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'A' ITEM NOTE

From:	General Secretariat of the Council
To:	Council
No. Cion doc.:	11956/21
Subject:	Council Regulation on the emergency framework regarding medical countermeasures *- Political agreement*

I. BACKGROUND

1. On 16 September 2021, the Commission submitted the proposal for a Council Regulation on the emergency framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level[1]. On the same day the Commission adopted its decision establishing the Health Emergency Preparedness and Response Authority (HERA).

[1] 11956/21

2. The proposal is one of the main pillars of the European Health Union. It is proposed in conjunction with the proposals put forward by the Commission in November 2020: the proposal for a Regulation on serious cross border threats to health and the extended mandates of the European Centre for Disease Prevention and Control (ECDC) European Medicines Agency (EMA).

3. The proposal is based on Article 122 (1) of the Treaty on the Functioning of the European Union (TFEU). The proposal was not accompanied by an impact assessment due to the urgency of the matter to strengthen the emergency framework in preparation for a future public health emergency. The key measures of the proposal are:

   – the establishment of a Health Crisis Board to ensure coordination and integration of approaches to crisis-relevant medical countermeasures at Union level in the event of a public health emergency;

   – the establishment of mechanisms for the monitoring, activation of emergency funding, procurement and purchase of crisis-relevant medical countermeasures and raw materials;

   – the activation of EU FAB facilities, the activation of emergency research and innovation plans, and the use of Union-wide clinical trial networks and provisions and platforms for the rapid sharing of data; and

   – measures concerning the production of crisis-relevant medical countermeasures.

II. STATE OF PLAY

4. Since 28 September 2021, the Slovenian Presidency has convened all together 9 meetings at technical level to examine the proposal.

5. Following the work at the level of the Working Party on Pharmaceuticals and Medical Devices, the Permanent Representatives Committee discussed a draft compromise text[2] on 1 December 2021, a revised draft compromise text[3] on 15 December 2021 and a further revised draft compromised text[4] on 17 December 2021.

6. During the discussion at the meeting of the Permanent Representatives Committee on 17 December, the Presidency proposed further limited modifications to the text in order to address some remaining concerns. The Permanent Representatives Committee examined the latest draft compromise text as revised by the Presidency during the meeting and set out in the Annex to this document.

7. The Presidency concluded that there was a large support on this text from delegations, four delegations not representing a blocking minority entering a scrutiny reservation (AT, BG, DE, NL).[5] The Commission has signalled its agreement with the text. The Presidency further noted the support from all delegations for the submission of this text to the ENVI Council for a political agreement at its meeting on 20 December 2021, under the A items of the agenda.

8. The Presidency continues to believe that the work on this proposal does not prejudge the discussions on the proposal for a Regulation on serious cross border threats to health. Once the final text of the Regulation on serious cross border threats to health is agreed upon, the necessary technical adjustments, notably the cross-references, will be introduced in the framework regulation before its final adoption by the Council.

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2 14031/21
3 14849/21
4 15110/21
5 After the meeting on 17 December 2021 these delegations lifted their scrutiny reservations. NL maintained its parliamentary reservation, which cannot be lifted before the ENVI Council and indicated its intention to abstain. BG submitted a statement (15132/21 ADD 1).

9. Following the request of the European Parliament, expressed in the letter dated 25 October 2021, the **budgetary scrutiny procedure** will be launched in line with the joint declaration of the European Parliament, the Council and the Commission on budgetary scrutiny of new proposals based on Article 122 TFEU with potential appreciable implications for the Union budget[6]. The possible outcome of this procedure will be considered with a view to the final adoption of this proposal by the Council.

III. CONCLUSION

10. The Council is invited to reach a political agreement on the text as set out in Annex.

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[6] 2020/C 444 I/05

ANNEX

Draft

COUNCIL REGULATION

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 the COVID-19 pandemic were reactive and the Union was not sufficiently prepared to ensure 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 the global supply chains.

(2) ~~However, t~~ **T**he experience gained showed the need for a framework for ensuring the supply of crisis-relevant medical countermeasures of measures 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 crisis-relevant medical countermeasures in the event of a public health emergency where that is appropriate to the economic situation. **To this effect, the current Regulation aims at establishing 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 strongly been witnessed 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 recognition of a public health emergency at Union level, the Council may, upon the proposal of the Commission pursuant to Article 122(1) TFEU, 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 line with Article 9 TFEU and possible risks of the global disruption of supplies of crisis-relevant medical countermeasures which may impact the health systems of Member States. The proposal of the Commission should explain the rationale and the need for proposed activation of the emergency framework including for each of the measures proposed to be activated, including an analysis of anticipated impact, subsidiarity, proportionality and financial implications for each of the proposed measures.** The use of measures within this framework should be limited in time **up** to 6 months, after which they can be prolonged in view of the situation. **The implementation of these measures should respect the responsibilities of the 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) of the Treaty on the Functioning of the European Union.**

(4) The framework of measures should include the establishment of a Health Crisis Board on crisis-relevant medical countermeasures to ensure coordination ~~and integration~~ of approaches at Union level. This is of particular importance given the spread of responsibilities between national and Union level. To support the Health Crisis Board, the Commission should **on its own initiative or on the proposal of the Health Crisis Board** be entitled to set up sub-groups **or ad-hoc working groups,** including if needed for industrial aspects. **In order to ensure effective and systematic involvement of the Member States in the decisions taken for the implementation of this regulation, rules for the deliberations of the Health Crisis Board should be defined. When deliberating, the members of the Health crisis Board should use their best endeavours to reach a consensus. If such a consensus cannot be reached, and in order to ensure a smooth deliberation mechanism in the Health Crisis Board, the Health Crisis Board should act by a two third majority, where one vote is given per Member State.**

Moreover, it is useful for the effective operation and swift decision making by the Health Crisis Board that it is supported through preparadness and planning carried out by Health Emergengy Response Authority established by Commission decision of 16.9.2021 including, inter alia, providing assessment for the purpuse of activating measures in this Regulation, proposing the rules of procedures, draft negotiating mandates and procedural rules for joint procurements and providing relevant information for the establishment of an inventory of crisis-relevant medical countermeasures 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 Health Emergency Preparedness and Response Authority. The Health Crisis Board may also coordinate, as appropriate, with the HERA Board set out in Commission decision of 16.9.2021 establishing the Health Emergency Preparedness and Response Authority.

(4a) Member States and the Commission should appoint their representative and alternate representative in the Health Crisis Board.

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

(6) 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 medical products and critical medical devices, under Regulation (EU) …/… of the European Parliament and of the Council [EMA Regulation (COM/2020/725)][7], 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 Article 6 to 12, the Commission, including HERA, should fully respect EMA's responsibilities.** ~~If use is made of the possibility to establish~~ a **In the** Health Crisis Board ~~during a public health emergency,~~ a representative of the Executive Steering Group on Shortages of Medical Devices, a representative from the Emergency Task Force and a representative from the Executive Steering Group on Shortages and Safety of Medicinal Products should be invited as observers to the Health Crisis Board, as established under Regulation (EU) No…/…[the EMA Regulation]. This should complement the smooth transition of data and information during public health emergencies at Union level, including via integrated IT systems.

(6a) Regarding the monitoring of demand and supply of medical countermeasures in third countries, the Commission should maintain a dialogue with their counter partners to foster international collaboration.

[7] Regulation (EU) No …/… of the European Parliament and of the Council of … on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices [OJ: please insert number, date and publication reference].

(7) The measures should also take into consideration the structures and mechanisms set up by the Union acts on serious cross-border threats to health, Regulation (EU) …/… of the European Parliament and of the Council [SCBTH Regulation (COM/2020/727)][8], and on the extended mandate of the ECDC laid down by Regulation (EU) …/… of the European Parliament and of the Council [ECDC Regulation (COM/2020/726)][9], to ensure response coordination within the Health Security Committee and the Advisory Committee on public health emergencies, taking into account input by ECDC on epidemiological surveillance and monitoring. The Director of the European Centre for Disease Prevention and Control, and a representative of the Advisory Committee on public health emergencies established under Regulation (EU) No…/…[the SCBTH Regulation] should be invited to attend the meetings of the Health Crisis Board. A member of the Health Security Committee should be invited as observer to the Health Crisis Board.

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8 Regulation (EU) No …/… of the European Parliament and of the Council of … on serious cross-border threats to health and repealing Decision No 1082/2013/EU [OJ: please insert number, date and publication reference].

9 Regulation (EU) No …/… of the European Parliament and of the Council of … amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control [OJ: please insert number, date and publication reference].

(8) The activation of emergency research and innovation plans, as well as the repurposing and 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 may use the European Health Data Space digital Infrastructure and platforms operating under the European Open Science Cloud and other accessible EU digital platforms, to get access to (real-world) data for quick analysis. Close coordination of the Commission with ECDC and EMA, as the Agency responsible for scientific advice and scientific assessment of new and repurposed medicinal products, should be ensured for these 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 medicines. Emergency research may also include diagnostic preparedness.This should allow key actors and relevant infrastructure to be immediately ready for operation in times of public health emergencies, thereby reducing any delays.

(9) Efficient procurement procedures for crisis-relevant medical countermeasures and raw materials should be ensured, and the Commission ~~should be entrusted with a negotiating mandate~~ **can** act as a central procurement body for **participating** Member States, ~~using~~ **under** the rules and procedures ~~under~~ **laid down** in Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council[10]**,** ~~as well as~~ **and where appropriate,** Council Regulation (EU) 2016/369[11] **as well as joint procurement procedures referred to in Article 12 of Regulation (EU) …/… of the European Parliament and of the Council [SCBTH Regulation (COM/2020/727)]. In order to allow for speed and efficient procurement during crisis times, procedural simplifications might be necessary. Moreover for the purpose of drawing lessons learned from the procurement experience from the Covid-19 better involvement of Member States should be ensured in the preparation and award of contracts. Agreements between the Commission and Member States should ensure all the Member States have equal and timely access to all information, their needs are duly taken into account.**

Procurements of medical countermeasures carried out in this Regulation can be exclusive or non exclusive depending on the agreement of the participating Member States.

(9b) Based on the needs of Member States, as advised by the Health Crisis Board, the Commission should seek to ensure that all medical countermeasures procured or developed under this Regulation meet the relevant EU, and where applicable, national regulatory requirements, while allowing for any derogations, or other national exemptions, as applicale.

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10 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 PE/13/2018/REV/1 (OJ L 193, 30.7.2018, p. 1).

11 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).

(10) These rules and procedures may be supported by any necessary preparatory steps, including on-site visits at the location of the production facilities of crisis-relevant medical countermeasures. This should allow for the **timely** procurement and purchase of crisis-relevant medical countermeasures across the Union and promote accessibility across the Member States, with the primary objective of securing the **speediest** possible equitative provision **and distribution** of the 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.**

(10a) 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 may be justified given the extreme urgency of the health crisis and resulting economic difficulties. Also adjustments to the contracts that are strictly necessary to adapt to the evolution of the public health emergency as well as the addition of contracting authorities during performance of the contract may be needed. For this specific purpose, it is necessary to 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 this emergency framework, they will be temporary and apply solely for the period of the activation of the measure referred to in Article 7 of this Regulation.

(11) During a public health emergency at Union level demand for crisis-relevant medical countermeasures may be greater than supply. In such a situation, surge production and manufacturing of crisis-relevant medical countermeasures is essential and the Commission should be entrusted to activate the surge 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 'EU-FAB'. As outlined in the Communication 'HERA Incubator: Anticipating together the threat of COVID-19 variants'[12] , 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 medicine manufacturing at European level.

(11a) **Effective mechanisms should be elaborated and agreed at Union level in order to ensure re-distribution in cases where the surge of manufacturing has resulted in supply exceeding demand.**

(12) Appropriate intellectual property tools are needed to mitigate the risks of abandonment of development efforts or supply issues of crisis-relevant medical countermeasures during a public health emergency, especially where public authorities 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 crisis-relevant medical 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 the crisis-relevant medical countermeasures, the Commission should take into account the upfront financing by the EU or the Member States of the developping and the production of those countermeasues.**

[12] COM/2021/78 final.

(13) Council Regulation (EU) 2016/369[13] provides for a flexible framework for emergency financial support. It allows to provide 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 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.**

(14) 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 facilities should be created and regularly updated on the basis of the compulsory transmission of information by the relevant economic operators.

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

(16) Informed by the detailed overviews of production capacities, raw materials, consumables, equipment and infrastructure, further measures to bolster supply chains and production capacities may be 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 these areas that serve to increase the availability and accessibility of crisis-relevant medical countermeasures and raw materials~~;~~

[13] 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).

(17) 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 Regulation (EU) 2018/1725 of the European Parliament and of the Council[14] and Regulation (EU) 2016/679 of the European Parliament and of the Council[15].

(18) 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.

(19) In order to ensure uniform conditions for the implementation of this Council 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.[16] 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.

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14 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).

15 Regulation (EU) 2016/769 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).

16 [ref]

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

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

2. The emergency **framework** referred to in paragraph 1 include:

   (a) establishment of a Health Crisis Board;

   (b) 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 **EU** funding and financing **including inter alia under the 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 production and production facilities, raw materials, consumables, equipment and infrastructure, and including measures aiming at increasing their production in the Union.

3. The **framework** ~~measures~~ referred to in paragraph 1 may be activated only to the extent that they are 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 shall apply:

(1) ‘monitoring’ means monitoring as defined in Article 3, point (5), of Regulation (EU) No…/…[the SCBTH Regulation];

(2) ‘public health emergency’ means a public health emergency at Union level recognised by the Commission in accordance with Article 23 of Regulation (EU) No…/…[the SCBTH Regulation];

(3) ‘medical countermeasures’ means medical countermeasures within the meaning of Article 3, point (8), of Regulation (EU) …/… [the SCBTH Regulation], [in addition to personal protective equipment and substances of human origin[17]];

(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.**

[17] [To be deleted if personal protective equipment and substances of human origin are included in the definition of medical countermeasures in the SCBHT Regulation]

1a. Where the Council activates one or several measures set out in Articles 6 to 12, Article 5 shall apply.

2. The Council shall set out in the Regulation activating the emergency framework which of the measures as set out in Articles ~~5~~ **6** to ~~11~~ **12** ~~and 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.

3. The duration of the activation is **no longer than** 6 months, renewable in accordance with the procedure set out in Article 4.

4. The regulation on the activation of the emergency framework shall be without prejudice to Decision No. 1313/2013/EU of the European Parliament and of the Council[18] and the overall coordination role of the Emergency Response Coordination Centre under the Union Civil Protection Mechanism **(UCPM) and Council Decision 2014/415/EU on the arrangements for the implementation by the Union of the solidarity clause and the political coordination role of the Integrated Political Crisis Response (IPCR)**.

Article 4

Prolongation, deactivation and expiry of the activation of the emergency framework

1. No later than ~~1~~ **3** week**s** before the expiry of the duration 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 the activation of the emergency framework 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.**

[18] 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.*

2. Where that assessment concludes that it is appropriate that the activation of the emergency framework is prolonged, the Commission may propose the prolongation to the Council **and which of the measures are appropriate to be prolonged.** The prolongation shall ~~not exceed~~ **be up** to 6 months. The Council may repeatedly decide to prolong the activation of the emergency framework where that is appropriate 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 deactivation of any~~one or more~~ activated ~~existing~~ measures** set out in Articles ~~5~~ **6** to ~~**11**~~ **12** ~~**and 13**~~ in addition to those measures that it had already activated, where that is appropriate to the economic situation **taking into account the need to ensure a high level of protection of human health.**

4. Upon expiry of the duration for which the emergency framework is activated, the measures taken in accordance with Articles ~~5~~ **6** to ~~11~~ **12** ~~and 13~~ shall cease to apply ~~in so far as they had been activated by the Council~~.

5. The measures set out in Articles 6 to12 shall be automatically deactivated in case the public health emergency at EU level is terminated in accordance with Article 23(2) of Regulation (EU) No…/… [the SCBHT Regulation].

Article 5

Establishment of the Health Crisis Board

1. The **Health Crisis Board shall be established**. ~~Where this measure is activated~~ and shall ensure coordination of action by the Council, the Commission, the relevant Union agencies**,** ~~and~~ bodies **and entities** and Member States to ensure the supply of and access to medical countermeasures.

   The **Health Crisis Board** shall ~~, in particular, be aimed at supporting~~ **assist and provide guidance to** the Commission in the preparation **and implementation** of measures to be taken pursuant to Articles 6 to **12** ~~11 and 13~~. **To this effect, the Commission shall maintain a constant supply of information to the Health Crisis Board on the measures planned or taken**.

1a. The Health Crisis Board shall cease to operate when all of the measures set out in Articles 6 to 12 are deactivated or expire.

2. The Health Crisis Board shall be composed of the Commission and one representative from each Member State. **Each Member State shall nominate their representative and alternate representative.** ~~The Commission shall be represented by its President, the Member of the Commission in charge of Health and other Members of the Commission as appropriate.~~ **The secretariat of the Health Crisis Board will be ensured by the Commission.**

2a. The Health Crisis Board shall be co-chaired by the Commission and the Member State, holding the rotating presidency of the Council.

~~The Commission~~ **The Health Crisis Board** shall ensure the participation of all relevant Union institutions and bodies, including the European Medicines Agency, the European Centre for Disease Prevention and Control, and the Advisory Committee on public health emergencies established under Regulation (EU) …/… [the SCBTH Regulation] as observers to the Health Crisis Board. ~~The Commission~~ **The Health Crisis Board** shall invite **as observers** a representative from the European Parliament and a Member State's representative of the Health Security Committee **and where relevant and in line with its rules of procedure a representative of the WHO** to the Health Crisis Board.

Each Member State shall nominate one ~~senior~~ representative and one alternate representative to the Health Crisis Board.

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

(a) Regulation (EU) …/… [the EMA Regulation] during the period of the public health emergency, related to medicinal products and medical devices;

(b) Regulation (EU) …/… [the ECDC Regulation] during the period of the public health emergency;

(c) Regulation (EU) …/… [the SCBTH Regulation], in particular with the Health Security Committee **and to 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 medical countermeasures and raw materials and ensuring, where necessary, corresponding on-site monitoring and coordination tasks.

3a. The Health Crisis Board shall ensure information exchange with the Integrated Political Crisis response Mechanism (IPCR), established under Council Decision 2014/415/EU on the arrangements for the implementation by the Union of the solidarity clause.

4. ~~The Commission~~ **The co-chairs of the Health Crisis Board** may invite experts with specific expertise, including representatives of Union agencies and bodies, national authorities including central purchasing bodies and health care organisations or associations, international organisations **such as WHO, FAO and OIE**, experts from the private sector as well as other stakeholders, with respect to a subject matter on the agenda, to take part **as observers** in the work of the Health Crisis Board or sub-groups on an ad hoc basis.

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

6. ~~The Health Crisis Board shall be chaired by the Commission~~. **In the course of the preparation and implementation of the measures set out in Articles 6 to 12 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.**

6a. The Health Crisis Board may issue opinions, upon request of the Commission or on its own initiative. In case 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.

6b. 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 States representatives. Each member state shall have one vote.

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

~~7. The Secretariat of the Health Crisis Board shall be provided by the Commission.~~

8. 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 defined in paragraph 1. **The working groups shall deliberate in accordance with the rules set in Article 5 paragpraph 6a. Member States shall nominate experts in the working groups.**

9. The Commission shall ensure transparency and provide all national 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 5a

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. In such cases the person concerned shall be excluded from relevant discussions and decisions.

Article 6

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 12a paragraph 2 and, on duly justified imperative grounds of urgency, in accordance with the procedure for immediately applicable implementing acts referred to in Article 12a paragraph 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 7 to **12** ~~11 and 13~~, taking into account the information obtained pursuant to:

   (a) Regulation (EU) …/… [the EMA Regulation] and in particular Articles XX *[Article numbers to be confirmed after adoption]* thereof, concerning the monitoring and mitigating shortages of critical medicinal products, medical devices and in vitro diagnostic medical devices;

   (b) Regulation (EU) …/… [the ECDC Regulation], and in particular Article 3, point (e), thereof, concerning available indicators of Member States' capacity regarding health services necessary to the management and response to communicable disease threats.

3. **Without prejudice to national security interests,** Member States shall**, as apropriate** provide the Commission with **additional** information**, not already collected by EU agencies** based on the monitoring template **of crisis-relevant medical countermeasures and raw materials** 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,** ~~W~~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 refered in paragraph 1**, it **may** ~~shall~~ inform ~~and consult~~ 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, medical devices and *in vitro* diagnostic medical devices, including their demand and supply, in accordance with Articles XX *[Article numbers to be confirmed after adoption]* of Regulation (EU) …/… [the EMA Regulation].

6. The Commission shall gather **additional** information **not already collected by EU agencies** through a secured IT system and monitor, **based on the template**, all relevant information concerning the supply and demand of crisis-relevant medical countermeasures and raw materials within and outside the Union. The interoperability of the IT system with the electronic monitoring and reporting systems developed by EMA pursuant to Article 9, point (c), *[Article numbers to be confirmed after adoption]*, of Regulation (EU) …/… [the EMA Regulation] shall be ensured by the Commission~~when necessary.~~

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 the Council ~~through the Integrated Political Crisis Response provided for in Council Implementing Decision (EU) 2018/1993~~[19].

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

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

[19] Council Implementing Decision (EU) 2018/1993 of 11 December 2018 on the EU integrated Political Crisis Response Arrangements (*OJ L 320, 17.12.2018, p. 28).*

Article 7

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

0. 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) …/… [the SCBTH Regulation], or European Innovation Partnerships.**

In particular, the Health Crisis Board shall advise the Commission on the need to use a purchasing mode where 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.

1. **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 the following paragraphs.**

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 a close coordination with the Health Crisis Board draw up the proposal for a framework agreement to be ~~a negotiating mandate shall be established by the Commission on behalf of~~ **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**.** ~~Through the activation of existing contracts or the negoatiation of new contracts using all avilable instruments, such as Article 4 of Regulation (EU) 2016/369é the joint procurement procedure reffered to in Articla 12 of theis Regualtion (EU) …/… [the SCBTH Regulation], or European Innovation Partnerships.~~

1a. This framework agreement shall include procedural rules for the initiation, preparation of procurement procedures set out in this article, the modalities 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 modalities for the involvement of participating Member States throughout the procurement process as well as allocation procedures of procured medical countermeasures.

1b. 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 Financial Regulation..

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.

1c. All participating Member States shall be associated to the procurement process. To this 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 the Financial Regulation.

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 concideration. If the opt out mechanism is applied, participating Member States shall have the right of at least 5 days to opt out.

2. ~~Without prejudice to paragraph 1 above, p~~**P**rocurement ~~under this Regulation~~ **referred to in paragraph 1** shall be carried out by the Commission in accordance with the rules set out in Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council[20] for its own procurement. **When duly justified by the extreme urgency of the health crisis or when strictly necessary to adapt to unforeseen circumstances in the evolution of the public health emergency, t**he 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 proof or evidence on exclusion and selection criteria after signature of contract provided that a declaration on honour has been submitted in this regard before the award;

(b) By way of derogation from Article 172(2) of the Regulation (EU, Euratom) 2018/1046, the Commission may modify the contract, as necessary to adapt 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 contracting authorities, not identified in procurement documents, after the signature of the contract;

(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 as from the date of sending the draft contracts resulting from the procurement carried out for the purposes of this Regulation, no later than 24 hours as from the award.

[20] 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).

3. In line with ~~the negotiating mandate given to it,~~ **the established framework agreement**, the Commission may have the ability and responsibility, on behalf of all participating Member States **and based on their needs,** to enter into purchase agreements with economic operators, including individual producers of crisis-relevant medical countermeasures, ~~concerning the purchase of such countermeasures or concerning the advance financing of~~ **including prepayment mechanism for** the production or development of such countermeasures in exchange for the right to the result.

   In order to prepare the fulfilment of such tasks, 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.

4. The Commission shall have the ability and responsibility to activate the 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. Specific procurement procedures for these agreed quantities of crisis-relevant medical countermeasures shall be conducted.

5. 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 this right may be set out in the specific agreements with economic operators.

6. ~~The Commission shall carry out the procurement procedures and conclude the resulting agreements with economic operators on behalf ot the participating Member States. The Commission shall invite Member States participating in the Health Crisis Board set up under Article 5 to nominate representatives to take part in the preparation of the procurement procedures as well as the negotiation of the purchising agreements. The deployment and use of the crisis-relevant medical countermeasures shall remain the responsibility of the participating Member States.~~ **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 on the request of the Member States concerned should elaborate a mechanism for realocation, resale and donation.**

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

Article 8

Activation of emergency research and innovation plans and the use of ~~Union-wide~~ clinical trial networks and data-sharing platforms

1. Where this measure is activated, the Commission and the Member States shall, **after the consultating the Health Crisis Board,** activate the emergency research and innovation aspects of the Union Preparedness and Response Plan referred to in Regulation (EU) …/… [the SCBTH Regulation].

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 ~~and~~ **as well as** observational studies **including**~~, or~~ 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 line with Article 12b.**

3. In setting up actions on clinical trials, the Commission shall involve the EMA Emergency Task force established by Regulation (EU) …/… [the EMA Regulation] **existing networks such as the European Clinical Reasearch Infrastructure Network while ensuring compliance with the Regulation (EU) 536/2014**[21] as well as coordination with ECDC.

4. The participation and contribution of the Union in the emergency research and innovation aspects of the Union Preparedness and Response Plan with the Member States shall be in accordance with the rules and procedures of the various Multiannual Financial Framework programmes.

Article 9

Inventory of crisis-relevant medical countermeasures production and production facilities

1. Where this measure is activated, the Commission may, ~~after consulting the Health Crisis Board~~ **by means of implementing acts**, ~~establish an inventory, and for this purpose~~ **draw up and regularly update an inventory of crisis-relevant medical countermeasures production and production facilities and a template for monitoring of production capacity and stocks.**

[21] [ref]

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 12a paragraph 2 and, on duly justified imperative grounds of urgency, in accordance with the procedure for immediately applicable implementing acts referred to in Article 12a paragraph 3.

2. **The Commission may, using the established template,** request the producers of crisis-relevant medical countermeasures to inform the Commission within 5 days about the actual total production capacity and possible existing stocks of the crisis-relevant medical countermeasures and components thereof in its Union production facilities and third country facilities which it operates or contracts or purchases supply from, while fully respecting trade and business secrets and to transmit to the Commission a schedule of the expected production output for the following 3 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 5 days about any Union crisis-relevant medical countermeasures production facility it operates, including information on its production capacity as regards crisis-relevant medical countermeasures via regular updates. For medicinal products, this information shall comprise facilities related to both finished products as well as 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 for supplies from third country facilities whether finished product, intermediates or other components, as well as the capacity of Union and third county crisis-relevant medical countermeasures production facilities, while adequately protecting commercially sensitive information of the producers.

Article 10

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

Where this measure is activated, the Commission shall extend the inventory **and template** provided for in Article 9 to crisis-relevant raw materials, consumables, devices, equipment and infrastructure, if it considers that there is a risk of a shortage in supply of crisis-relevant raw materials, consumables, devices, equipment or any problems with infrastructure.

Article 11

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

1. Where this measure is activated, the Commission **may** ~~shall~~, 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 **in agreement** with the ~~**participating**~~ Member States **concerned and after consultation with the economic operators concerned,** specific measures to ensure the efficient re-organisation of supply chains and production lines and utilise existing stocks to increase the availability and supply of crisis-relevant medical countermeasures, as quickly as possible.

2. In particular, the measures referred to in paragraph 1 **may** ~~shall~~ 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, the introduction of measures ensuring regulatory flexibility, aimed at supporting the production and placing on the market of crisis-relevant medical countermeasures, **while respecting prerogatives of EMA and national medicines authorities with regards to 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 12

Activation of emergency funding

Where this measure is activated **and the requirements according to Regulation (EU) 2016/369 are met**, emergency support instrument under Regulation (EU) 2016/369 is activated to finance expenditure necessary to address the public health emergency ~~in accordance with this Regulation.~~

Article 12a

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 the third subparagraph of Article 5(4) 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 12b

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) No 2016/679 and Directive 2002/58/EC on privacy and electronic communications, or the obligations of the Commission and, where appropriate, other Union institutions and bodies, relating to their processing of personal data under Regulation (EU) No 2018/1725, when fulfilling their responsibilities.

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

3. Where processing of personal data is not strictly necessary to 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.

These implementing acts shall be adopted in accordance with the examination procedure referred to Article 12a(2).

Article 13

Review

By ~~2025~~ **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 the Council. **This review shall include an evaluation of the work of HERA under the emergency framework established by this Regulation, and their relation to the preparedness activities of HERA [, taking account of the evaluation referred to in Article 29(1) of the SCBTH Regulation] and shall include an assessment of 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 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 14

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 Brussels,

For the Council
The President