

(e) publish***, on behalf of the Commission***, the scientific opinions, views, and advice of the panels while ensuring confidentiality in accordance with Article106(12) second subparagraph and Article 109 of Regulation (EU) 2017/745;

(f) ensure that remuneration and expenses are provided to the experts in accordance with ~~Article 11 of Implementing Decision (EU) 2019/1396~~ ***implementing acts adopted by the Commission pursuant to Article 106(1) of Regulation (EU) 2017/745****;*

(g) monitor compliance with the panels' common rules of procedure and available guidelines and methodologies relevant to the functioning of the panels;

(h) provide annual reports to the Commission ***and the MDCG*** on the work undertaken by the expert panels, including the number of opinions, views and advice delivered.

2. In order to perform the Agency's tasks, as described under the previous paragraph, the Agency shall establish a collaborative strategy on the administrative and technical support of the work of the expert panels together with Commission and MDCG.

3. The Agency should periodically, at least twice a year, consult ~~meet with~~ the MDCG on the ongoing work of the expert panels in order to present a report of the tasks performed and to discuss and align the strategy defined in point 2.

Chapter V

Final Provisions

Article 29

*Cooperation between Steering Groups**, Emergency Task Force and the expert panels***

1. The Agency shall ensure cooperation between the Medicines and Medical Devices Steering Groups in relation to measures to address major events and public health emergencies.

2. Members of the Medicines and Medical Devices Steering Groups and their working parties may attend each other's meetings and working parties and, where appropriate, cooperate on monitoring exercises, reporting and opinions.

3. In agreement with the ***(Co-)***Chairs, joint meetings of the Medicines and Medical Devices Steering Groups may be held.

4. Where relevant, the Agency shall ensure cooperation between the Emergency Task Force and the expert panels in relation to preparedness and management of public health crises.

Article 30

~~Confidentiality~~ ***Commercially confidential information***

1. Unless otherwise provided for in this Regulation and without prejudice to Regulation (EC) No 1049/200124 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;~~

~~(b)~~ commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights~~;~~

~~(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.

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.

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.

New Article 30aa

Personal data protection

1. Transfers of personal data under this Regulation shall comply with the principles and conditions laid down in Regulation (EU) 2016/679 and Regulation (EU) 2018/1725.

2. In the absence of an adequacy decision, or of appropriate safeguards, as referred to in Article 49(1) of Regulation (EU) 2016/679 and Article 50(1) of Regulation (EU) 2018/1725, the Commission, the Agency, and Member States may exchange~~,~~ personal data with regulatory authorities of third countries where necessary for the prevention of or response to a serious threat to public health of a Member State or a third country.

Article 30ab

Union funding

The financing of the Agency's activities in support of the work of the Medicines Shortages and Medical Devices Steering Groups, the Emergency Task Force their working parties and expert panels, involving its cooperation with the Commission and the European Centre for Disease Prevention and Control shall be ensured by the Union. The Union's financial assistance to the activities under this Regulation shall be implemented in accordance with Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council.

Article 30a

Evaluation and Reporting

By [xxx] and every [xxx] years thereafter the Commission shall carry out an evaluation of this Regulation and present a report on the main findings to the European Parliament and the Council on the crisis preparedness and management framework for medicines and medical devices, considering the possible extension of the scope to medicinal products for veterinary use ~~medicines~~ and to PPE for medical use.

Article 31

Entry into Force ***and date of application***

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

2. It shall apply from [date of application]

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	The President