II

(Non-legislative acts)

REGULATIONS

COUNCIL REGULATION (EU) 2022/2372

of 24 October 2022

on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 122(1) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) The ad-hoc measures taken by the Commission in order to restrict the spread of COVID-19 were reactive, and the Union was not sufficiently prepared to ensure the efficient development, manufacturing, procurement and distribution of crisis-relevant medical countermeasures, especially in the early phase of the COVID-19 pandemic. The pandemic also revealed insufficient oversight of research activities and manufacturing capacities as well as vulnerabilities related to global supply chains.

(2) The experience gained has shown the need for a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency, in order to enable the Union to take measures that are necessary to ensure the sufficient and timely availability and supply of such countermeasures where that is appropriate to the economic situation. To that effect, this Regulation aims to establish an instrument of economic policy fundamental to avoid the adverse economic consequences of health crises, such as negative growth, unemployment, market disruptions, fragmentation of the internal market, and impediments to swift manufacturing – consequences which have been witnessed on a large scale in the context of the COVID-19 pandemic – with a view to ultimately safeguarding the economic stability of the Union and of its Member States.

(3) In the event of the recognition of a public health emergency at Union level, it should be possible for the Council, upon a proposal from the Commission pursuant to Article 122(1) of the Treaty on the Functioning of the European Union (TFEU), to decide to activate the framework of measures to the extent that those measures are appropriate to the economic situation, taking into account the need to ensure a high level of protection of human health in accordance with Article 9 TFEU and possible risk of the global disruption of supplies of crisis-relevant medical countermeasures, which could affect the health systems of Member States. The proposal from the Commission should explain the rationale and the need for the proposed activation of an emergency framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency, as established by this Regulation ('the emergency framework'), including for each of the measures proposed, including

an analysis of anticipated impact, subsidiarity, proportionality and financial implications for each of the measures proposed. The use of measures within the emergency framework should be limited in time for a maximum period of six months. It should be possible to prolong the use of such measures in view of the situation. The implementation of such measures should respect the responsibilities of Member States for the organisation and delivery of health services and medical care, including the allocation of the resources at national level, as referred to in Article 168(7) TFEU.

(4) The emergency framework should include the establishment of a Health Crisis Board on crisis-relevant medical countermeasures to ensure the coordination of approaches at Union level. That is of particular importance given the distribution of responsibilities between Union and national level. To support the Health Crisis Board, the Commission should, on its own initiative or on the proposal of the Health Crisis Board, be able to set up subgroups or ad-hoc working groups, including if needed for industrial aspects. In order to ensure the effective and systematic involvement of Member States in the decisions taken for the implementation of this Regulation, rules for the deliberations of the Health Crisis Board should be laid down. When deliberating, the members of the Health Crisis Board should use their best endeavours to reach a consensus. If a consensus cannot be reached, and in order to ensure a smooth deliberation mechanism, the Health Crisis Board should act by a two-thirds majority, where one vote is given to each Member State. Moreover, it is useful for the effective operation and swift decision-making by the Health Crisis Board that it be supported through preparedness and response planning carried out by the Health Emergency Preparedness and Response Authority (HERA) established by a Commission Decision ([1]) of 16 September 2021. Such preparedness and response planning is to provide an assessment for the purpose of activating measures pursuant to this Regulation, propose the rules of procedure of the Health Crisis Board, draft negotiating mandates and procedural rules for joint procurements, and provide relevant information for the establishment of an inventory of crisis-relevant medical countermeasure production and production facilities. The involvement of Member States should also contribute to the necessary coordination between the implementation of this Regulation and the operations of the HERA. The Health Crisis Board should be able to also coordinate, where appropriate, with the HERA Board referred to in the Commission Decision of 16 September 2021.

(5) Member States and the Commission should appoint their representative and alternate representative in the Health Crisis Board.

(6) The Commission should ensure that a list of crisis-relevant medical countermeasures and raw materials is established and that their supply and demand are monitored. That should provide a comprehensive overview of the needed crisis-relevant medical countermeasures as well as of the Union's capacity to meet that need and to guide relevant decision-making during public health emergencies.

(7) In view of the mandate of the European Medicines Agency (EMA) and its role as regards monitoring and mitigating potential and actual shortages of medicinal products, medical devices and *in vitro* diagnostic medical devices, including establishing lists of critical medicinal products and critical medical devices, under Regulation (EU) 2022/123 of the European Parliament and of the Council ([2]), close cooperation and coordination between the Commission and EMA should be ensured to implement the measures provided for in this Regulation. When carrying out the tasks set out in Articles 7 to 13 of this Regulation, the Commission, including HERA, should fully respect EMA's responsibilities. A representative of the Executive Steering Group on Shortages of Medical Devices, as established by Article 21 of Regulation (EU) 2022/123, a representative of the Emergency Task Force, as established by Article 15 of that Regulation, and a representative of the Executive Steering Group on Shortages and Safety of Medicinal Products, as established by Article 3 of that Regulation, should be invited, as observers, to the Health Crisis Board. That should complement the smooth transmission of data and information during public health emergencies at Union level, including via integrated IT systems.

([1]) Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority (OJ C 393I, 29.9.2021, p. 3).

([2]) 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 (OJ L 20, 31.1.2022, p. 1).

(8) With regard to the monitoring of demand and supply of medical countermeasures in the third countries, the Commission should maintain a dialogue with its counterparts to foster international collaboration.

(9) The measures should also take into account the structures and mechanisms set up by the Union acts on serious cross-border threats to health, namely Regulation (EU) 2022/2371 of the European Parliament and of the Council ([3]), and on the extended mandate of the European Centre for Disease Prevention and Control (ECDC) laid down by Regulation (EU) 2022/2370 of the European Parliament and of the Council ([4]), in order to ensure response coordination within the Health Security Committee and the Advisory Committee on public health emergencies, as established respectively by Articles 4 and 24 of Regulation (EU) 2022/2371 , taking into account input from the ECDC on epidemiological surveillance and monitoring. The Director of the ECDC and a representative of the Advisory Committee on public health emergencies should be invited to attend the meetings of the Health Crisis Board. A member of the Health Security Committee should also be invited, as an observer, to the Health Crisis Board.

(10) Efficient procurement procedures for crisis-relevant medical countermeasures and raw materials should be ensured. In that regard, the Commission can act as a central purchasing body for participating Member States, under the rules and procedures laid down in Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ([5]), and, where appropriate, Council Regulation (EU) 2016/369 ([6]) as well as joint procurement procedures referred to in Article 12 of Regulation (EU) 2022/2371 . In order to allow for speed and efficient procurement during times of crisis, procedural simplifications might be necessary. Moreover, for the purpose of drawing lessons learned from the procurement experience during the COVID-19 pandemic, better involvement of Member States should be ensured in the preparation and award of contracts. Agreements between the Commission and Member States should ensure that all Member States have equal and timely access to all information and that their needs are duly taken into account. Procurements of crisis-relevant medical countermeasures carried out under this Regulation can be exclusive or non-exclusive depending on the agreement of the participating Member States to such restrictions.

(11) On the basis of the needs of Member States, as advised by the Health Crisis Board, the Commission should seek to ensure that all crisis-relevant medical countermeasures procured or developed under this Regulation meet the relevant Union, and, where applicable, national regulatory requirements, while allowing, as applicable, for any derogations, or other national exemptions.

(12) Those procurement procedures can be supported by any necessary preparatory steps, including on-site visits at the location of the production facilities of crisis-relevant medical countermeasures. That should allow for the timely procurement and purchase of crisis-relevant medical countermeasures across the Union and promote accessibility across Member States, with the primary objective of securing the speediest possible equitable provision and distribution of the crisis-relevant medical countermeasures in the required quantity needed by each Member State and with all necessary guarantees. The possibility of relocation, redistribution, resale, loan and donation should already be taken into account contractually at the time of purchase.

(13) In the cases covered by this Regulation, the immediate award and performance of the contracts resulting from procurement procedures carried out for the purposes of this Regulation could be justified given the extreme urgency of the health crisis and resulting economic difficulties. Also, it could be necessary to make adjustments to the contracts that are strictly necessary to adapt them to the evolution of the public health emergency as well as to add contracting authorities during the performance of the contract. For that specific purpose, it is necessary to

([3]) Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26).

([4]) Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control (OJ L 314, 6.12.2022, p. 1).

([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 (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union (OJ L 70, 16.3.2016, p. 1).

allow derogations from specific provisions of Regulation (EU, Euratom) 2018/1046 while duly documented by the contracting authority. As those derogations are introduced for the purpose of the emergency framework, they should be temporary and apply solely for the period of the activation of the measure referred to in Article 8 of this Regulation.

(14) During a public health emergency at Union level, the demand for crisis-relevant medical countermeasures could be greater than the supply. In such a situation, surge production and manufacturing of crisis-relevant medical countermeasures are essential, and the Commission should be entrusted to activate the surge in Union manufacturing capacities for crisis-relevant medical countermeasures, including ensuring resilient supply chains for the needed raw materials and ancillary supplies, such as under the Network of Ever-warm Production Capacities for Vaccines and Therapeutics manufacturing ('EU-FAB'). As outlined in the Commission communication of 17 February 2021 entitled 'HERA Incubator: Anticipating together the threat of COVID-19 variants', an EU-FAB project is a network of 'ever-warm', single and/or multi-user, single and/or multi-technology production capacities for vaccine and medicinal products manufacturing at the European level.

(15) Effective mechanisms should be elaborated and agreed upon at Union level in order to ensure redistribution in cases where the surge of manufacturing has resulted in a situation where supply exceeds demand.

(16) Appropriate intellectual property tools are needed to mitigate the risks of abandonment of development efforts, or supply issues, concerning crisis-relevant medical countermeasures during a public health emergency, especially where public authorities have provided financial support for the development and production of such countermeasures. The Commission should therefore be able to require the licensing, under fair and reasonable terms, of intellectual property rights and know-how pertaining to such countermeasures, the development and production of which the Commission has financed, in justified exceptional cases, as a safety net and an incentivising element. When facilitating the licensing of intellectual property and know-how pertaining to such countermeasures, the Commission should take into account the upfront financing by the Union or Member States of the development and the production of such countermeasures.

(17) The activation of emergency research and innovation plans, as well as the repurposing of medicinal products and the activation of clinical trial networks, and conduct of clinical trials, should be ensured to reduce any delays in the development phase of crisis-relevant medical countermeasures. Research and innovation activities should be able to use European digital infrastructures as well as platforms operating under the European Open Science Cloud and other accessible EU digital platforms, in order to get access to (real-world) data for quick analysis. Close coordination of the Commission with the ECDC and the EMA, as the Agency responsible for scientific advice and scientific assessment of new and repurposed medicinal products, should be ensured for those matters, as well as for those related to regulatory aspects concerning the authorisation of medicinal products, including for the establishment of new manufacturing sites for authorised medicinal products, and to guarantee the acceptability of the clinical trials and the evidence they generate for the authorisation of new or repurposed medicinal products. Emergency research can also include diagnostic preparedness. That should allow key actors and relevant infrastructure to be immediately ready for operation in times of public health emergencies, thereby reducing any delays.

(18) During a public health emergency, detailed overviews of the Union's current and short-term future production capacities of crisis-relevant medical countermeasures are an integral element of demand and supply management. Therefore, an inventory of crisis-relevant medical countermeasure production and production facilities should be established and regularly updated on the basis of the compulsory transmission of information by the relevant economic operators.

(19) Supply shortages of raw materials, consumables, medical devices, equipment or infrastructure could affect the production of crisis-relevant medical countermeasures. Upon identification of a supply shortage or the risk thereof, the inventory should also cover those elements. That complements the detailed overview of the Union's current and short-term future production capacities, in order to allow for the factoring-in of supply elements that could affect production capacities and to improve demand and supply management of crisis-relevant medical countermeasures at Union level.

(20) On the basis of the detailed overviews of production capacities, raw materials, consumables, medical devices, equipment and infrastructure, it could transpire that further measures to bolster supply chains and production capacities are needed. Where the market does not, or cannot, ensure adequate supply of needed crisis-relevant medical countermeasures, the Commission should therefore be able to implement measures in those areas that serve to increase the availability and accessibility of crisis-relevant medical countermeasures and raw materials.

(21) Regulation (EU) 2016/369 provides for a flexible framework for emergency financial support. It allows for the provision of support that cannot be implemented through the existing spending programmes. Such a tool should become available if there is a recognition of a public health emergency at Union level to the extent that is appropriate to the economic situation, taking into account the need to ensure a high level of protection of human health. Emergency funding should be provided by the emergency support instrument in line with the appropriate budgetary procedures.

(22) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ([7]). The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the public health emergency, imperative grounds of urgency so require.

(23) Where the activities to be carried out pursuant to this Regulation involve the processing of personal data, such processing should comply with the relevant Union legislation on personal data protection, namely Regulations (EU) 2016/679 ([8]) and (EU) 2018/1725 ([9]) of the European Parliament and of the Council.

(24) The implementation of the emergency framework should be reviewed by the Commission. During the conduct of the review, the crisis activities of HERA should be considered together with its preparedness activities. Consideration should also be given to relevant learning, from both preparatory and crisis modes, and to the necessity of establishing a distinct entity, such as an agency.

(25) Since the objective of this Regulation to establish a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the measures necessary to ensure the sufficient and timely availability and supply of such medical countermeasures throughout the Member States, be better achieved at Union level, the Union may adopt a framework of 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 that objective,

([7]) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

([8]) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (OJ L 119, 4.5.2016, p. 1).

([9]) 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).

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation establishes a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency ('the emergency framework').

2. The emergency framework shall include:

(a) the establishment of a Health Crisis Board;

(b) the monitoring, procurement and purchase of crisis-relevant medical countermeasures and crisis-relevant raw materials;

(c) the activation of emergency research and innovation plans, including the use of Union-wide clinical trial networks and data-sharing platforms;

(d) emergency Union funding, including under Regulation (EU) 2016/369;

(e) measures concerning the production, availability and supply of crisis-relevant medical countermeasures, including the establishment of an inventory of crisis-relevant medical countermeasures production and production facilities, and, as appropriate, of crisis-relevant raw materials, consumables, medical devices, equipment and infrastructure, and including measures aimed at increasing their production in the Union.

3. The emergency framework may be activated only to the extent that it is appropriate to the economic situation, taking into account the need to ensure a high level of protection of human health.

Article 2

Definitions

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

(1) 'monitoring' means monitoring as defined in Article 3, point (6), of Regulation (EU) 2022/2371 ;

(2) 'public health emergency' means a public health emergency at Union level recognised by the Commission in accordance with Article 23 of Regulation (EU) 2022/2371;

(3) 'medical countermeasures' means medical countermeasures within the meaning of Article 3, point (10), of Regulation (EU) 2022/2371, including personal protective equipment and substances of human origin;

(4) 'raw materials' means the materials required in order to produce the required quantities of crisis-relevant medical countermeasures;

(5) 'real-world data' means data relating to patient health status or the delivery of healthcare from sources other than clinical trials.

Article 3

Activation of the emergency framework

1. In the event of recognition of a public health emergency, the Council, upon the proposal of the Commission, may adopt a regulation activating the emergency framework where that is appropriate to the economic situation, taking into account the need to ensure a high level of protection of human health.

2. Where the Council activates one or several measures set out in Articles 7 to 13, Article 5 shall apply.

3. The Council shall set out in the regulation activating the emergency framework which of the measures set out in Articles 7 to 13 are appropriate to the economic situation, taking into account the need to ensure a high level of protection of human health, and which measures are therefore to be activated.

4. The emergency framework shall be activated for a maximum period of six months. This period may be prolonged in accordance with the procedure set out in Article 4.

5. The regulation activating the emergency framework shall be without prejudice to Decision No 1313/2013/EU of the European Parliament and of the Council ([10]) and the overall coordination role of the Emergency Response Coordination Centre under the Union Civil Protection Mechanism (UCPM), both established by that Decision, and the political coordination role of the Integrated Political Crisis Response (IPCR), established under Council Decision 2014/415/EU ([11]).

Article 4

Prolongation, deactivation and expiry of the period for which the emergency framework is activated

1. No later than three weeks before the expiry of the period for which the emergency framework was activated, the Commission shall submit to the Council a report, drawn up in consultation with the Health Crisis Board, assessing whether that period should be prolonged. The report shall in particular analyse the public health situation and the economic consequences of the public health crisis in the Union as a whole and in Member States, as well as the impact of the measures previously activated under this Regulation.

2. The Commission may propose prolongation to the Council, specifying which of the measures are appropriate for prolongation, when the assessment referred to in paragraph 1 concludes that it is appropriate that the period for which the emergency framework is activated be prolonged. The prolongation shall be for up to six months. The Council may repeatedly decide to prolong the period for which the emergency framework is activated where that is appropriate in view of the economic situation, taking into account the need to ensure a high level of protection of human health.

3. The Commission may propose to the Council to adopt a regulation activating additional measures or deactivating any activated measures set out in Articles 7 to 13, in addition to those measures that it had already activated, where that is appropriate in view of the economic situation, taking into account the need to ensure a high level of protection of human health.

4. Upon expiry of the period for which the emergency framework is activated, the measures taken in accordance with Articles 7 to 13 shall cease to apply.

5. The measures set out in Articles 7 to 13 shall be automatically deactivated where the public health emergency is terminated in accordance with Article 23(2) of Regulation (EU) 2022/2371 .

Article 5

The Health Crisis Board

1. Where the Council activates one or several measures set out in Articles 7 to 13 in accordance with Article 3, the Health Crisis Board shall be established and shall ensure coordination of action by the Council, the Commission, the relevant Union bodies, offices and agencies and Member States to ensure the supply of and access to crisis-relevant medical countermeasures.

([10]) Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism (OJ L 347, 20.12.2013, p. 924).

([11]) Council Decision of 24 June 2014 on the arrangements for the implementation by the Union of the solidarity clause (2014/415/EU) (OJ L 192, 1.7.2014, p. 53).

The Health Crisis Board shall assist and provide guidance to the Commission in the preparation and implementation of measures to be taken pursuant to Articles 7 to 13. To that effect, the Commission shall maintain a constant supply of information to the Health Crisis Board on any planned measures or measures that have been taken.

2. The Health Crisis Board shall cease to operate when all of the measures set out in Articles 7 to 13 are deactivated or expire.

3. The Health Crisis Board shall be composed of the Commission and one representative from each Member State. Each Member State shall nominate its representative and alternate representative. The secretariat of the Health Crisis Board shall be ensured by the Commission.

4. The Health Crisis Board shall be co-chaired by the Commission and the Member State holding the rotating presidency of the Council.

The Health Crisis Board shall ensure the participation of all relevant Union institutions, bodies, offices and agencies, including the European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC), and the Advisory Committee on public health emergencies, as observers. The Health Crisis Board shall invite, as observers, a representative from the European Parliament and a Member State representative of the Health Security Committee and, where relevant, and in line with its rules of procedure, a representative of the World Health Organization (WHO).

5. The Health Crisis Board shall ensure coordination and information exchange with the structures established under:

(a) Regulation (EU) 2022/123 during the period of the public health emergency, related to medicinal products and medical devices;

(b) Regulation (EC) No 851/2004 of the European Parliament and of the Council ([12]) during the period of the public health emergency;

(c) Regulation (EU) 2022/2371 , in particular the Health Security Committee and the Advisory Committee on public health emergencies;

(d) Decision No 1313/2013/EU, and in particular the Emergency Response Coordination Centre, for the purpose of bridging operational gaps in accessing crisis-relevant medical countermeasures and raw materials and ensuring, where necessary, corresponding on-site monitoring and coordination tasks.

6. The Health Crisis Board shall ensure information exchange with the IPCR.

7. The co-chairs of the Health Crisis Board may invite experts with specific expertise to take part, as observers, in the work of the Health Crisis Board or subgroups on an ad-hoc basis, with regard to a subject matter on the agenda. Such experts may include: representatives of Union bodies, offices and agencies; representatives of national authorities, including central purchasing bodies and healthcare organisations and associations; representatives of international organisations such as WHO, the Food and Agriculture Organization of the United Nations (FAO) and the World Organisation for Animal Health (WOAH); and experts from the private sector and from other stakeholders.

8. The Health Crisis Board shall meet whenever the situation requires, upon request from the Commission or a Member State.

9. In the course of the preparation and implementation of the measures set out in Articles 7 to 13, the Commission shall act in close coordination with the Health Crisis Board. In particular, the Commission shall consult the Health Crisis Board in a timely manner, whenever possible before taking action, and shall take the utmost account of the result of deliberations within the Health Crisis Board. The Commission shall report back to the Health Crisis Board on the action taken.

([12]) Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control (OJ L 142, 30.4.2004, p. 1).

10. The Health Crisis Board may issue opinions, upon the request of the Commission or on its own initiative. Where the Commission does not follow the opinion of the Health Crisis Board, it shall explain the reasons for its action to the Health Crisis Board, without prejudice to the Commission's right of initiative.

11. As far as possible, the Health Crisis Board shall deliberate by consensus. If consensus cannot be reached, the Health Crisis Board shall deliberate by a majority of two thirds of the Member State representatives. Each Member State shall have one vote.

The Health Crisis Board shall adopt its rules of procedure on the basis of a proposal submitted by the Commission. The rules of procedure shall detail when observers are, and are not, to be invited to participate in the deliberations of the Health Crisis Board and how potential conflicts of interest are to be managed.

12. The Commission may, on its own initiative or on the proposal of the Health Crisis Board, set up working groups on an ad hoc basis to support the Health Crisis Board in its work for the purpose of examining specific questions on the basis of the tasks referred to in paragraph 1. The working groups shall deliberate in accordance with the rules set out in paragraph 11. Member States shall nominate experts for the working groups.

13. The Commission shall ensure transparency and provide all Member State representatives with equal access to information, in order to ensure that the decision-making process reflects the situation and the needs of all Member States.

Article 6

Declaration of interest

1. The members of the Health Crisis Board shall undertake to act in the public interest.

2. The members of the Health Crisis Board, as well as observers and external experts participating in the meetings, shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made in writing on the establishment of the Health Crisis Board and at each meeting in order to declare any interests which might be considered prejudicial to their independence in relation to any item on the agenda. If there are interests which might be considered prejudicial to their independence in relation to any item on the agenda, the person concerned shall be excluded from relevant discussions and decisions.

Article 7

Mechanism for monitoring crisis-relevant medical countermeasures

1. Where this measure is activated, the Commission shall, after seeking the advice of the Health Crisis Board, draw up and regularly update, by means of implementing acts, a list of crisis-relevant medical countermeasures and raw materials, as well as a template for monitoring their supply and demand, including production capacity, stockpiles, possible critical aspects or the risk of disruption in the supply chains and purchasing agreements.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2) and, on duly justified imperative grounds of urgency, in accordance with the procedure for immediately applicable implementing acts referred to in Article 14(3).

2. The list referred to in paragraph 1 shall include a shortlist of specific crisis-relevant medical countermeasures and raw materials for the preparation of measures to be taken in accordance with this Article and Articles 8 to 13, taking into account the information obtained pursuant to:

(a) Regulation (EU) 2022/123, and in particular Articles 3 to 14 and 21 to 30 thereof, concerning the monitoring and mitigation of shortages of medicinal products and medical devices included in the critical medicines lists and public health emergency critical medical devices list, respectively;

(b) Regulation (EC) No 851/2004, and in particular Article 3(2), point (f), thereof, concerning available data on Member States' health system capacity necessary to the management and response to communicable disease threats.

3. Without prejudice to national security interests, Member States shall, where appropriate, provide the Commission with additional information not already collected by Union agencies on the basis of the template referred to in paragraph 1.

4. Without prejudice to national security interests and the protection of commercially confidential information resulting from agreements entered into by Member States, where a Member State intends to adopt at national level measures for the procurement, purchase or manufacturing of crisis-relevant medical countermeasures or raw materials from the list referred in paragraph 1, it may inform the Health Crisis Board in a timely manner.

5. Upon request of the Commission, including on behalf of the Health Crisis Board, EMA shall provide it with information with regard to monitoring of medicinal products and medical devices, including their demand and supply, in accordance with Article 9(2), points (c) and (d), and Article 25(2), points (c) and (d), of Regulation (EU) 2022/123.

6. The Commission shall gather additional information not already collected by Union agencies through a secured IT system and monitor, on the basis of the template referred to in paragraph 1, all relevant information concerning the supply and demand of crisis-relevant medical countermeasures and raw materials within and outside the Union. The Commission shall ensure the interoperability of the IT system with the electronic monitoring and reporting systems developed by EMA pursuant to Article 9(1), point (c), of Regulation (EU) 2022/123.

7. The Commission shall regularly provide information on the results of the monitoring of crisis-relevant medical countermeasures and raw materials to the European Parliament and to the Council.

The Commission shall make available to the European Parliament, to the Council and to the Health Security Committee modelling and forecasts regarding the needs for crisis-relevant medical countermeasures and raw materials with, where appropriate, the support of relevant Union agencies.

The Commission shall subsequently inform the Health Crisis Board of the monitoring and its results.

Article 8

Procurement, purchase and manufacturing of crisis-relevant medical countermeasures and raw materials

1. Where this measure is activated, the Health Crisis Board shall advise the Commission on the appropriate mechanism to purchase crisis-relevant medical countermeasures and raw materials, either through the activation of existing contracts or the negotiation of new contracts, using available instruments, such as Article 4 of Regulation (EU) 2016/369, the joint procurement procedure referred to in Article 12 of Regulation (EU) 2022/2371 , or European Innovation Partnerships, established by Regulation (EU) 2021/695 of the European Parliament and of the Council ([13]).

([13]) Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (OJ L 170, 12.5.2021, p. 1).

In particular, the Health Crisis Board shall advise the Commission on the need to use a purchasing mode whereby the Commission acts as a central purchasing body on behalf of Member States, either in conjunction with other available instruments or as an autonomous procurement mode.

2. Where appropriate, Member States may mandate the Commission to act as a central purchasing body to procure crisis-relevant medical countermeasures and raw materials on their behalf, under the conditions laid down in this Article.

Member States shall be free to participate in the procurement procedure, including through opt-out mechanisms and, in duly justified cases, through opt-in mechanisms.

The Commission shall, in close coordination with the Health Crisis Board, draw up the proposal for a framework agreement to be signed by Member States that wish to be represented by the Commission ('participating Member States') to act as a central purchasing body for crisis-relevant medical countermeasures.

3. The framework agreement referred to in paragraph 2 shall include procedural rules for the initiation and preparation of procurement procedures set out in this Article, the practical arrangements for Member States' free participation, including the conditions and time frames for possible opt-in and opt-out by Member States, as well as the practical arrangements for the involvement of participating Member States throughout the procurement process as well as allocation procedures of procured crisis-relevant medical countermeasures.

4. Assisted by the Health Crisis Board, the Commission shall carry out the procurement procedures and conclude the resulting agreements with economic operators on behalf of the participating Member States, in accordance with Regulation (EU, Euratom) 2018/1046.

The Commission shall inform the Health Crisis Board, on a regular basis, of the progress made in the procurement process and on the substance of negotiations. The Commission shall take the utmost account of the advice of the Health Crisis Board and of the real needs of Member States. In particular, the Commission shall only consider launching negotiations where a sufficient number of Member States have expressed their support.

5. All participating Member States shall be associated to the procurement process. To that effect, the Commission shall invite participating Member States to nominate representatives to take part in the preparation of the procurement procedures as well as the negotiation of the purchasing agreements. Representatives of participating Member States shall have the status of experts associated to the procurement process, in accordance with Regulation (EU, Euratom) 2018/1046.

Where the Commission intends to conclude a contract containing an obligation to acquire crisis-relevant medical countermeasures, it shall inform the participating Member States of such intention and the detailed terms. The participating Member States shall have the opportunity to express their comments on the draft contracts, that the Commission shall take into consideration. If the opt-out mechanism is applied, participating Member States shall have the right of at least five days to opt out.

6. Procurement referred to in paragraph 2 shall be carried out by the Commission in accordance with the rules set out in Regulation (EU, Euratom) 2018/1046 for its own procurement. When duly justified by the extreme urgency of the health crisis or when strictly necessary in order to adapt to unforeseen circumstances in the evolution of the public health emergency, the following simplifications of procurement procedures may be used:

(a) by way of derogation from Article 137 of Regulation (EU, Euratom) 2018/1046, possibility to provide, after the signature of the contract, proof or evidence on exclusion and selection criteria, provided that a declaration on honour has been submitted in that regard before the award;

(b) by way of derogation from Article 172(2) of Regulation (EU, Euratom) 2018/1046, the Commission may modify the contract as necessary to adapt it to the evolution of the public health emergency;

(c) by way of derogation from Article 165 of Regulation (EU, Euratom) 2018/1046, possibility to add, after the signature of the contract, contracting authorities that are not identified in procurement documents;

(d) by way of derogation from Article 172(1) of Regulation (EU, Euratom) 2018/1046, the contracting authorities shall be entitled to request the delivery of goods or services from the date on which the draft contracts resulting from the procurement carried out for the purposes of this Regulation are sent, which shall be no later than 24 hours as from the award.

7. In line with the framework agreement referred to in paragraph 2, the Commission may have the ability and responsibility, on behalf of participating Member States and according to their needs, to enter into purchase agreements with economic operators, including individual producers of crisis-relevant medical countermeasures. Those agreements can include a prepayment mechanism for the production or development of such countermeasures in exchange for the right to the result.

In order to enter, on behalf of all participating Member States, into purchase agreements with economic operators, representatives of the Commission, or experts nominated by the Commission, may carry out on-site visits in cooperation with relevant national authorities at the locations of production facilities of crisis-relevant medical countermeasures.

8. The Commission shall have the ability and responsibility to activate the Network of Ever-warm Production Capacities for Vaccines and Therapeutics manufacturing (EU-FAB) facilities in order to make available reserved surge manufacturing capacities to ensure the delivery of crisis-relevant medical countermeasures and raw materials, corresponding to the agreed quantities and in accordance with the timing of the EU-FAB contracts. The Commission shall conduct specific procurement procedures for those agreed quantities of crisis-relevant medical countermeasures.

9. Where the Commission provides financing for the production and/or development of crisis-relevant medical countermeasures, the Commission shall have the right to require the licensing, under fair and reasonable conditions, of intellectual property and know-how pertaining to such countermeasures, if an economic operator abandons their development effort or is unable to ensure their sufficient and timely delivery under the terms of the agreement concluded. Further conditions and procedures relating to the exercise of that right may be set out in specific agreements with economic operators.

10. The deployment and use of the crisis-relevant medical countermeasures shall remain the competence of the participating Member States. In cases where the negotiated amounts exceed demand, the Commission, at the request of the Member States concerned, shall elaborate a mechanism for reallocation, resale and donation.

11. The Commission shall ensure that participating Member States are treated equally when carrying out the procurement procedures and when implementing the resulting agreements.

Article 9

Emergency research and innovation aspects of the preparedness and response plans and the use of clinical trial networks and data-sharing platforms

1. Where this measure is activated, the Commission and Member States shall, after consulting the Health Crisis Board, activate the emergency research and innovation aspects of the Union prevention, preparedness and response plan referred to in Regulation (EU) 2022/2371 .

2. The Commission shall support access to relevant data from clinical trials, but also to real-world data. If possible, the Commission shall build upon existing preparedness research initiatives such as Union-wide and international networks for clinical trials as well as observational studies including strategic cohorts, supported by digital platforms and infrastructures, such as high performance computing, enabling the open sharing of findable, accessible, interoperable and reusable (FAIR) data, as well as the activities of the national competent bodies supporting availability and access to data, including health data, in accordance with Article 15.

3. In setting up actions on clinical trials, the Commission shall involve the EMA Emergency Task force established by Regulation (EU) 2022/123 as well as existing networks, such as the European Clinical Research Infrastructure Network, while ensuring compliance with Regulation (EU) No 536/2014 of the European Parliament and of the Council ([14]) as well as coordination with ECDC.

4. The participation and contribution of the Union, and that of the Member States, in the emergency research and innovation aspects of the Union prevention, preparedness and response plan shall be in accordance with the rules and procedures of the Multiannual Financial Framework programmes.

Article 10

Inventory of crisis-relevant medical countermeasure production and production facilities

1. Where this measure is activated, the Commission may, by means of implementing acts, draw up and regularly update an inventory of crisis-relevant medical countermeasure production and production facilities and a template for monitoring of production capacity and stocks.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2) and, on duly justified imperative grounds of urgency, in accordance with the procedure for immediately applicable implementing acts referred to in Article 14(3).

2. The Commission may, using the template referred to in paragraph 1, request the producers of crisis-relevant medical countermeasures to inform the Commission, within five days, of the actual total production capacity, and possible existing stocks of the crisis-relevant medical countermeasures and components thereof, in their Union production facilities and the third-country facilities which they operate, with which they have contracts, or from which they purchase supplies, while fully respecting trade and business secrets. The Commission may also request those producers to transmit to it a schedule of the expected production output for the following three months for each Union production facility.

3. Upon request of the Commission, each producer of crisis-relevant medical countermeasures shall inform the Commission, within a maximum of five days, of any Union crisis-relevant medical countermeasure production facility it operates, including information on its production capacity as regards such countermeasures by means of regular updates. For medicinal products, that information shall comprise facilities related to both finished products and active pharmaceutical ingredients.

4. The Commission shall regularly inform the European Parliament and the Council about the production of crisis-relevant medical countermeasures and the expected production rate within the Union and the production of supplies from third-country facilities, whether the products are finished, intermediates or other components, as well as about the capacity of Union and third-county crisis-relevant medical countermeasure production facilities, while adequately protecting commercially sensitive information of the producers.

Article 11

Inventory of crisis-relevant raw materials, consumables, medical devices, equipment and infrastructure

Where this measure is activated, the Commission shall extend the inventory and template provided for in Article 10 to crisis-relevant raw materials, consumables, medical devices, equipment and infrastructure, if it considers that there is a risk of a shortage in supply of crisis-relevant raw materials, consumables, medical devices, equipment or a risk of any problems with infrastructure.

([14]) 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).

Article 12

Measures to ensure the availability and supply of crisis-relevant medical countermeasures

1. Where this measure is activated, the Commission may, when it considers that there is a risk of a shortage of crisis-relevant raw materials, consumables, medical and other devices, equipment and infrastructure, implement, as quickly as possible, in agreement with the Member States concerned and after consultation with the economic operators concerned, specific measures to ensure the efficient reorganisation of supply chains and production lines and utilise existing stocks to increase the availability and supply of crisis-relevant medical countermeasures.

2. In particular, the measures referred to in paragraph 1 may include:

(a) facilitating the expansion or repurposing of existing, or the establishment of new, production capacities for crisis-relevant medical countermeasures;

(b) facilitating the expansion of existing, or the establishment of new, capacities related to activities and the introduction of measures ensuring regulatory flexibility, in order to support the production and placing on the market of crisis-relevant medical countermeasures, while respecting the responsibilities of EMA and national medicines authorities with regard to the evaluation and supervision of medicinal products;

(c) implementing procurement initiatives, reserving stockpiles and production capacities to coordinate approaches, and providing critical supply, services and resources for the production of crisis-relevant medical countermeasures;

(d) facilitating the collaboration of relevant companies in a joint industry effort to ensure the availability and supply of crisis-relevant medical countermeasures; and

(e) facilitating the licensing of intellectual property and know-how pertaining to the crisis-relevant medical countermeasures.

3. The Commission may provide timely financial incentive mechanisms necessary to ensure the rapid implementation of the measures referred to in paragraph 2.

Article 13

Emergency funding

Where this measure is activated and the requirements laid down in Regulation (EU) 2016/369 are met, emergency support under that Regulation shall be activated to finance expenditure necessary to address the public health emergency.

Article 14

Committee Procedure

1. The Commission shall be assisted by a Health Crisis Implementing Committee. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and Article 5(4), third subparagraph, of Regulation (EU) No 182/2011 shall apply.

3. On duly justified imperative grounds of urgency relating to the public health emergency, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 8 of Regulation (EU) No 182/2011.

Article 15

Personal data protection

1. This Regulation shall be without prejudice to the obligations of Member States relating to their processing of personal data under Regulation (EU) 2016/679 and Directive 2002/58/EC of the European Parliament and of the Council ([15]), or the obligations of the Commission and, where appropriate, other Union institutions, bodies, offices and agencies, relating to their processing of personal data under Regulation (EU) 2018/1725, when fulfilling their responsibilities.

2. Personal data shall not be processed or communicated except in cases where it is strictly necessary for the purposes of this Regulation. In such cases, the conditions of Regulations (EU) 2016/679 and (EU) No 2018/1725 shall apply as appropriate.

3. Where processing of personal data is not strictly necessary for the fulfilment of the mechanisms established in this Regulation, personal data shall be rendered anonymous in such a manner that the data subject is not identifiable.

4. The Commission, by means of an implementing act, shall adopt detailed rules to ensure that the requirements provided for by Union legislation concerning the roles of the actors involved in the collection and processing of personal data are fully complied with.

Those implementing acts shall be adopted in accordance with the examination procedure referred to Article 14(2).

Article 16

Review

By 2024 at the latest, the Commission shall carry out a review of this Regulation and present a report on the main findings of that review to the European Parliament and to the Council. That review shall include an evaluation of the work of the Health Preparedness and Emergency Response Authority (HERA) under the emergency framework established by this Regulation, and its relation to the preparedness activities of HERA.That review shall also include an assessment as regards the need to establish HERA as a distinct entity considering relevant agencies or authorities active in the field of health crisis. Member States shall be consulted and their views and recommendations on the implementation of the emergency framework shall be reflected in the final report. The Commission shall, if appropriate, present proposals based on that report in order to amend this Regulation or make further proposals.

Article 17

Entry into force

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

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

Done at Luxembourg, 24 October 2022.

For the Council
The President
A. HUBÁČKOVÁ

([15]) Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (OJ L 201, 31.7.2002, p. 37).