►B REGULATION (EU) 2022/123 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 25 January 2022

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

(Text with EEA relevance)

(OJ L 20, 31.1.2022, p. 1)

Amended by:

		Official Journal		
		No	page	date
►M1	Regulation (EU) 2024/568 of the European Parliament and of the Council of 7 February 2024	L 568	1	14.2.2024

Corrected by:

►C1	Corrigendum, OJ L 71, 9.3.2023, p. 37 (2022/123)	

▼B

REGULATION (EU) 2022/123 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 25 January 2022

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

(Text with EEA relevance)

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject Matter

Within the European Medicines Agency (the 'Agency'),this Regulation provides for a framework for and the means of:

▼C1

(a) preparing for, preventing, coordinating and managing the impact of public health emergencies on medicinal products and on medical devices and the impact of major events on medicinal products at Union level;

▼B

(b) monitoring, preventing, and reporting on shortages of medicinal products and on shortages of medical devices;

(c) setting up an interoperable information technology (IT) platform at Union level to monitor and report on shortages of medicinal products;

(d) providing advice on medicinal products that have the potential to address public health emergencies;

(e) providing support for the expert panels provided for in Article 106(1) of Regulation (EU) 2017/745.

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

(a) 'public health emergency' means a situation of public health emergency recognised by the Commission in accordance with Article 12(1) of Decision No 1082/2013/EU;

(b) '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, which concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin, or a serious incident that can affect the supply of or demand for medicinal products, or quality, safety or efficacy of medicinal products, which 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;

▼B

(c) ‘medicinal product’ means a medicinal product as defined in Article 1, point (2), of Directive 2001/83/EC;

(d) ‘veterinary medicinal product’ means a veterinary medicinal product as defined in Article 4, point (1), of Regulation (EU) 2019/6 of the European Parliament and the Council ([1]);

(e) ‘medical device’ means a medical device as defined in Article 2, point (1), of Regulation (EU) 2017/745 or an *in vitro* diagnostic medical device as defined in Article 2, point (2), of Regulation (EU) 2017/746, and includes accessories for such devices within the meaning of Article 2, point (2), of Regulation (EU) 2017/745, and Article 2, point (4), of Regulation (EU) 2017/746, respectively;

(f) ‘supply’ means the total volume of stock of a given medicinal product or medical device that is placed on the market by a marketing authorisation holder or a manufacturer;

(g) ‘demand’ means the request for a medicinal product or a medical device by a healthcare professional or patient in response to clinical need; the demand is satisfactorily met when the medicinal product or the medical device is acquired in appropriate time and in sufficient quantity to allow continuity of the best care of patients;

(h) ‘shortage’ means a situation in which the supply of a medicinal product that is authorised and placed on the market in a Member State or of a CE-marked medical device does not meet demand for that medicinal product or medical device at a national level, whatever the cause;

(i) ‘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 the development of that product.

CHAPTER II

MONITORING AND MITIGATING SHORTAGES OF CRITICAL MEDICINAL PRODUCTS AND MANAGEMENT OF MAJOR EVENTS

Article 3

Executive Steering Group on Shortages and Safety of Medicinal Products

1. The Executive Steering Group on Shortages and Safety of Medicinal Products (the ‘Medicine Shortages Steering Group – MSSG’) is hereby established within the Agency.

The MSSG shall be responsible for fulfilling the tasks referred to in Article 4(3) and (4) and Articles 5 to 8.

The MSSG shall meet regularly and also whenever the situation requires, either in person or remotely, in preparation for or during a public health emergency or when an issue of concern has been raised with the MSSG or when the Commission has recognised a major event in accordance with Article 4(3).

([1]) Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

▼B

The Agency shall provide the secretariat of the MSSG.

2. The members of the MSSG shall consist of a representative of the Agency, a representative of the Commission and one representative appointed by each Member State.

Members of the MSSG may be accompanied to meetings of the MSSG by experts in specific scientific or technical fields.

The list of the members of the MSSG shall be published on the Agency's web portal.

A representative of the Agency's Patients' and Consumers' Working Party ('PCWP') and a representative of the Agency's Healthcare Professionals' Working Party ('HCPWP') may attend meetings of the MSSG as observers.

3. The MSSG shall be co-chaired by the representative of the Agency and by one of the representatives of the Member States, who shall be elected by and from among the representatives of the Member States in the MSSG.

The co-chairs of the MSSG, on their own initiative or at the request of one or more members of the MSSG, may invite, as observers and to provide expert advice, representatives of national competent authorities for veterinary medicinal products, representatives of other relevant competent authorities and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, wholesale distributors, any other appropriate actor in the supply chain for medicinal products, and representatives of healthcare professionals, of patients and consumers, to attend its meetings, as necessary.

4. The MSSG, in coordination with the national competent authorities for medicinal products, shall facilitate appropriate communication with marketing authorisation holders or their representatives, manufacturers, other relevant actors of the supply chain for medicinal products, and representatives of healthcare professionals, of patients and consumers, with a view to receiving relevant information on actual or potential shortages of medicinal products considered to be critical during a public health emergency or a major event as provided for in Article 6.

5. The MSSG shall establish its rules of procedure, including procedures relating to the working party referred to in paragraph 6 of this Article and procedures for adoption of the critical medicines lists, sets of information and recommendations referred to in Article 8(3) and (4).

The rules of procedure referred to in the first subparagraph shall enter into force once the MSSG has received a favourable opinion from the Commission and the Management Board of the Agency.

6. The MSSG shall be supported in its work by a working party established in accordance with Article 9(1), point (d).

The working party referred to in the first subparagraph shall consist of representatives of the national competent authorities for medicinal products, who shall be the single points of contact in relation to shortages of medicinal products.

▼B

7. The MSSG may consult with the Committee for Medicinal Products for Veterinary Use (‘CVMP’) established by Article 56(1), point (b), of Regulation (EC) No 726/2004 whenever the MSSG deems necessary to do so, in particular, in order to deal with public health emergencies or major events related to zoonoses or diseases that only affect animals and that have or may have a major impact on human health or where the use of active substances for veterinary medicinal products may be useful in addressing the public health emergency or major event.

Article 4

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

1. The Agency, in collaboration with Member States, shall continuously monitor any event that is likely to lead to a public health emergency or major event. As necessary, the Agency shall cooperate with the European Centre for Disease Prevention and Control (‘ECDC’) and, where relevant, other Union agencies.

2. ►C1 To facilitate the monitoring referred to in paragraph 1, the national competent authorities for medicinal products, acting through the single points of contact referred to in Article 3(6), second subparagraph, or the platform referred to in Article 13 (the ‘ESMP’), once it is fully functional, shall report in a timely manner to the Agency ◄ on any event that is likely to lead to a public health emergency or major event, including an actual or potential shortage of a medicinal product in a given Member State. Such reporting shall be based on the reporting methods and criteria pursuant to Article 9(1), point (b).

Where a national competent authority informs the Agency of a shortage of a medicinal product as referred to in the first subparagraph, it shall provide the Agency with any information that it has received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC, if that information is not available in the ESMP.

Where the Agency receives a report of an event from a national competent authority for medicinal products, the Agency may request information from the national competent authorities, through the working party referred to in Article 3(6), in order to evaluate the impact of the event in other Member States.

3. Where the Agency considers that an actual or imminent major event needs to be addressed, it shall raise the issue of concern with the MSSG.

Following a positive opinion of the MSSG, the Commission may recognise the major event.

The Commission or at least one Member State may raise the issue of concern with the MSSG on its own initiative.

▼B

4. The MSSG shall inform the Commission and the Executive Director of the Agency once the MSSG considers that the major event has been sufficiently addressed and considers that its assistance is no longer needed.

On the basis of the information referred to in the first subparagraph or on its own initiative, the Commission or the Executive Director may confirm that the major event has been sufficiently addressed and therefore that the assistance of the MSSG is no longer needed.

5. Following the recognition of a public health emergency or the recognition of a major event in accordance with paragraph 3 of this Article, Articles 5 to 12 apply as follows:

(a) where the public health emergency or the major event may affect the quality, safety or efficacy of medicinal products, Article 5 applies;

(b) where the public health emergency or the major event may lead to shortages of medicinal products in more than one Member State, Articles 6 to 12 apply.

Article 5

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

1. Following the recognition of a public health emergency or the recognition of a major event in accordance with Article 4(3), the MSSG shall evaluate information related to the public health emergency or the major event and consider the need for urgent and coordinated action with regard to the quality, safety and efficacy of the medicinal products concerned.

2. The MSSG shall provide recommendations to the Commission and Member States on any appropriate action that it believes needs to be taken at Union level on the medicinal products concerned in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004.

3. The MSSG may consult with the CVMP whenever the MSSG deems necessary to do so, in particular, in order to deal with public health emergencies or major events related to zoonoses or diseases that only affect animals and that have or may have a major impact on human health, or where the use of active substances for veterinary medicinal products may be useful in addressing the public health emergency or the major event.

▼B

Article 6

Lists of critical medicinal products and information to be provided

1. Without prejudice to paragraph 2, the MSSG shall establish a list with the main therapeutic groups of medicinal products that are necessary for emergency care, surgery and intensive care, in order to inform the preparation of the critical medicines lists as referred to in paragraphs 2 and 3 to be used to respond to a public health emergency or major event. The list shall be established by 2 August 2022 and updated annually and whenever necessary.

2. Immediately following the recognition of a major event in accordance with Article 4(3) of this Regulation, the MSSG shall consult the working party referred to in Article 3(6) of this Regulation. Immediately following that consultation, the MSSG shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers to be critical during the major event (the 'major event critical medicines list').

The MSSG shall update the major event critical medicines list whenever necessary until the major event has been sufficiently addressed and it has been confirmed that the assistance of the MSSG is no longer needed pursuant to Article 4(4) of this Regulation.

3. Immediately following the recognition of a public health emergency, the MSSG shall consult the working party referred to in Article 3(6) of this Regulation. Immediately following that consultation, the MSSG shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers to be critical during the public health emergency (the 'public health emergency critical medicines list'). The MSSG shall update the public health emergency critical medicines list whenever necessary until the termination of the recognition of the public health emergency. The public health emergency critical medicines list may be updated to take into account the results of the review process under Article 18 of this Regulation, where appropriate. In such cases, the MSSG shall liaise with the Emergency Task Force referred to in Article 15 of this Regulation ('ETF').

4. For the purposes of Article 9(2), the MSSG shall adopt and make publicly available the set of information referred to in Article 9(2), points (c) and (d), that is necessary to monitor the supply of and demand for medicinal products included on the lists referred to in paragraphs 2 and 3 of this Article (the 'critical medicines lists') and shall inform the working party referred to in Article 3(6) of that set of information.

5. Following the adoption of critical medicines lists in accordance with paragraphs 2 and 3, the Agency shall immediately publish those lists and any updates to those lists on its web portal as referred to in Article 26 of Regulation (EC) No 726/2004.

▼B

6. The Agency shall establish within its web portal a publicly accessible webpage that provides information on actual shortages of medicinal products included in the critical medicines lists in cases in which the Agency has assessed the shortage and has provided recommendations to healthcare professionals and patients. The webpage shall provide at least the following information:

(a) the name and common name of the medicinal product on the critical medicines lists;

(b) the therapeutic indications for the medicinal product on the critical medicines lists;

(c) the reason for the shortage of the medicinal product on the critical medicines lists;

(d) the start and end dates of the shortage of the medicinal product on the critical medicines lists;

(e) the Member States affected by the shortage of the medicinal product on the critical medicines lists;

(f) other relevant information for healthcare professionals and patients, including information on whether alternative medicinal products are available.

The webpage referred to in the first subparagraph shall also provide references to national registries on shortages of medicinal products.

Article 7

Monitoring shortages of medicinal products on the critical medicines lists

Following the recognition of a public health emergency or the recognition of a major event in accordance with Article 4(3), the MSSG shall monitor the supply of and demand for medicinal products included on the critical medicines lists, with a view to identifying any actual or potential shortages of those medicinal products. The MSSG shall conduct such monitoring using the critical medicines lists and the information and data provided, in accordance with Articles 10 and 11, and available through the ESMP, once it is fully functional.

For the purposes of the monitoring referred to in the first paragraph of this Article, where relevant, the MSSG shall liaise with the Health Security Committee established by Article 17 of Decision No 1082/2013/EU (‘HSC’) and, in the case of a public health emergency, with any other relevant advisory committee on public health emergencies established pursuant to Union law and with the ECDC.

▼B

Article 8

Reporting and recommendations on shortages of medicinal products

▼C1

1. For the duration of a public health emergency, or following the recognition of a major event as referred to in Article 4(3) until it has been confirmed that the major event has been sufficiently addressed pursuant to Article 4(4), the MSSG shall regularly report the results of the monitoring referred to in Article 7 to the Commission and the single points of contact referred to in Article 3(6), second subparagraph, and, in particular, shall signal any actual or potential shortages of medicinal products included on the critical medicines lists or any event that is likely to lead to a major event.

▼B

2. ►C1 Where requested by the Commission or one or more single point of contact as referred to in Article 3(6), second subparagraph, the MSSG shall provide aggregated data and demand forecasts to support its findings and conclusions. In that regard, the MSSG shall: ◄

(a) use data from the ESMP, once it is fully functional;

(b) liaise with the ECDC to obtain epidemiological data, models and development scenarios to help forecast medicinal product needs; and

(c) liaise with the Executive Steering Group on Shortages of Medical Devices referred to in Article 21 (‘MDSSG’) where medicinal products included on the critical medicines lists are used jointly with a medical device.

The aggregated data and demand forecasts referred to in the first subparagraph may also be made available to other actors in the supply chain for medicinal products, where appropriate, in accordance with competition law, with a view to better preventing or mitigating actual or potential shortages of medicinal products.

3. As part of the reporting referred to in paragraphs 1 and 2, the MSSG may provide recommendations on measures that the Commission, Member States, marketing authorisation holders and other entities, including representatives of healthcare professionals and of patients, could take to prevent or mitigate actual or potential shortages of medicinal products.

Member States may request the MSSG to provide recommendations on measures referred to in the first subparagraph.

For the purposes of the second subparagraph, the MSSG shall liaise, as relevant, with the HSC and, in the case of a public health emergency, with any other relevant advisory committee on public health emergencies established pursuant to Union law.

▼B

4. The MSSG, on its own initiative or at the request of the Commission or a Member State, may provide recommendations on measures that the Commission, Member States, marketing authorisation holders, representatives of healthcare professionals and other entities could take to ensure preparedness for dealing with actual or potential shortages of medicinal products caused by public health emergencies or major events.

5. Where requested by the Commission, the MSSG may coordinate measures taken by the national competent authorities, the marketing authorisation holders and other entities, including representatives of healthcare professionals and of patients, as relevant, to prevent or mitigate actual or potential shortages of medicinal products in the context of a public health emergency or major event.

Article 9

Working methods and provision of information on medicinal products

1. In order to prepare for the fulfilment of the tasks referred to in Articles 4 to 8, the Agency, shall:

(a) specify the procedures and criteria for establishing and reviewing 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, with a basic minimum data set;

(c) develop streamlined IT monitoring and reporting systems, in coordination with the relevant national competent authorities, that facilitate interoperability with other existing IT systems and IT systems under development until the ESMP is fully functional, on the basis of data fields that are harmonised across Member States;

(d) establish the working party referred to in Article 3(6) and ensure that each Member State is represented on that working party;

(e) establish and maintain a list of single points of contact for marketing authorisation holders for all medicinal products authorised in the Union, through the database provided for in Article 57(1), point (l), of Regulation (EC) No 726/2004;

(f) specify the methods for the provision of recommendations referred to in Article 5(2) and Article 8(3) and (4) and for the coordination of measures referred to in Article 8(5);

(g) publish information covered by points (a), (b) and (f) on a dedicated webpage on its web portal.

For the purposes of the first subparagraph, point (a), Member States, marketing authorisation holders, other relevant actors in the supply chain for medicinal products and representatives of healthcare professionals, of patients and consumers, may be consulted as necessary.

▼B

2. Following the recognition of a public health emergency or the recognition of a major event in accordance with Article 4(3), the Agency shall:

(a) establish a list of single points of contact for the marketing authorisation holders for the medicinal products included on the critical medicines lists;

(b) maintain the list of single points of contact referred to in point (a) for the duration of the public health emergency or major event;

(c) request relevant information on medicinal products on the critical medicines lists from the single points of contact referred to in point (a) and set a deadline for the submission of that information, if that information is not available in the ESMP;

▼C1

(d) request information on medicinal products on the critical medicines lists from the single points of contact referred to in Article 3(6), second subparagraph, on the basis of the set of information referred to in Article 6(4), and set a deadline for the submission of that information, if that information is not available in the ESMP.

▼B

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

(a) the name of the marketing authorisation holder of the medicinal product;

(b) the name of the medicinal product;

(c) the identification of active manufacturing sites for finished products and active substances of the medicinal product;

(d) the Member State in which the marketing authorisation is valid and the marketing status of the medicinal product in each Member State;

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

(f) sales and market share data of the medicinal product;

(g) available stocks of the medicinal product;

(h) the forecast of supply for the medicinal product, including information on potential vulnerabilities in the supply chain, quantities already delivered and projected deliveries;

(i) demand forecasts for the medicinal product;

(j) details of available alternative medicinal products;

(k) shortage prevention and mitigation plans that include, at a minimum, information on production and supply capacity and approved production sites of the finished medicinal product and of active substances, potential alternative production sites and minimum stock levels of the medicinal product.

▼B

4. In order to supplement the shortage prevention and mitigation plans for critical medicinal products referred to in paragraph 3, point (k), the Agency and national competent authorities for medicinal products may request information from wholesale distributors and other relevant actors regarding any logistical challenges incurred in the wholesale supply chain.

Article 10

Obligations on marketing authorisation holders

1. Marketing authorisation holders for medicinal products authorised in the Union shall provide the information for the purposes of Article 9(1), point (e), of this Regulation by 2 September 2022, in the form of an electronic submission to the database referred to in Article 57(1), point (l), of Regulation (EC) No 726/2004. Those marketing authorisation holders shall provide updates when necessary.

2. In order to facilitate the monitoring referred to in Article 7, the Agency may request marketing authorisation holders for medicinal products included on the critical medicines lists to submit the information referred to in Article 9(2) point (c).

▼C1

The marketing authorisation holders referred to in the first subparagraph of this paragraph shall submit the requested information by the deadline set by the Agency, through the single points of contact referred to in Article 9(2), point (a), using the monitoring and reporting methods and systems established pursuant to Article 9(1), points (b) and (c), respectively. Those marketing authorisation holders shall provide updates where necessary.

▼B

3. The marketing authorisation holders referred to in paragraphs 1 and 2 shall justify any failure to provide any requested information and any delays in providing requested information by the deadline set by the Agency.

4. Where the marketing authorisation holders referred to in paragraph 2 indicate that the information that they submitted at the request of the Agency or the national competent authorities for medicinal products contains information of a commercially confidential nature, they shall identify the relevant parts of that information having such nature and explain why that information is of a commercially confidential nature.

The Agency shall assess the merits of each indication of information as being of a commercially confidential nature and protect such commercially confidential information against unjustified disclosure.

5. Where the marketing authorisation holders referred to in paragraph 2 or other relevant actors in the supply chain for medicinal products have any information in addition to that required under paragraph 2, second subparagraph, which provides evidence of an actual or potential shortage of medicinal products, they shall immediately provide such information to the Agency.

▼B

6. Following the reporting on the results of the monitoring referred to in Article 7 and any recommendations on preventive or mitigating measures provided in accordance with Article 8(3) and (4), the marketing authorisation holders referred to in paragraph 2 shall:

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

(b) take into account any recommendations referred to in Article 8(3) and (4) and any guidelines referred to in Article 12, point (c);

(c) comply with any measures taken at Union or Member State level pursuant to Articles 11 and 12;

(d) inform the MSSG of any measures taken and report on the monitoring and results of those measures, including providing information on the resolution of the actual or potential shortage of medicinal products.

Article 11

Role of Member States in the monitoring and mitigation of shortages of medicinal products

1. In order to facilitate the monitoring referred to in Article 7, unless the information concerned is available on the ESMP, the Agency may request a Member State to:

▼C1

(a) submit the set of information referred to in Article 9(2), point (d), including available and estimated data on volume of demand and demand forecasts, through the single point of contact referred to in Article 3(6), second subparagraph, using the reporting methods and systems established pursuant to Article 9(1), points (b) and (c), respectively;

▼B

(b) indicate the existence of any commercially confidential information and explain why that information is of a commercially confidential nature, in accordance with Article 10(4);

(c) indicate any failure to provide requested information, and whether there are any delays in providing that information by the deadline set by the Agency in accordance with Article 10(3).

Member States shall comply with the Agency's request by the deadline set by the Agency.

2. For the purposes of paragraph 1, wholesale distributors and other persons or legal entities that are authorised or entitled to supply medicinal products included on the critical medicines lists to the public shall provide that Member State with relevant information and data, including information and data on the levels of stock of those medicinal products at the request of that Member State.

▼C1

3. Where Member States have any information in addition to the information to be provided in accordance with paragraphs 1 and 2 of this Article on volumes of sales of and volumes of prescriptions for medicinal products which provides evidence of an actual or potential shortage of a medicinal product included on the critical medicines lists, including data referred to in Article 23a, third paragraph, of Directive 2001/83/EC, they shall immediately provide such information to the MSSG through their respective single points of contact referred to in Article 3(6), second subparagraph, of this Regulation.

▼B

4. Following the reporting on the results of the monitoring referred to in Article 7 and any recommendations on preventive or mitigating measures provided in accordance with Article 8(3) and (4), Member States shall:

(a) take into account any recommendations and guidelines referred to in Article 12, point (c), and coordinate their actions in relation to any actions taken at Union level pursuant to Article 12, point (a);

(b) inform the MSSG of any measures taken and report on the results of the actions referred to in point (a), including providing information on the resolution of the actual or potential shortage of medicinal products.

For the purposes of the first subparagraph, points (a) and (b), Member States that take an alternative course of action at national level shall share the reasons for doing so with the MSSG in a timely manner.

The recommendations, guidelines and actions referred to in the first subparagraph, point (a), and a summary report of the lessons learned, shall be made publicly available via the web portal referred to in Article 14.

Article 12

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

The Commission shall take into account the information from and recommendations of the MSSG referred to in Article 8(1) and (2) and in Article 8(3) and (4), respectively, and shall:

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

(b) facilitate the coordination between marketing authorisation holders and other relevant entities to address demand surges, where necessary;

(c) consider the need for guidelines and recommendations to be addressed to Member States, marketing authorisation holders, and other entities, including relevant entities from the supply chain for medicinal products, where relevant;

▼B

(d) inform the MSSG of any measures taken by the Commission and report on the results of those measures;

(e) request the MSSG to provide recommendations or coordinate measures as provided for in Article 8(3), (4) and (5);

(f) consider the need for medical countermeasures in accordance with Decision No 1082/2013/EU and other applicable Union law;

(g) liaise with third countries and relevant international organisations, as appropriate, to mitigate actual or potential shortages of medicinal products included on the critical medicines lists or their active substances, where those medicinal products or active substances are imported into the Union and where such actual or potential shortages have international implications, and report on any related actions as well as the results of those actions to the MSSG, where relevant.

Article 13

European shortages monitoring platform

1. The Agency shall set up, maintain, and manage an IT platform to be known as the European shortages monitoring platform (‘ESMP’), which shall be linked to the database referred to in Article 57(1), point (l), of Regulation (EC) No 726/2004.

The ESMP shall be used to facilitate the collection of information on shortages of, supply of, and demand for medicinal products, including information on whether the medicinal product is placed or ceases to be placed on the market in a Member State.

2. The information collected through the ESMP shall be used to monitor, prevent, and manage:

(a) actual or potential shortages of medicinal products on the critical medicines lists during public health emergencies and major events; and

(b) actual or potential shortages of medicinal products that are likely to lead to a public health emergency or a major event in accordance with Article 4(2).

3. For the purposes of paragraph 2, during public health emergenciesand major events:

(a) marketing authorisation holders shall use the ESMP to report information relating to medicinal products on the critical medicines lists to the Agency, through the single points of contact referred to in Article 9(2), point (a), in accordance with Articles 9 and 10;

▼C1

(b) Member States shall use the ESMP to report information relating to medicinal products on the critical medicines lists to the Agency, through the single points of contact referred to in Article 3(6), second subparagraph, in accordance with Articles 9 and 11.

▼B

The reporting referred to in the first subparagraph, point (b), shall include information in addition to that referred to in that point received from marketing authorisation holders and wholesale distributors, or other persons or legal entities that are authorised or entitled to supply to the public medicinal products included on the critical medicines lists, where relevant.

4. For the purposes of paragraph 2, and as regards ensuring preparedness for public health emergencies and major events:

(a) marketing authorisation holders shall use the ESMP to report to the Agency:

(i) the information referred to in Article 13(4) of Regulation (EC) No 726/2004 for authorisations granted in accordance with that Regulation;

(ii) information based on the categories set out in Article 9(3) that relate to actual or potential shortages of medicinal products that are likely to lead to a public health emergency or major event, where appropriate;

▼C1

(b) Member States shall use the ESMP to report to the Agency on shortages of medicinal products that are likely to lead to a public health emergency or major event in accordance with Article 4(2), through the single points of contact referred to in Article 3(6), second subparagraph.

▼B

5. The reporting referred to in paragraph 4, point (b):

(a) shall include the information referred to in Article 23a of the Directive 2001/83/EC that was reported to national competent authorities for medicinal products for authorisations granted in accordance with that Directive;

(b) may include additional information received from marketing authorisation holders, wholesale distributors and other persons or legal entities that are authorised or entitled to supply medicinal products to the public.

6. To ensure the optimal use of the ESMP, the Agency shall:

▼B

(a) develop the technical and functional specifications of the ESMP, including the data exchange mechanism for exchanging with the existing national systems and the format for electronic submissions, in collaboration with the MSSG;

(b) require that data submitted to the ESMP comply with the standards developed by the International Organization for Standardization for the identification of medicinal products and be based on the domains of master data in pharmaceutical regulatory processes, namely substance, product, organisation, and referential data, where relevant;

(c) develop standardised reporting terminology to be used by marketing authorisation holders and Member States when reporting to the ESMP, in collaboration with the MSSG;

(d) establish relevant guidance for reporting through the ESMP, in collaboration with the MSSG;

(e) ensure that data is interoperable between the ESMP, Member States' IT systems and other relevant IT systems and databases, without any duplication of reporting;

(f) ensure that the Commission, the Agency, national competent authorities and the MSSG have appropriate levels of access to the information contained in the ESMP;

(g) ensure that commercially confidential information submitted to the system is protected against unjustified disclosure;

(h) ensure the ESMP is fully operational by 2 February 2025 and draw up a plan for the implementation of the ESMP.

Article 14

Communication regarding the MSSG

1. The Agency shall provide information to the public and interest groups with regard to the work of the MSSG in a timely manner and shall respond to disinformation targeting the work of the MSSG as appropriate, via a dedicated webpage on its web portal and other appropriate means, in cooperation with national competent authorities.

2. Proceedings of the MSSG shall be transparent.

The summaries of the agenda and of the minutes of the meetings of the MSSG, as well as its rules of procedure referred to in Article 3(5) and recommendations referred to in Article 8(3) and (4), shall be documented and made publicly available on a dedicated webpage on the Agency web portal.

Where the rules of procedure referred to in Article 3(5) allow members of the MSSG to have divergent opinions recorded, the MSSG shall make such divergent opinions, and the grounds on which they are based, available to national competent authorities for medicinal products at their request.

▼B

CHAPTER III

MEDICINAL PRODUCTS WITH THE POTENTIAL TO ADDRESS PUBLIC HEALTH EMERGENCIES

Article 15

Emergency Task Force

1. The Emergency Task Force (‘ETF’) is hereby established within the Agency.

The ETF shall be convened in preparation for and during public health emergencies, either in person or remotely.

The Agency shall provide the secretariat of the ETF.

2. During public health emergencies, the ETF 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 that have the potential to address the public health emergency, including requesting data from developers and engaging with them in preliminary discussions;

(b) providing advice on the main aspects of clinical trial protocols, and providing advice to developers on clinical trials for medicinal products intended to treat, prevent or diagnose the disease causing the public health emergency, in accordance with Article 16 of this Regulation without prejudice to the tasks of the Member States as regards the assessment of submitted clinical trial applications to be conducted within their territories in accordance with Regulation (EU) No 536/2014;

(c) providing scientific support to facilitate clinical trials for medicinal products intended to treat, prevent or diagnose the disease causing the public health emergency;

(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 have the potential to address public health emergencies, in accordance with Article 18;

(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 that relate to the public health emergency and to medicinal products which have the potential to address public health emergencies, as necessary.

▼B

The support referred to in the first subparagraph, point (c), shall include advice to sponsors of similar or linked planned clinical trials on the establishment of joint clinical trials and may include advice on establishing agreements to act as a sponsor or as co-sponsor in accordance with Article 2(2), point (14), and Article 72 of Regulation (EU) No 536/2014.

3. The members of the ETF shall consist of:

(a) chairs or vice chairs, or both, of the scientific committees of the Agency, and other representatives of those committees;

(b) representatives of the working parties of the Agency, including representatives of the PCWP and representatives of the HCPWP;

(c) staff members of the Agency;

(d) representatives of the coordination group established in accordance with Article 27 of Directive 2001/83/EC;

(e) representatives of the Clinical Trials Coordination and Advisory Group established in accordance with Article 85 of Regulation (EU) No 536/2014; and

(f) other clinical trial experts who represent national competent authorities for medicinal products.

The members of the ETF shall be nominated by the entities they represent.

External experts may be appointed to the ETF on an ad hoc basis, as necessary, especially in the cases referred to in Article 5(3).

Representatives of other Union bodies and agencies shall be invited on an ad hoc basis, as necessary, to participate in the work of the ETF, especially in the cases referred to in Article 5(3).

The ETF shall be chaired by the representative of the Agency and co-chaired by the chair or vice-chair of the CHMP.

4. The composition of the ETF shall be approved by the Management Board of the Agency, taking into account specific expertise relevant to the therapeutic response to the public health emergency.

The Executive Director of the Agency or the representative of the Executive Director, as well as representatives of the Commission and of the Management Board of the Agency, shall be entitled to attend all meetings of the ETF.

The composition of the ETF shall be made publicly available.

5. The co-chairs of the ETF may invite other representatives of Member States, members of scientific committees and working parties of the Agency, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers, clinical trial sponsors, representatives of clinical trial networks, independent clinical trial experts and researchers, and representatives of healthcare professionals and of patients to attend its meetings.

▼B

6. The ETF shall establish its rules of procedure, including rules on the adoption of recommendations.

The rules of procedure referred to in the first subparagraph shall enter into force once the ETF has received a favourable opinion from the Commission and the Management Board of the Agency.

7. The ETF shall perform its tasks as an advisory and support body separate from, and without prejudice to, the tasks of the scientific committees of the Agency as regards the authorisation, supervision and pharmacovigilance of the medicinal products concerned and related regulatory actions to ensure the quality, safety and efficacy of those medicinal products.

The CHMP and other relevant scientific committees of the Agency shall take the ETF recommendations into consideration when adopting their opinions.

The ETF shall take account of any scientific opinion issued by the committees referred to in the second subparagraph of this paragraph in accordance with Regulation (EC) No 726/2004 and Directive 2001/83/EC.

8. Article 63 of Regulation (EC) No 726/2004 applies to the ETF as regards transparency and the independence of its members.

9. The Agency shall publish information regarding the medicinal products that the ETF considers to have the potential to address public health emergencies and any updates on its web portal. The Agency shall inform Member States and the HSC, as appropriate, of any such publication without undue delay and, in any case, prior to such publication.

Article 16

Advice on clinical trials

1. During a public health emergency, the ETF shall provide advice on the main aspects of clinical trials and clinical trial protocols submitted or intended to be submitted in a clinical trial application by developers as part of an accelerated scientific advice process, without prejudice of the responsibility of the Member State or States concerned under Regulation (EU) No 536/2014.

2. Where a developer engages in an accelerated scientific advice process, the ETF shall provide the advice referred to in paragraph 1 free of charge at the latest 20 days after the developer submits a complete set of the requested information and data to the Agency. The advice shall be endorsed by the CHMP.

3. The ETF shall establish procedures and guidance for requesting and submitting 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.

▼B

4. The ETF shall involve representatives of the Member States with clinical trial expertise in the preparation of the scientific advice, in particular in cases where an application for authorisation of a clinical trial is submitted or is intended to be submitted.

5. When authorising a clinical trial application for which the ETF has provided scientific advice, Member States shall take that advice into consideration. The scientific advice provided by the ETF shall be without prejudice to the ethical review provided for in Regulation (EU) No 536/2014.

6. Where a developer is the recipient of the scientific advice referred to in paragraph 5 of this Article, that developer shall subsequently submit the data resulting from clinical trials to the Agency if the Agency makes a request for those data pursuant to Article 18.

7. Without prejudice to paragraphs 1 to 6 of this Article, the scientific advice referred to in paragraph 5 of this Article shall otherwise be provided in accordance with the procedures established pursuant to Article 57 of Regulation (EC) No 726/2004.

Article 17

Public information regarding clinical trials and marketing authorisation decisions

1. For the duration of a public health emergency, the sponsors of clinical trials conducted in the Union shall, in particular, make the following information publicly available through the EU portal and EU database established respectively by Articles 80 and 81 of Regulation (EU) No 536/2014:

(a) the clinical trial protocol, at the start of each trial for all trials authorised under Regulation (EU) No 536/2014 that examine medicinal products which have the potential to address the public health emergency;

(b) the summary of the results, 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 of relevance to the public health emergency receives a marketing authorisation, the Agency shall publish, in particular:

(a) the product information with details of the conditions of use at the time of the marketing authorisation;

(b) the European Public Assessment Reports as soon as possible and, where possible, within seven days of the marketing authorisation;

(c) the clinical data submitted to the Agency in support of the application, where possible within two months of the marketing authorisation by the Commission;

▼B

(d) the entire risk management plan referred to in Article 1, point 28c, of Directive 2001/83/EC, and any updated versions thereof.

For the purposes of the first subparagraph, point (c), the Agency shall anonymise all personal data and redact commercially confidential information.

Article 18

Review of medicinal products and recommendations on their use

1. Following the recognition of a public health emergency, the ETF shall undertake a review of the available scientific data on medicinal products which have the potential to be used to address the public health emergency. That review shall be updated whenever needed during the public health emergency, including where the ETF and the CHMP agree on the preparation of the assessment of a marketing authorisation application.

2. In the preparation of the review referred to in paragraph 1, the ETF may request information and data from marketing authorisation holders and from developers and may engage with them in preliminary discussions. The ETF may also make use of health data generated outside of clinical studies, where available, taking into account the reliability of those data.

The ETF may liaise with the third country agencies for medicinal products with respect to additional information and data exchanges.

3. Following a request from one or more Member States, or the Commission, the ETF shall provide recommendations to the CHMP for an opinion in accordance with paragraph 4 on:

(a) the compassionate use of medicinal products falling under the scope of Directive 2001/83/EC or Regulation (EC) No 726/2004; or

(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 a recommendation provided pursuant to paragraph 3, the CHMP shall adopt its opinion on the conditions to be imposed on the use and distribution of the medicinal product concerned and on the patients targeted. That opinion shall be updated where necessary.

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

6. In the preparation of its recommendations provided pursuant to paragraphs 3, the ETF may consult the Member State concerned and

▼B

request it to provide any available information or data that the Member State used for its 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.

Article 19

Communication regarding the ETF

The Agency shall provide information to the public and relevant interest groups with regard to the work of the ETF in a timely manner and shall respond to disinformation targeting the work of the ETF, as appropriate, via a dedicated webpage on its web portal and other appropriate means, in cooperation with national competent authorities.

The Agency shall regularly publish on its web portal the list of the members of the ETF, the rules of procedure referred to in Article 15(6) and the list of medicinal products under review, as well as the opinions adopted pursuant to Article 18(4).

Article 20

IT tools and data

In preparation for and to support the work of the ETF during public health emergencies, the Agency shall:

(a) develop and maintain IT tools, including an interoperable IT platform, for the submission of information and data, including electronic health data generated outside of clinical studies, that facilitate interoperability with other existing IT tools and with IT tools under development, and provide adequate support to national competent authorities;

(b) coordinate independent monitoring studies on the use, effectiveness and safety of medicinal products intended to treat, prevent or diagnose diseases related to the public health emergency, using relevant data, including, where relevant, data held by public authorities;

(c) as part of its regulatory tasks, make use of digital infrastructures or IT tools in order to facilitate rapid access to or analysis of available electronic health data generated outside of clinical studies and to facilitate the exchange of such data between Member States, the Agency and other Union bodies;

(d) provide the ETF with access to external sources of electronic health data to which the Agency has access, including health data generated outside of clinical studies.

For the purposes of the first paragraph, point (b), coordination as regards vaccines shall be conducted in conjunction with the ECDC, in particular, through a new vaccine monitoring IT platform.

▼B

CHAPTER IV

MONITORING AND MITIGATING SHORTAGES OF CRITICAL MEDICAL DEVICES AND SUPPORT FOR EXPERT PANELS

Article 21

Executive Steering Group on Shortages of Medical Devices

1. The Executive Steering Group on Shortages of Medical Devices (the 'Medical Device Shortages Steering Group – MDSSG') is hereby established within the Agency.

The MDSSG shall be responsible for fulfilling the tasks referred to in Articles 22, 23 and 24.

The MDSSG shall meet regularly and also whenever the situation requires, either in person or remotely, in preparation for or during a public health emergency.

The Agency shall provide the secretariat of the MDSSG.

2. The members of the MDSSG shall consist of a representative of the Agency, a representative of the Commission and one representative appointed by each Member State.

The representatives of the Member States shall have expertise in the field of medical devices, as relevant. Those representatives may be the same as the representatives appointed to the Medical Devices Coordination Group established by Article 103 of Regulation (EU) 2017/745 ('MDCG'), where appropriate.

Members of the MDSSG may be accompanied to meetings of the MDSSG by experts in specific scientific or technical fields.

The list of the members of the MDSSG shall be published on the Agency's web portal.

A representative of the PCWP and a representative of the HCPWP may attend meetings of the MDSSG as observers.

3. The MDSSG shall be co-chaired by the representative of the Agency and by one of the representatives of the Member States, who shall be elected by and from among the representatives of the Member States in the MDSSG.

The co-chairs of the MDSSG, on their own initiative or at the request of one or more members of the MDSSG, may invite, as observers and to provide expert advice, third parties, including representatives of medical device interest groups, such as representatives of manufacturers and notified bodies, or any other relevant actor in the supply chain for medical devices, and representatives of healthcare professionals, of patients and consumers, to attend its meetings, as necessary.

▼B

4. The MDSSG shall establish its rules of procedure, including procedures relating to the working party referred to in paragraph 5 of this Article, and procedures for adoption of the lists referred to in Article 22, sets of information and recommendations referred to in Article 24(3) and (4).

The rules of procedure referred to in the first subparagraph shall enter into force once the MDSSG has received a favourable opinion from the Commission and the Management Board of the Agency.

5. The MDSSG shall be supported in its work by a working party established in accordance with Article 25(1).

The working party referred to in the first subparagraph shall consist of representatives of the national competent authorities responsible for shortage monitoring and management of medical devices, who shall be the single points of contact in relation to shortages of medical devices.

Article 22

List of critical medical devices and information to be provided

1. Immediately following the recognition of a public health emergency, the MDSSG shall consult the working party referred to in Article 21(5). Immediately following that consultation, the MDSSG shall adopt a list of categories of critical medical devices which it considers to be critical during the public health emergency (‘public health emergency critical devices list’).

To the extent possible, relevant information on critical medical devices and related manufacturers shall be gathered from Eudamed, once it is fully functional. The information shall also be gathered from importers and distributors, as appropriate. Until Eudamed is fully functional, available information may also be gathered from national databases or other available sources.

The MDSSG shall update the public health emergency critical devices list whenever necessary until the termination of the recognition of the public health emergency.

▼C1

2. For the purposes of Article 25(2), the MDSSG shall adopt and make publicly available the set of information referred to in Article 25(2), points (c) and (d), that is necessary to monitor the supply of and demand for medical devices included on the public health emergency critical devices list, and inform the working party referred to in Article 21(5) of that set of information.

▼B

3. The Agency shall publish on a dedicated webpage on its web portal:

▼B

(a) the public health emergency critical devices list, as well as any updates to that list; and

(b) information on actual shortages of critical medical devices included on the public health emergency critical devices list.

Article 23

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

1. During a public health emergency the MDSSG shall monitor the supply of and demand for medical devices included on the public health emergency critical devices list, with a view to identifying any actual or potential shortages of those medical devices. The MDSSG shall conduct such monitoring using the public health emergency critical devices list and the information and data provided in accordance with Articles 26 and 27.

For the purposes of the monitoring referred to in the first subparagraph of this paragraph, where relevant, the MDSSG shall liaise with the MDCG, the HSC and any other relevant advisory committee on public health emergencies established pursuant to Union law.

2. For the purposes of the monitoring referred to in paragraph 1 of this Article, the MDSSG may make use of data from device registries and databases where such data is available to the Agency. In so doing, the MDSSG may take into account the data generated pursuant to Article 108 of Regulation (EU) 2017/745 and Article 101 of Regulation (EU) 2017/746.

Article 24

Reporting and recommendations on shortages of medical devices

▼C1

1. For the duration of the public health emergency, the MDSSG shall regularly report the results of the monitoring referred to in Article 23 to the Commission and the single points of contact referred to in Article 21(5), second subparagraph, and, in particular, shall signal any actual or potential shortages of medical devices included on the public health emergency critical devices list.

▼B

2. Where requested by the Commission, Member States or one or more single point of contact referred to in Article 25(2), point (a), the MDSSG shall provide aggregated data and demand forecasts to support its findings and conclusions.

▼B

For the purposes of the first subparagraph, the MDSSG shall liaise with the ECDC to obtain epidemiological data to help forecast medical device needs, and with the MSSG where medical devices included on the public health emergency critical devices list are used jointly with a medicinal product.

The findings and conclusions of the MDSSG referred to in the first subparagraph may be made available to other actors in the medical device sector, where appropriate, in accordance with competition law, with a view to better preventing or mitigating or actual or potential shortages.

3. As part of the reporting referred to in paragraphs 1 and 2, the MDSSG may provide recommendations on measures that the Commission, Member States, medical device manufacturers, notified bodies and other entities could take to prevent or mitigate actual or potential shortages of medical devices.

For the purposes of the first subparagraph, the MDSSG shall liaise, where relevant, with the MDCG, with the HSC and with any other relevant advisory committee on public health emergencies established pursuant to Union law.

4. The MDSSG, on its own initiative or at the request of the Commission, may provide recommendations on measures that the Commission, Member States, manufacturers of medical devices, notified bodies and other entities could take to ensure preparedness for dealing with actual or potential shortages of medical devices caused by public health emergencies.

▼C1

5. Where requested by the Commission, the MDSSG may coordinate measures taken by the national competent authorities for medical devices, manufacturers of medical devices, notified bodies, and other entities, as relevant, to prevent or mitigate actual or potential shortages of medical devices in the context of a public health emergency.

▼B

Article 25

Working methods and provision of information on medical devices

1. In order to prepare for the fulfilment of the tasks referred to in Articles 22, 23 and 24, the Agency shall:

(a) specify the procedures and criteria for establishing and reviewing the public health emergency critical devices list.;

(b) develop streamlined IT monitoring and reporting systems, in coordination with the relevant national competent authorities, that facilitate interoperability with existing IT tools and Eudamed, once it is fully functional, and provide the adequate support to national competent authorities for monitoring and reporting;

▼B

(c) establish the working party referred to in Article 21(5) and ensure that each Member State is represented on that working party;

(d) specify the methods for the provision of recommendations referred to in Article 24(3) and (4) and for the coordination of measures referred to in Article 24.

For the purposes of the first subparagraph, point (a), the MDCG, representatives of manufacturers, other relevant actors in the supply chain for the medical device sector and representatives of healthcare professionals, of patients and consumers may be consulted as necessary.

2. Following the recognition of a public health emergency, the Agency shall:

(a) establish a list of single points of contact for the manufacturers of medical devices, or their authorised representatives, importers and notified bodies, for the medical devices included on the public health emergency critical devices list;

(b) maintain the list of single points of contact referred to in point (a) for the duration of the public health emergency;

(c) request relevant information on medical devices included on the public health emergency critical devices list from the single points of contact referred to in point (a) on the basis of the set of information adopted by the MDSSG and set a deadline for the submission of that information;

(d) request relevant information on medical devices included on the public health emergency critical devices list from the single points of contact referred to in Article 21(5), second subparagraph, on the basis of the set of information adopted by the MDSSG in accordance with Article 22(2) and set a deadline for the submission of that information.

The Agency may use sources other than those referred to in the first subparagraph, including existing databases and databases in development, to gather information required under paragraph 3.

For the purposes of the first subparagraph, point (a), where it is considered relevant, national or Union databases, including Eudamed, once it is fully functional, or medical device associations may be used as sources of information.

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

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

(b) the information identifying the medical device and the intended purpose and where necessary, specific characteristics of the medical device;

▼B

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

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

(e) sales and market share data of the medical device;

(f) available stocks of the medical device;

(g) the forecast of supply of the medical device, including information on the potential vulnerabilities in the supply chain;

(h) quantities already delivered and projected deliveries of the medical device;

(i) the demand forecasts for the medical device;

(j) shortage prevention and mitigation plans that include, at a minimum, information on production and supply capacity;

(k) information from relevant notified bodies regarding their 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, within an appropriate period of time considering the emergency;

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

(m) where conformity assessments are ongoing, the status of the conformity assessment by the relevant notified bodies in relation to medical devices included in the public health emergency critical devices list and possible critical issues on the final outcome of the assessment and which need to be considered in order to complete the conformity assessment process.

For the purposes of the first subparagraph, point (k), the relevant notified bodies shall communicate the date by which the assessment is expected to be completed. In that regard, notified bodies shall prioritise conformity assessments of medical devices included in the public health emergency critical devices list.

▼B

Article 26

Obligations on manufacturers of medical devices, authorised representatives, importers, distributors and notified bodies

1. In order to facilitate the monitoring referred to in Article 23, the Agency may request manufacturers of medical devices, or their authorised representatives, as applicable, and, if appropriate, importers and distributors, included on the public health emergency critical devices list and, where necessary, relevant notified bodies, to submit the information requested by a deadline set by the Agency.

The manufacturers of medical devices, or their authorised representatives, as applicable, and, if appropriate, importers and distributors, referred to in the first subparagraph, shall submit the requested information through the single points of contact referred to in Article 25(2), point (a), using the monitoring and reporting systems established pursuant to Article 25(1), point (b). They shall provide updates where necessary.

2. Manufacturers of medical devices, or their authorised representatives, as applicable, notified bodies and, if appropriate, importers or distributors shall justify any failure to provide requested information and any delays in providing requested information by the deadline set by the Agency.

3. Where manufacturers of medical devices, or their authorised representatives, notified bodies, or, if appropriate, importers or distributors indicate that the information that they submitted contains information of a commercially confidential nature, they shall identify the relevant parts of that information having such nature and explain why that information is of a commercially confidential nature.

The Agency shall assess the merits of each indication of information as being of a commercially confidential nature and protect such commercially confidential information against unjustified disclosure.

4. Where manufacturers of medical devices, or their authorised representatives, notified bodies, or, if appropriate, importers or distributors have any information in addition to that required under paragraph 1, which provides evidence of an actual or potential shortage of medical devices, they shall immediately provide such information to the Agency.

5. Following the reporting on the results of the monitoring referred to in Article 23 and any recommendations on preventive or mitigating measures provided in accordance with Article 24, manufacturers of medical devices, or their authorised representatives, and, if appropriate, importers and distributors referred to in paragraph 1, shall:

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

(b) take into account any recommendations referred to in Article 24(3) and (4) and any guidelines referred to in Article 28, point (b);

▼B

(c) comply with any measures taken at Union or Member State level pursuant to Article 27 or 28;

(d) inform the MDSSG of any measures taken and report on the results of those measures, including providing information on the resolution of the actual or potential shortage of medical devices.

6. Where manufacturers of medical devices referred to in paragraph 1 are established outside the Union, the information requested in accordance with this Article shall be provided by the authorised representatives, or, if appropriate, by importers or distributors.

Article 27

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 23, the Agency may request a Member State to:

▼C1

(a) submit the set of information referred to in Article 25(2), point (d), including available information about needs related to the medical devices included in the public health emergency critical devices list, and available and estimated data on volume of demand and demand forecasts for those medical devices, through the respective single point of contact referred to in Article 21(5), second subparagraph, using the monitoring and reporting methods and systems established pursuant to Article 25(1), point (b);

▼B

(b) indicate the existence of any commercially confidential information and explain why that information is of a commercially confidential nature, in accordance with Article 26(3);

(c) indicate any failure to provide requested information and whether there are any delays in providing that information by the deadline set by the Agency in accordance with Article 26(2).

Member States shall comply with the Agency's request by the deadline set by the Agency.

2. For the purposes of paragraph 1, Member States shall gather information from manufacturers of medical devices and their authorised representatives, healthcare providers, importers and distributors, as applicable, and notified bodies on medical devices included on the public health emergency critical devices list.

▼C1

3. Where Member States have any information in addition to the information to be provided in accordance with paragraphs 1 and 2 of this Article, which provides evidence of an actual or potential shortage of medical devices, they shall immediately provide such information to the MDSSG through their respective single point of contact referred to in Article 21(5), second subparagraph.

▼B

4. Following the reporting on the results of the monitoring referred to in Article 23 and any recommendations on preventive or mitigating measures provided in accordance with Article 24, 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 actual or potential shortages of medical devices included on the public health emergency critical devices list while ensuring a high level of patient and product safety;

▼C1

(b) take into account any recommendations referred to in Article 24(3) and any guidelines referred to in Article 28, point (b), and coordinate their actions in relation to any actions taken at Union level pursuant to Article 28, point (a);

▼B

(c) inform the MDSSG of any measures taken and report on the results of the actions referred to in point (b), including providing information on the resolution of the actual or potential shortage of medical devices concerned.

For the purposes of the first subparagraph, points (b) and (c), Member States that take an alternative course of action at national level shall share the reasons for doing so with the MDSSG.

The recommendations, guidelines and actions referred to in the first subparagraph, point (b), of this paragraph, and a summary report of the lessons learned shall be made publicly available via the web portal referred to in Article 29.

Article 28

Role of the Commission regarding the monitoring and mitigation of shortages of medical devices

The Commission shall take into account the information from and recommendations of the MDSSG and shall:

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

(b) consider the need for guidelines and recommendations to be addressed to Member States, manufacturers of medical devices, notified bodies, and other entities, where relevant;

▼B

(c) request the MDSSG to provide recommendations or coordinate measures provided for in Article 24(3), (4) and (5);

(d) consider the need for medical countermeasures in accordance with Decision No 1082/2013/EU and other applicable Union law;

(e) liaise with third countries and relevant international organisations, as appropriate, to mitigate actual or potential shortages of medical devices included on the public health emergency critical devices list or their component parts, where those devices or parts of such devices are imported into the Union, and where such actual or potential shortages have international implications, and report on any related actions as well as the results of those actions to the MDSSG, where relevant.

Article 29

Communication regarding the MDSSG

1. The Agency shall provide information to the public and relevant interest groups with regard to the work of the MDSSG in a timely manner and shall respond to disinformation targeting the work of the MDSSG, as appropriate, via a dedicated webpage on its web portal and other appropriate means, in cooperation with national competent authorities.

2. Proceedings of the MDSSG shall be transparent.

The summaries of the agenda and of the minutes of the meetings of the MDSSG, as well as its rules of procedure referred to in Article 21(4) and recommendations referred to in Article 24(3) and (4), shall be documented and made publicly available on the dedicated webpage on the Agency web portal.

Where the rules of procedure referred to in Article 21(4) allow members of the MDSSG to have divergent opinions recorded, the MDSSG shall make such divergent opinions, and the grounds on which they are based, available to national competent authorities at their request.

Article 30

Support for the expert panels on medical devices

From 1 March 2022, on behalf of the Commission, the Agency shall provide the secretariat for the expert panels designated in accordance with Article 106(1) of Regulation (EU) 2017/745 (the ‘expert panels’) and shall provide the support necessary to ensure that those expert panels can efficiently perform the tasks set out in Article 106(9) and (10) of that Regulation.

▼B

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 with the systems and procedures established by the Commission pursuant to that Regulation to actively manage and prevent potential conflicts of interest in accordance with Article 106(3), third subparagraph, of that Regulation;

(d) maintain and regularly update a webpage for the expert panels and make all necessary information not already publicly available in Eudamed publicly available on that webpage in order to ensure the transparency of the activities of the expert panels, including providing the justifications of notified bodies where those bodies did not follow the advice of the expert panels provided pursuant to Article 106(9) of Regulation (EU) 2017/745;

(e) publish the scientific opinions, views and advice of the expert panels while ensuring confidentiality in accordance with Article 106(12), second subparagraph, and Article 109 of Regulation (EU) 2017/745;

▼M1

(f) levy fees in accordance with Article 106(14) of Regulation (EU) 2017/745 and ensure that remuneration and expenses are provided to experts in accordance with implementing acts adopted by the Commission pursuant to Article 106(1) of Regulation (EU) 2017/745;

▼B

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

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

CHAPTER V

FINAL PROVISIONS

Article 31

Cooperation between the MSSG, the MDSSG, the ETF and the expert panels

1. The Agency shall ensure that the MSSG and the MDSSG cooperate in relation to measures to address public health emergencies and major events.

▼B

2. Members of the MSSG and MDSSG, and members of the working parties referred to in Article 3(6) and in Article 25(2), point (a), respectively, may attend one another's meetings and working parties and, where appropriate, cooperate on monitoring exercises, reporting and the preparation of opinions.

3. With the agreement of the respective chairs or co-chairs, joint meetings of the MSSG and the MDSSG may be held.

4. Where relevant, the Agency shall ensure that the ETF and the expert panels cooperate in relation to preparedness and management of public health emergencies.

Article 32

Transparency and conflicts of interest

1. The MSSG and the MDSSG shall carry out their activities in an independent, impartial and transparent manner.

2. The members of the MSSG and of the MDSSG and, where relevant, observers, shall not have any financial or other interests in the medicinal products industry or medical devices industry which could affect their independence or impartiality.

3. The members of the MSSG and the MDSSG and, where relevant, observers, shall make a declaration of their financial and other interests and shall update those declarations of interest annually and whenever necessary.

The declarations referred to in the first subparagraph shall be made publicly available on the Agency's web portal.

4. The members of the MSSG and the MDSSG and, where relevant, observers, shall disclose any other facts of which they become aware that might reasonably be expected in good faith to involve or give rise to a conflict of interest.

5. Before each meeting, the members of the MSSG and the MDSSG and, where relevant, observers who participate in meetings of the MSSG and the MDSSG shall declare any interests which could be considered to be prejudicial to their independence or impartiality with respect to the items on the agenda.

6. Where the Agency decides that an interest declared in accordance with paragraph 5 constitutes a conflict of interest, the member or observer concerned shall not take part in any discussions or decision making, or obtain any information, concerning the item of concern on the agenda.

7. The declarations and the decisions of the Agency referred to in paragraphs 5 and 6, respectively, shall be recorded in the summary minutes of the meeting.

8. The members of the MSSG and the MDSSG and, where relevant, observers, shall be subject to a requirement of professional secrecy, even after their duties have ceased.

▼B

9. Members of the ETF shall update the annual declaration of their financial or other interests provided for in Article 63 of Regulation (EC) No 726/2004 whenever a relevant change to their declaration occurs.

Article 33

Protection against cyber attacks

The Agency shall equip itself with a high level of security controls and processes against cyber attacks, cyber espionage and other data breaches to ensure the protection of health data and the normal functioning of the Agency at all times, especially during public health emergencies or major events at Union level.

For the purposes of the first paragraph, the Agency shall actively identify and implement cybersecurity best practices adopted within Union institutions, bodies, offices and agencies for preventing, detecting, mitigating, and responding to cyber attacks.

Article 34

Confidentiality

1. Unless otherwise provided for in this Regulation and without prejudice to Regulation (EC) No 1049/2001 of the European Parliament and of the Council ([2]) and Directive (EU) 2019/1937 of the European Parliament and of the Council ([3]), 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 commercially confidential information and trade secrets of natural or legal persons in accordance with Directive (EU) 2016/943 of the European Parliament and of the Council ([4]), including intellectual property rights.

2. Without prejudice to paragraph 1, 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 within the meaning of Article 101 TFEU.

3. Without prejudice to paragraph 1, information exchanged on a confidential basis between national competent authorities and between national competent authorities and the Commission and the Agency shall not be disclosed without the prior agreement of the authority from which that information originates.

([2]) Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

([3]) Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of persons who report breaches of Union law (OJ L 305, 26.11.2019, p. 17).

([4]) Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (OJ L 157, 15.6.2016, p. 1).

▼B

4. Paragraphs 1, 2, and 3 do not affect the rights and obligations of the Commission, the Agency, Member States or other actors identified in this Regulation with regard to the exchange of information and the dissemination of warnings, nor do they affect 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 with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

Article 35

Personal data protection

1. Transfers of personal data under this Regulation shall be subject to Regulations (EU) 2016/679 and (EU) 2018/1725, as applicable.

2. As regards transfers of personal data to a third country, in the absence of an adequacy decision or appropriate safeguards as referred to in Article 46 of Regulation (EU) 2016/679 and Article 48 of Regulation (EU) 2018/1725 respectively, the Commission, the Agency, and Member States may carry out certain transfers of personal data to regulatory authorities of third countries with which they have put in place confidentiality arrangements where those transfers are necessary for important reasons of public interest, such as the protection of public health. Such transfers shall be made in conformity with the conditions laid down in Article 49 of Regulation (EU) 2016/679 and Article 50 of Regulation (EU) 2018/1725.

Article 36

Reporting and review

1. By 31 December 2026, and every fourth year thereafter, the Commission shall present a report to the European Parliament and the Council on the application of this Regulation. In particular, that report shall review:

(a) the crisis preparedness and management framework for medicinal products and medical devices, including the outcomes of periodic stress tests;

(b) instances of non-compliance with the obligations set out in Articles 10 and 26 by marketing authorisation holders, manufacturers of medical devices, authorised representatives, importers, distributors and notified bodies;

(c) the remit and functioning of the ESMP.

2. Notwithstanding paragraph 1, following a public health emergency or a major event, the Commission shall present, in a timely manner, a report to the European Parliament and the Council on the instances referred to in paragraph 1, point (b).

3. Based on the report referred to in paragraph 1, the Commission shall, where appropriate, present a legislative proposal in order to amend this Regulation. In particular, the Commission shall consider the need for:

▼B

(a) extending the scope of this Regulation to veterinary medicinal products and to personal protective equipment for medical use;

(b) amending Article 2;

(c) introducing measures to strengthen at Union or national level compliance with the obligations established in Articles 10 and 26; and

(d) expanding the remit of the ESMP, the need for further facilitating the ESMP interoperability with national and Union IT systems, the need for national shortage monitoring platforms, and the need for meeting any additional requirements to address structural shortages of medicinal products that may be introduced in the context of a revision of Directive 2001/83/EC and Regulation (EC) No 726/2004.

Article 37

Union financing

1. The Union shall provide the financing of the Agency's activities in support of the work of the MSSG and the MDSSG, the ETF, the working parties referred to in Article 3(6) and in Article 25(1), point (c), and the expert panels, that involve its cooperation with the Commission and the ECDC.

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 ([5]).

2. The Agency shall remunerate the assessment activities of the rapporteurs in relation to the ETF under this Regulation, in addition to reimbursing the expenses incurred by Member States' representatives and experts in relation to the meetings of the MSSG, the MDSSG, the ETF and the working parties referred to in Article 3(6) and in Article 21(5), in accordance with financial arrangements established by the Management Board of the Agency. Such remuneration shall be paid to the relevant national competent authorities.

3. The Union contribution provided for in Article 67 of Regulation (EC) No 726/2004 shall cover the tasks of the Agency provided for under this Regulation, and shall cover the full amount of remuneration paid to national competent authorities for medicinal products where fee exemptions apply in accordance with Council Regulation (EC) No 297/95 ([6]).

([5]) Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

([6]) Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products (OJ L 35, 15.2.1995, p. 1).

▼B

Article 38

Entry into Force and date of application

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

It shall apply from 1 March 2022.

However, with the exception of Article 30, Chapter IV shall apply from 2 February 2023.

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