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Proposal for a

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

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

This proposal for a Regulation aims to put in place **a framework of measures to be activated in case of a public health emergency** by enabling the Union to take the necessary measures for a sufficient and timely availability and supply of crisis-relevant medical countermeasures.

On 15 June 2021, the Commission presented a Communication on the early lessons from the COVID-19 pandemic[1] setting out the need for the Union to have special arrangements in place to better react in times of health crisis. In November 2020, the Commission had put forward proposals for a stronger European Health Union, and is now creating a new Union **Health Emergency preparedness and Response Authority** (HERA) within its services. This will provide an agile, robust and sustainable health security structure to improve the availability of medical countermeasures. It would operate during both preparedness and crisis situations.

The COVID-19 pandemic revealed significant vulnerabilities in the European health preparedness for and response to public health emergencies. The measures set out in this Regulation relate to the crisis response mode. They will complement the development of HERA as a new driver for Union action to address cross-border threats.

EU structures, Member States and the industrial sector involved in medical countermeasures were not sufficiently prepared to ensure the efficient development, manufacturing, procurement, and equitable distribution of key medical countermeasures[2] in response to the pandemic. The pandemic also revealed too many fragmented research activities across the Union, often rather limited in scope and limited manufacturing capacities for medical countermeasures, as well as vulnerability in related global supply chains. These limitations ultimately resulted in delays and inefficiencies in the response, which cost lives and harmed the economy.

In particular, the following problems related to crisis-relevant medical countermeasures were identified.

- **Insufficient and scattered intelligence gathering and analysis**, which is crucial for underpinning preparedness and response plans for crisis-relevant medical countermeasures as well as for ensuring that response interventions adequately ensure availability and accessibility of crisis-relevant medical countermeasures.
- **Sub-optimal intervention tools and the absence of fully functional public-private ecosystems,** which did not allow the Union to take a proactive approach with strategic and well-informed interventions, which are required to mobilise resources and accelerate the short timeframes for the process of research to final market product.

[1] COM(2021)380

[2] These are medicinal products for human use as defined in Directive 2001/83/EC and medical devices as defined in Regulation (EU) 2017/745 or other goods or services for the purpose of preparedness and response to a serious cross-border threat to health.

- **Impediments to swift manufacturing of crisis-relevant medical countermeasures,** which can be linked to vulnerabilities and difficulties experienced in manufacturing and supply chains, emergency funding and regulatory frameworks, research and data sharing as well as **insufficient manufacturing capacities in particular at the beginning of the COVID-19 pandemic**.
- **Fragmented and dispersed efforts at the Union and national levels**, aggravated by inadequate coordination and information sharing, which resulted in an inability to secure the availability of crisis-relevant medical countermeasures and to provide timely access to them.

Some steps to address these shortcomings come through better preparedness. But others require powers, instruments and actions which are only appropriate to cross border emergency situations. The Union did not have a specific emergency mandate for the coordination of Union activities able to ensure rapid availability and accessibility of crisis-relevant medical countermeasures for all Member States. Member States each had different capacities to prepare, respond with and manage crisis-relevant medical countermeasures. Neither national nor EU level had the capacity to respond as required already in place: the response had to be created from imperfect foundations. This situation is likely to be replicated: probably no single country can adequately address all the challenges associated with public health emergencies that have the ability to affect one or more Member States, such as COVID-19. Rapidly changing technological and competitive environments make country-specific responses still more difficult. Uncoordinated efforts may also lead to fragmentation of an already complex market and duplication of public funding.

Moreover, due to globalisation, climate change, natural and man-made disasters, biodiversity loss, habitat encroachment as well as armed conflicts and terrorism, the continuation, emergence and threat of public health emergencies remains a serious likelihood globally, requiring swift availability and accessibility of crisis-relevant medical countermeasures.

- **Consistency with existing policy provisions in the policy area**

This proposal for a Regulation forms one of the main pillars of the European Health Union by solidifying the Union's capacity to support timely availability and accessibility for crisis-relevant medical countermeasures during a public health emergency. 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[3] and the extended mandates of the European Centre for Disease Prevention and Control (ECDC)[4] and the European Medicines Agency (EMA).[5] Overall, it reinforces the Union's crisis management framework. With regard to the proposal for an extended EMA mandate, there will be a close link between the Commission and the EMA in order to ensure consistency and inform Commission decision making with regard to crisis-relevant medical

[3] Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU (COM(2020) 727 final).

[4] Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control (COM/2020/726 final).

[5] Proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (COM/2020/725 final).

countermeasures. This close link specifically pertains to the information and the recommendations of the Medicines Steering Group and the Commission's role to take action to ensure mitigation of potential or actual shortages of medicinal products on the critical medicines list and the need for medical countermeasures, in line with Articles 12 and 26 of the proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.[6].

The proposed measures complement the following current Union measures in the fields of crisis response and health:

– Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014[7];

– the medical response envisaged under Decision No 1313/2013/EU of the European Parliament and of the Council on a Union Civil Protection Mechanism[8];

– the Union's Emergency Support Instrument (Council Regulation (EU) 2016/369 on the provision of emergency support within the Union[9]); and

– the proposed Pharmaceutical Strategy for Europe[10].

The proposed measures also complement other policies and actions under the European Green Deal[11] in the field of climate and environment that will support enhanced environmental health, disease prevention and increased resilience.

These measures will support Member States, ensuring cooperation towards the availability and supply of crisis-relevant medical countermeasures and raw materials. The Commission, the European Parliament and the Council have strongly affirmed the Union's commitment to scaling up global health emergency preparedness.

- **Consistency with other Union policies**

The proposed measures are in line with the overarching objectives of the Union. These include a stronger European Health Union, the smooth functioning of the internal market, fostering sustainable health systems including through the cohesion policy that supports regional authorities' investments in public health and supporting cross-border cooperation notably in neighbouring regions, global health security preparedness, improved preparedness to protect workers[12], and an ambitious research and innovation agenda. The proposal will also provide synergies with the Union's Digital Single Market agenda and in the context of the future European Health Data Space, by encouraging innovation and research, facilitating the sharing of information and data (including of real world evidence), and supporting the

6 COM/2020/725 final.
7 OJ L 107, 26.3.2021, p. 1.
8 OJ L 347, 20.12.2013, p. 924.
9 OJ L 70, 16.3.2016, p. 1.
10 COM(2020) 761
11 COM(2019) 640 final.
12 COM(2021) 323 final, EU strategic framework on health and safety at work 2021-2027. Occupational safety and health in a changing world of work.

development of a Union-level IT infrastructure for monitoring medical countermeasures.

The measures will also further strengthen the framework of preparedness and response to threats of biological, chemical, or unknown origin threats at Union level, as well as human, animal and environmental health in a coordinated One Health approach. This framework also includes the Union's One Health Action Plan against antimicrobial resistance (AMR)[13] as well as the EU's Action Plan to enhance preparedness against chemical, biological, radiological and nuclear security risks[14].

Many EU policy areas are currently drawing the lessons from the crisis and the need for dedicated measures to be ready to be put in place in the event of a crisis.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

Given that the proposal for this Regulation aims to ensure the supply and the timely availability and accessibility of crisis-relevant medical countermeasures addressing the economic impacts caused by public health emergencies, it is based on Article 122(1) of the Treaty on the Functioning of the European Union (TFEU). The Council may act pursuant to Article 122(1) TFEU to adopt measures that are appropriate to address the economic situation, in particular if severe difficulties arise in the supply of certain products.

- **Subsidiarity (for non-exclusive competence)**

Public health emergencies of the magnitude of the COVID-19 pandemic have an impact on all Member States. Actions by individual Member States could neither address the challenges resulting from such an emergency nor are they able to provide a sufficient response on their own. Unilateral action through Member State initiatives aiming to ensure the sufficient and timely availability and supply of crisis-relevant medical countermeasures runs the risk of increasing internal competition and sub-optimal Union level response. Such unilateral action can ultimately result in significant economic consequences and affect the health of Union citizens.

In particular, in a highly interconnected and interdependent world, people and goods move across borders and pathogens and contaminated products can circulate rapidly across the globe. Public health measures at national level therefore need to be coordinated across borders and in the area of crisis-relevant medical countermeasures, in order to contain further spread and minimise the consequences of such threats. Where appropriate to the economic situation, a coordinated response at Union-level to ensure the availability and accessibility of crisis-relevant medical countermeasures can help avoiding uncoordinated investments across Member States.

- **Proportionality**

The proposal constitutes a proportionate response to addressing the problems described in point 1, in particular by putting in place a framework in place that will enable the Union to take the necessary measures to ensure the sufficient and timely

[13] https://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/amr_2017_action-plan.pdf.
[14] COM(2017) 610 final.

availability and supply of crisis-relevant medical countermeasures in case of a public health emergency at Union level where that is appropriate to the economic situation.

In accordance with the principle of proportionality, as set out in Article 5 of the Treaty on European Union, this proposal and the measures proposed do not go beyond what is necessary in order to achieve those objectives.

- **Choice of the instrument**

The proposal takes the form of a Council Regulation. This is considered to be the most suitable instrument as a key element of the proposal is to establish procedures and structures for cooperation on joint, Union-level work focussing on response to cross-border health emergencies. The measures do not require the implementation of national measures and can be directly applicable.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Stakeholder consultations**

The framework of measures to be activated to strengthen the response in the event of a public health emergency was not, as such, subject to consultation, but there has been a thorough consultation with relevant stakeholder groups about the setting up of HERA to ensure that their views were presented and considered in the policymaking process. That feedback gave insight in the emergency measures that are considered necessary for an effective response and informed the proposal for this Regulation.

More specifically, the following consultation activities were carried out:

- a 4-week feedback period on the Inception Impact Assessment (27 January to 24 February 2021);
- a 6-week internet-based public consultation (31 March to 12 May 2021), which received contributions from 135 stakeholders[15]; and
- targeted consultations with stakeholders, via the creation of a High Level Group with Member States, a 'Sherpa' group with the industry, as well as bilateral meetings with Member States, international actors, and the European Parliament.

Overall, the Commission has received support for the creation of HERA, with stakeholders noting the clear added value of this initiative as well as the need for the Union to increase its activities related to crisis-relevant medical countermeasures for preparedness and crisis management. Given the broadly shared view that there is a need for swift and effective response at Union level, the Commission proposes a set of emergency measures that can be activated in the event of health emergencies to ensure such a swift and effective response.

- **Collection and use of expertise**

N/A

[15] Factual summary report on the public consultation on the European Health Emergency Preparedness and Response Authority (HERA): https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12870-European-Health-Emergency-Preparedness-and-Response-Authority-HERA-/public-consultation_en.

- **Impact assessment**

  Due to the urgency of the matter to strengthen the emergency framework in preparation of a future public health emergency, this proposal is not accompanied by a formal impact assessment, as this could not have been delivered in the timeframe available prior to the adoption of the proposal. As regards medical devices and *in vitro* diagnostic medical devices, the proposal however takes into account the impact assessment carried out in preparation for the adoption of Regulation (EU) 2017/745 of the European Parliament and of the Council[16] and Regulation (EU) 2017/746 of the European Parliament and of the Council[17]. The proposal also draws on the recommendations contained in the joint opinion 'Improving pandemic preparedness and management' by the Group of Chief Scientific Advisors (GCSA)[18], the European Group on Ethics in Science and New Technologies (EGE), and the Special Advisor to the President of the European Commission on the response to COVID-19.

- **Fundamental rights**

  The proposal contributes to achieving a high level of human health protection as well as to upholding the highest standards in the protection of human rights and civil liberties, as enshrined in the Charter of Fundamental Rights of the European Union ('the Charter'). The measures under this Regulation may limit the freedom to conduct business and the freedom of contract, which are protected by Article 16 of the Charter and the right to property, protected by Article 17 of the Charter. Any limitation of those rights will, in accordance with Article 52(1) of the Charter, be provided for by law, respect the essence of those rights and freedom, and comply with the principle of proportionality.

  Where the activities to be carried out pursuant to this Regulation involve the processing of personal data, the lawfulness of that processing will be based on the acts assigning their tasks to the different actors involved, not this Regulation. Any such processing must comply with the relevant Union legislation on personal data protection, namely Regulation (EU) 2018/1725 of the European Parliament and of the Council[19] and Regulation (EU) 2016/679 of the European Parliament and of the Council[20].

4. BUDGETARY IMPLICATIONS

In the event of a public health emergency at Union level, in order to ensure the necessary flexibility and rapidity in implementation, the Council could also trigger

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16 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 295, 21.11.2018, p. 39).

17 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 119, 4.5.2016, p. 1).

18 https://op.europa.eu/en/publication-detail/-/publication/a1016d77-2562-11eb-9d7e-01aa75ed71a1

19 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).

20 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).

financing through the Emergency Support Instrument (ESI).[21] As ESI does not have an annual dedicated budget, when it is activated, the Commission will analyse the necessity of transferring funding from existing programmes or resort to Special Instruments. As foreseen under Article 4 of Council Regulation (EU) 2016/369, contributions could also be made by Member States (and by other public or private donors as external assigned revenue) in accordance with Article 21(5) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council.[22]

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The Commission plans to conduct a review in 2025, or at the latest after the first activation of the emergency measures, on the framework of measures related to medical countermeasures in event of a public health emergency. The main findings of the evaluation will be presented in a report to the European Parliament and the Council.

- **Detailed explanation of the specific provisions of the proposal**

The proposal for a framework for ensuring the supply of medical countermeasures in the event of a public health emergency puts forward the following key measures:

- the establishment of a Health Crisis Board to ensure coordination and integration of approaches to crisis-relevant medical countermeasures at a 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, including swift and solid assessment of supply chains and production capacity of manufacturers, possibly also by on-site visits ahead of the conclusion of advanced purchase agreement or innovation partnership;
- the activation of EU FAB facilities to make available reserved surge manufacturing capacities to ensure the delivery of the crisis-relevant medical countermeasures and raw materials;
- the activation of emergency research and innovation plans in dialogue with Member States, 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, including the establishment of an inventory of crisis-relevant medical countermeasures production and production facilities, raw materials, consumables, devices, equipment and infrastructure and including measures aiming at increasing their production in the EU.

[21] 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).

[22] 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.

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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, the 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.

(3) In the event of recognition of a public health emergency at Union level, the Council may, upon the proposal of the Commission, decide to activate the framework of measures to the extent that those measures are appropriate to the economic situation. The use of measures within this framework should be limited in time to 6 months, after which they can be prolonged in view of the situation.

(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 be entitled to set up sub-groups, including if needed for industrial aspects.

(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)][23], close cooperation and coordination between the Commission and EMA should be ensured to implement the measures provided for in this Regulation. If use is made of the possibility to establish a 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.

(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)][24], 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)][25], 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.

(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. This should allow key actors and relevant infrastructure to be immediately ready for operation in times of public health emergencies, thereby reducing any delays.

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23 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].

24 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].

25 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].

(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 to act as a central procurement body for Member States, using rules and procedures under Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council[26] as well as Council Regulation (EU) 2016/369[27].

(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 rapid 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 provision of the countermeasures in the required quantity and with all necessary guarantees.

(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, under the 'EU-FAB'. As outlined in the Communication 'HERA Incubator: Anticipating together the threat of COVID-19 variants'[28] , 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.

(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.

(13) Council Regulation (EU) 2016/369[29] 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.

(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

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26 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*)*.

27 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).

28 COM/2021/78 final.

29 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).

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,

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 measures 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 funding and financing;

   (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 measures referred to in paragraph 1 may be activated only to the extent that they are appropriate to the economic situation.

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;

(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.

2. The Council shall set out in the Regulation activating the emergency framework which of the measures as set out in Articles 5 to 11 and 13 are appropriate to the economic situation and which measures are therefore to be activated.

3. The duration of the activation is 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[30] and the overall coordination role of the Emergency Response Coordination Centre under the Union Civil Protection Mechanism.

Article 4

Prolongation and expiry of the activation of the emergency framework

1. No later than 1 week before the expiry of the duration for which the emergency framework was activated, the Commission shall submit to the Council a report 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.

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. The prolongation shall not exceed 6 months. The Council may

[30] 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.

repeatedly decide to prolong the activation of the emergency framework where that is appropriate to the economic situation.

3. The Commission may propose to the Council to adopt a regulation activating additional measures set out in Articles 5 to 11 and 13 in addition to those measures that it had already activated, where that is appropriate to the economic situation.

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

Article 5

Establishment of the Health Crisis Board

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

   The coordination shall, in particular, be aimed at supporting the Commission in the preparation of measures to be taken pursuant to Articles 6 to 11 and 13.

2. The Health Crisis Board shall be composed of the Commission and one representative from each Member State. 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 Commission 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 shall invite a representative from the European Parliament and a member of the Health Security Committee as observers 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 SCBTH Regulation];

   (c) 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.

4. The Commission 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, experts from the private sector as well as other stakeholders, with respect to a subject matter on the agenda, to take part 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.

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

8. The Commission may set up working groups 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.

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 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.

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 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. Member States shall provide the Commission with information based on the monitoring template referred to in paragraph 1.

4. Where a Member State intends to adopt measures for the procurement, purchase or manufacturing of crisis-relevant medical countermeasures or raw materials, it shall inform and consult the Health Crisis Board.

5. Upon request of the Commission, 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 information through a secured IT system and monitor 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 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[31].

The Commission shall make available to the European Parliament and the Council 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.

Article 7

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

1. Where this measure is activated, a negotiating mandate shall be established by the Commission on behalf of 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 negotiation of new contracts using all 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.

2. Without prejudice to paragraph 1 above, procurement under this Regulation 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[32] for its own procurement. 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 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

[31] 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).

[32] 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).

from the procurement carried out for the purposes of this Regulation, no later than 24 hours as from the award.

3. In line with the negotiating mandate given to it, the Commission may have the ability and responsibility, on behalf of all participating Member States, 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 the production or the development of such countermeasures in exchange for a 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 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 of 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 purchasing agreements. The deployment and use of the crisis-relevant medical countermeasures shall remain the responsibility of the participating Member States.

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 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 networks for clinical trials and observational studies, 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.

3. In setting up actions on clinical trials, the Commission shall involve the EMA Emergency Task force established by Regulation (EU) …/… [the EMA Regulation] as well as ensure 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, establish an inventory, and for this purpose 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, and to transmit to the Commission a schedule of the expected production output for the following 3 months for each Union production facility.

2. 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.

3. 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 provided for in Article 9 to crisis-relevant 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 shall, when it considers that there is a risk of a shortage of crisis-relevant raw materials, consumables, devices, equipment and infrastructure, implement together with the relevant Member States 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 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;

   (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 financial incentives necessary to ensure the rapid implementation of the measures referred to in paragraph 2.

Article 12

Review

By 2025 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.

Article 13

Activation of emergency funding

Where this measure is activated, emergency support under Regulation (EU) 2016/369 is activated to finance expenditure necessary to address the public health emergency in accordance with this Regulation.

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

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LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

European Health Emergency Preparedness and Response Authority (HERA)

1.2. Policy area(s) concerned

Heading 1: Single market, innovation and digital

Heading 2b: Resilience and values

1.3. The proposal/initiative relates to:

X **a new action**

☐ **a new action following a pilot project/preparatory action**[33]

☐ **the extension of an existing action**

☐ **a merger or redirection of one or more actions towards another/a new action**

1.4. Objective(s)

1.4.1. General objective(s)

The HERA would seek to improve public health by strengthening the EU's preparedness and response for serious cross-border threats to health, both of natural and intentional origin.

1.4.2. Specific objective(s)

Specific objective No

1. Ensure timely availability and equitable access to medical countermeasures during a cross-border threat to health
2. Improve intelligence gathering, analysis and sharing on serious cross-border health threats, identify and address raw material dependencies as well as market and regulatory challenges/failures
3. Improve medical countermeasures development and production, setting up structures to integrate research and technological development projects
4. Coordinate action on medical countermeasures between national competent authorities, public buyers, industrial and research stakeholders, as well as global actors

1.4.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

Specific objective No 1:

Ensure timely availability and equitable access to medical countermeasures during a cross-border threat to health

Expected result(s) and impact:

[33] As referred to in Article 58(2)(a) or (b) of the Financial Regulation.

Better preparedness in terms of availability and supply (procurement, stockpiling, reservation) of critical medical countermeasures.

Specific objective No 2:

Improve intelligence gathering, analysis and sharing on serious cross-border health threats, identify and address raw material dependencies as well as market and regulatory challenges/failures

Expected result(s) and impact:

Anticipatory threat assessment, horizon scanning, market intelligence, foresight of serious cross-border threats to health at EU level

Specific objective No 3:

Improve medical countermeasures development and production, setting up structures to integrate research and technological development projects.

Expected result(s) and impact:

Better integration of advanced research, innovation and development of corresponding technologies and countermeasures (including end stage R&D, clinical trials and regulatory pathways).

Ensuring production, establishing EU flexible and scalable manufacturing capacities for the production of crisis-relevant countermeasures (including crisis relevant raw materials) adequate to respond to health emergencies.

Specific objective No 4:

Coordinate action on medical countermeasures between national competent authorities, public buyers, industrial and research stakeholders, as well as global actors.

Expected result(s) and impact:

Capacity building in Member States e.g. through trainings, expert exchanges

International engagement and reinforcement for medical countermeasures access and development, as well as threat assessments, surveillance and capacity building

1.4.4. Indicators of performance

Specify the indicators for monitoring progress and achievements.

General objectives:

I. Strengthening the EU's preparedness and response for serious cross-border threats to health, both of natural and intentional origin.

Indicator 1: Sufficient and timely availability of critical medical countermeasures in case of a crisis.

Indicator 2: Scaled up production/stockpiling/reservation of critical medical countermeasures to ensure an equitable access to them.

Indicator 3: Improved preparedness and response planning for serious cross-border threats to health in the area of medical countermeasures at the national and EU level.

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative

The current COVID-19 crisis has shown that emergency preparedness and response must be given higher priority. It demonstrated the need for coordinated EU level action to respond to health emergencies. It revealed gaps in foresight, including demand/supply dimensions, and preparedness and response tools. The European Health Emergency Preparedness and Response Authority (HERA) is a central element for strengthening the European Health Union with better EU preparedness and response to serious cross-border health threats, by enabling rapid availability, access and distribution of needed countermeasures

1.5.2. Added value of Union involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this point 'added value of Union involvement' is the value resulting from Union intervention which is additional to the value that would have been otherwise created by Member States alone.

Reasons for action at European level (ex-ante):

The current COVID pandemic has revealed the importance of preparedness and response capacities of the Member States to swiftly react to health emergencies which require an engagement across borders.

Expected generated Union added value (ex-post):

A strong, legally sound and financially well equipped framework for EU health crisis preparedness and response, able to cope with cross-border health threats, including those from outside the EU, where EU intervention can add tangible value. The social and economic activity in the EU should be secured in all times. From a post-crisis recovery perspective, the HERA will make an important contribution to ensuring that the EU will be better prepared to face future health threats affecting the whole or large parts of its territory.

1.5.3. Lessons learned from similar experiences in the past

No similar experience in the past.

1.5.4. Compatibility with the Multiannual Financial Framework and possible synergies with other appropriate instruments

The HERA will be using funds within existing programmes under the MFF 2021-2027 such as the EU4Health programme, Horizon Europe Health Cluster, UCPM/RescEU. It will work in synergy and complementarity with existing EU policies and funds such as actions implemented under the Digital Europe Programme, the InvestEU fund, Single Market Programme, European Regional Development Fund or the Recovery and Resilience Facility.

1.5.5. Assessment of the different available financing options, including scope for redeployment

1.6. Duration and financial impact of the proposal/initiative

☐ Proposal/initiative of **limited duration**

☑ **unlimited duration**

– Implementation with an estimated start-up period from September 2021 till middle of 2023,

– followed by full-scale operation.

1.7. Management mode(s) planned[34]

☑ **Direct management** by the Commission

– ☑ by its departments, including by its staff in the Union delegations;

– ☑ by the executive agencies

☐ **Shared management** with the Member States

☑ **Indirect management** by entrusting budget implementation tasks to:

– ☐ third countries or the bodies they have designated;

– ☐ international organisations and their agencies (to be specified);

– ☐ the EIB and the European Investment Fund;

– ☑ bodies referred to in Articles 70 and 71 of the Financial Regulation;

– ☐ public law bodies;

– ☐ bodies governed by private law with a public service mission to the extent that they provide adequate financial guarantees;

– ☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that provide adequate financial guarantees;

– ☐ persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU, and identified in the relevant basic act.

– *If more than one management mode is indicated, please provide details in the 'Comments' section.*

Comments

Part of the activities envisaged to be managed by HERA and currently foreseen under specific EU programme (EU4Health / Horizon) are delegated to executive agencies. The HERA may decide to further delegate part of the implementation of its programmes to an executive agency.

Moreover it may entrust decentralised Agencies (ECDC, EMA, EFSA, ECHA, Europol, EMCDDA, European Climate and Health Observatory) with tasks aiming to achieve the objectives of the HERA.

Indirect management with international organisations:

[34] Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: https://myintracomm.ec.europa.eu/budgweb/EN/man/budgmanag/Pages/budgmanag.aspx

For the implementation of its mandate, cooperation with international organisations like UN agencies, notably the WHO, Council of Europe, OECD, or any other relevant international organisations will be ensured, extended or pursued.

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

Performance frameworks will be developed within the programmes being implemented by HERA, building on the relevant practices of the programmes 2021-2027 to ensure that data is collected efficiently, effectively and timely.

2.2. Management and control system(s)

2.2.1. Justification of the management mode(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed

The HERA will be implemented through direct and indirect management, using the implementation modes offered by the Financial Regulation, mainly being grants and procurement. Direct management allows to establish grant agreements/contracts with beneficiaries/contractors directly engaged in activities that serve Union policies. The Commission ensures direct monitoring over the outcome of the actions financed. The payment modalities of the actions funded will be adapted to the risks pertaining to the financial transactions.

In order to ensure the effectiveness, efficiency and economy of the Commission controls, the control strategy will be oriented towards a balance of ex-ante and ex-post checks and focus on three key stages of grant/contract implementation, in accordance with the Financial Regulation:

– Selection of proposals/tenders that fit the policy objectives of the programme;

– Operational, monitoring and ex-ante controls that cover project implementation, public procurement, pre-financing, interim and final payments, management of guarantees;

Ex-post controls at the beneficiaries/contractors' sites will also be carried out on a sample of transactions. The selection of these transactions will combine a risk assessment and a random selection.

2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them

The implementation of the HERA focuses on the attribution of public procurement contracts as well as a number of grants for specific activities and organisations.

The public procurement contracts will mainly be concluded in areas such as procurement of medicines, vaccines, potential new treatments, surveys, studies, collection of data, benchmark exercises, monitoring and assessment activities, information campaigns, IT and communication services, etc. The contractors are mainly consultancy firms and other private companies; institutes and laboratories might also be main contractors.

Grants will mainly be awarded for support activities to competent authorities of the Member States, health organisations, national agencies, etc. The period of execution of the subsidised projects and activities varies from one to three years mostly.

The main risks are the following:

• Risk of not fully achieving the objectives of the programme due to insufficient uptake or quality/delays in the implementation of the selected projects or contracts;

• Risk of inefficient or non-economic use of funds awarded, both for grants (complexity of funding rules) and for procurement (limited number of economic providers with the required specialist knowledge entailing insufficient possibilities to compare price offers in some sectors);

• Reputational risk for the Commission, if fraud or criminal activities are discovered; only partial assurance can be drawn from the third parties' internal control systems due to the rather large number of heterogeneous contractors and beneficiaries, each operating their own control system.

The Commission puts in place internal procedures that aim at covering the risks identified above. The internal procedures are in full compliance with the Financial Regulation and include anti-fraud measures and cost-benefit considerations. Within this framework, the Commission continues to explore possibilities to enhance the management and to realise efficiency gains. Main features of the control framework are the following:

Controls before and during the implementation of the projects:

• An appropriate project management system will be put in place focussing on the contributions of projects and contracts to the policy objectives, ensuring a systematic involvement of all actors, establishing a regular project management reporting complemented by on-site-visits on a case by case basis, including risk reports to senior management, as well as maintaining appropriate budgetary flexibility.

• Model grant agreements and service contracts used are developed within the Commission. They provide for a number of control provisions such as audit certificates, financial guarantees, on-site audits as well as inspections by OLAF. The rules governing the eligibility of costs are being simplified, for example, by using unit costs, lump sums, contributions not linked to costs and other possibilities offered by the Financial Regulation. This will reduce the cost of controls and put the focus on checks and controls in high risk areas.

• All staff sign up to the code of good administrative behaviour. Staff who are involved in the selection procedure or in the management of the grant agreements/contracts (also) sign a declaration of absence of a conflict of interest. Staff is regularly trained and uses networks to exchange best practices.

• Technical implementation of a project is checked at regular intervals at the desk on the basis of technical progress reports of the contractors and beneficiaries; in addition contractors'/beneficiaries' meetings and on-site-visits are foreseen on a case by case basis.

Controls at the end of the project: Ex-post audits are performed on a sample of transactions to verify on-the-spot the eligibility of cost claims. The aim of these controls is to prevent, detect and correct material errors related to the legality and regularity of financial transactions. With a view to achieving a high control impact, the selection of beneficiaries to be audited foresees to combine a risk based selection with a random sampling, and to pay attention to operational aspects whenever possible during the on-site audit.

2.2.3. Estimation and justification of the cost-effectiveness of the controls (ratio of "control costs ÷ value of the related funds managed"), and assessment of the expected levels of risk of error (at payment & at closure)

As a reference, the yearly costs of the suggested level of controls under the Health programme 2014-2020 represented approximately 4 to 7% of the yearly budget of the operational expenditure. This was justified by the diversity of transactions to be controlled, and implementation through direct management involving the attribution of numerous contracts and grants for actions of very small to large sizes. The Commission considers that the average costs of controls is likely to decrease in view of the extended scope and increased budget of the programmes.

The HERA will earmark credits within several programmes to ensure its implementation. The existing control system for these programmes should be able to prevent and/or to detect errors and/or irregularities, and in case of errors or irregularities, to correct them. It will ensure that residual error rates (after correction) remain below the threshold of 2%.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures, e.g. from the Anti-Fraud Strategy.

As for its activities in direct and indirect management, the Commission shall take appropriate measures ensuring that the financial interests of the European Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportional and deterrent penalties. To this effect, the Commission adopted an anti-fraud strategy, latest update of April 2019 (COM(2019) 176), covering notably the following preventive, detective and corrective measures:

The Commission or its representatives and the Court of Auditors shall have the power of audit, on the basis of documents and on-the-spot, over all grant beneficiaries, contractors and subcontractors who have received Union funds. OLAF shall be authorised to carry out on-the-spot checks and inspections on economic operators concerned directly or indirectly by such funding.

The Commission also implements a series of measures such as:

- decisions, agreements and contracts resulting from the implementation of the programme will expressly entitle the Commission, including OLAF, and the Court of Auditors to conduct audits, on-the-spot checks and inspections and to recover amounts unduly paid and, where appropriate, impose administrative sanctions;

- during the evaluation phase of a call for proposals/tender, the applicants and tenderers are checked against the published exclusion criteria based on declarations and the Early Detection and Exclusion System (EDES);

- the rules governing the eligibility of costs will be simplified in accordance with the provisions of the Financial Regulation;

- regular training on issues related to fraud and irregularities is given to all staff involved in contract management as well as to auditors and controllers who verify the beneficiaries' declarations on the spot.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading multiannual financial framework	Budget line	Type of expenditure	Contribution			
		Diff./Non-diff.	from EFTA countries	from candidate countries	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation
1	01 02 02 10 - Horizon Europe	Diff.	Yes	Yes	Yes	No
2b	06 06 01 - EU4Health Programme	Diff.	Yes	Yes	Yes	No
2b	06 05 01 - Union Civil Protection Mechanism (rescEU)	Diff.	Yes	Yes	Yes	No
	Other programmes as detailed in the Communication, section xx (budget lines to be further detailed)					
Budget lines for use in times of crisis (no budget allocation foreseen in tables below)						
2b	06 07 01 - Emergency Support Instrument	Diff.	No	No	No	No

3.2. Estimated financial impact of the proposal on appropriations

3.2.1. Summary of estimated impact on operational appropriations

– ☐ The proposal/initiative does not require the use of operational appropriations

– X The proposal/initiative requires the use of operational appropriations, as explained below (all appropriations indicated will be covered by redeployement under the Horizon cluster 4 Health, UCPM, EU4Health and other programmes)

EUR million (to three decimal places)

Heading of multiannual financial framework	**1**	**Single Market, Innovation and Digital**

DG: RTD			**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	***Post 2027***	**TOTAL**
• Operational appropriations (C1 and NGEU credits)											
01 02 02 10 – Horizon Europe [3536]	Commitments	(1)		394.553	418.135	212.937	222.619	229.512	231.272		**1 709.027**
	Payments	(2)		157.821	285.620	328.981	278.369	222.471	228.148	207.616	**1 709.027**
• Appropriations of an administrative nature financed from the envelope of specific programmes											
01 01 – Support expenditure	Commitments = Payments	(3)		pm	pm	pm	pm	pm	pm		**pm**
TOTAL appropriations from budgetary procedures for the envelope of the programme	Commitments	=1+1 a +3		394.553	418.135	212.937	222.619	229.512	231.272		**1 709.027**
	Payments	=2+2		157.821	285.620	328.981	278.369	222.471	228.148	207.616	**1 709.027**

35 Other budget lines under Horizon Europe programme may also be contributing

36 This amount includes the potential contribution to an executive agency as well as technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research which will be charged on support expenditure lines (in p.m).

		a +3									

EUR million (to three decimal places)

Heading of multiannual financial framework	**2b**	**Resilience and Values**

DG: SANTE			**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	***Post 2027***	**TOTAL**
• Operational appropriations (C1 credits)											
06 06 01 – EU4Health programme[37]	Commitments	(1)		274.883	243.145	474.048	484.140	492.488	826.514		**2 795.218**
	Payments	(2)		82.465	155.409	325.111	384.714	482.608	589.357	775.555	**2 795.218**
• Appropriations of an administrative nature financed from the envelope of specific programmes											
06 01 05 - Support	Commitments = Payments	(3)		pm	pm	pm	pm	pm	pm		**pm**
TOTAL appropriations from budgetary procedures for the envelope of the programme	Commitments	=1+1 a +3		274.883	243.145	474.048	484.140	492.488	826.514	0.000	**2 795.218**
	Payments	=2+2 a +3		82.465	155.409	325.111	384.714	482.608	589.357	775.555	**2 795.218**

[37] This amount includes the potential contribution to an executive agency as well as technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research which will be charged on support expenditure line (in p.m).

EUR million (to three decimal places)

Heading of multiannual financial framework	**2b**	**Resilience and Values**

DG: ECHO			**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	***Post 2027***	**TOTAL**
• Operational appropriations (NGEU credits)											
06 05 01 – UCPM/RescEU[38]	Commitments	(1)		630.000	636.000	pm	pm	pm	pm		**1 266.000**
	Payments	(2)		189.000	379.800	442.800	254.400	0.000	0.000		**1 266.000**
• Appropriations of an administrative nature financed from the envelope of specific programmes											
06 01 04 - support	Commitments = Payments	(3)		pm	pm	pm	pm	pm	pm		**pm**
TOTAL appropriations from budgetary procedures for the envelope of the programme	Commitments	=1+1a +3		630.000	636.000	0.000	0.000	0.000	0.000		**1 266.000**
	Payments	=2+2a +3		189.000	379.800	442.800	254.400	0.000	0.000		**1 266.000**

38 This amount includes the cost of technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research which will be charged on the support expenditure line (in p.m).

Heading of multiannual financial framework	2b	Resilience and Values

DG			2021	2022	2023	2024	2025	2026	2027	*Post 2027*	TOTAL
• Operational appropriations											
06 07 01 – Emergency Support Instrument	Commitments	(1)		pm	pm	pm	pm	pm	pm		**pm**
	Payments	(2)		pm	pm	pm	pm	pm	pm		**pm**
Appropriations of an administrative nature financed from the envelope of specific programmes											
06 01 03 - support	Commitments = Payments	(3)		pm	pm	pm	pm	pm	pm		**pm**
TOTAL appropriations from budgetary procedures for the envelope of the programme	Commitments	=1+1a +3		pm	pm	pm	pm	pm	pm		**pm**
	Payments	=2+2a +3		pm	pm	pm	pm	pm	pm		**pm**

			2021	2022	2023	2024	2025	2026	2027	*Post 2027*	TOTAL
• Operational appropriations (C1 credits)											
Other programmes as detailed in the Communication (budget lines to be further detailed)	Commitments	(1)		41.167	41.167	41.167	41.167	41.167	**41.167**		**247.000**
	Payments	(2)		12.350	24.700	41.167	41.167	41.167	41.167	45.283	**247.000**
• Appropriations of an administrative nature financed from the envelope of specific programmes[39]											
	Commitments = Payments	(3)		pm	pm	pm	pm	pm	pm		**pm**
TOTAL appropriations from budgetary procedures for the envelope of the programme	Commitments	=1+1a +3		41.167	41.167	41.167	41.167	41.167	41.167	0.000	**247.000**
	Payments	=2+2a +3		12.350	24.700	41.167	41.167	41.167	41.167	45.283	**247.000**

• TOTAL operational appropriations (all operational headings)	Commitments	(4)		1.340.603	1.338.447	728.152	747.926	763.167	1.098.953	0	6.017.245
	Payments	(5)		441.636	845.529	1.138.059	958.650	746.246	858.672	1.028.454	6.017.245
TOTAL appropriations of an administrative nature financed from the envelope for specific programmes (all operational headings)		(6)		pm	pm	pm	pm	pm	pm		**pm**
TOTAL appropriations under HEADINGS 1 to 6 of the multiannual financial framework (Reference amount)	Commitments	=4+6		1.340.603	1.338.447	728.152	747.926	763.167	1.098.953	0	6.017.245
	Payments	=5+6		441.636	845.529	1.138.059	958.650	746.246	858.672	1.028.454	6.017.245

[39] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research. This amount includes the potential contribution to an executive agency.

Heading of multiannual financial framework	**7**	'Administrative expenditure'

This section should be filled in using the 'budget data of an administrative nature' to be firstly introduced in the Annex to the Legislative Financial Statement (Annex V to the internal rules), which is uploaded to DECIDE for interservice consultation purposes.

EUR million (to three decimal places)

		2021	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**TOTAL**
HERA									
• Human resources		5.776	11.148	14.644	14.644	14.644	14.644	14.644	90.144
• Other administrative expenditure			0.818	0.864	0.864	0.864	0.864	0.864	5.138
TOTAL appropriations under HEADING 7 – HERA	Appropriations	**5.776**	**11.966**	**15.508**	**15.508**	**15.508**	**15.508**	**15.508**	**95.282**

TOTAL appropriations under HEADING 7 of the multiannual financial framework	(Total commitments = Total payments)	**5.776**	**11.966**	**15.508**	**15.508**	**15.508**	**15.508**	**15.508**	**95.282**

EUR million (to three decimal places)

		2021	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	***Post 2027***	**TOTAL**
TOTAL appropriations under HEADINGS of the multiannual financial framework **– from budgetary procedures**	Commitments	5.776	1.352.569	1.353.955	743.660	763.434	778.675	1.114.461	0	6.112.527
	Payments	5.776	453.602	861.037	1.153.567	974.158	761.754	874.180	1.028.454	6.112.527

3.2.2. Estimated output funded with operational appropriations

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs ⇩			**2021**		**2022**		**2023**		**2024**		**2025**		**2026**		**2027**		**TOTAL**	
	OUTPUTS																	
	Type[40]	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No	Total cost
SPECIFIC OBJECTIVE No 1[41]…																		
- Output																		
- Output																		
- Output																		
Subtotal for specific objective No 1																		
SPECIFIC OBJECTIVE No 2 ...																		
- Output																		
Subtotal for specific objective No 2																		
TOTALS																		

40 Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

41 As described in point 1.4.2. 'Specific objective(s)…'

3.2.3. Summary of estimated impact on administrative appropriations

– ☐ The proposal/initiative does not require the use of appropriations of an administrative nature

– X The proposal/initiative requires the use of appropriations of an administrative nature, as explained below:

EUR million (to three decimal places)

	2021	2022	2023	2024	2025	2026	2027	TOTAL
HEADING 7 of the multiannual financial framework								
Human resources	5.776	11.148	14.644	14.644	14.644	14.644	14.644	90.144
Other administrative expenditure		0.818	0.864	0.864	0.864	0.864	0.864	5.138
Subtotal HEADING 7 of the multiannual financial framework	**5.776**	**11.966**	**15.508**	**15.508**	**15.508**	**15.508**	**15.508**	**95.282**
Outside HEADING 7[42] of the multiannual financial framework								
Human resources	1.240	1.322	1.474	1.474	1.474	1.474	1.474	9.932
Other expenditure of an administrative nature		0.022	0.024	0.024	0.024	0.024	0.024	0.142
Subtotal outside HEADING 7 of the multiannual financial framework	**1.240**	**1.344**	**1.498**	**1.498**	**1.498**	**1.498**	**1.498**	**10.074**
TOTAL	**7.016**	**13.310**	**17.006**	**17.006**	**17.006**	**17.006**	**17.006**	**105.356**

The appropriations required for human resources and other expenditure of an administrative nature will be met by appropriations from the Commission that are already assigned to management of the action and/or have been redeployed within the Commission, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

[42] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

3.2.3.1. Estimated requirements of human resources

– ☐ The proposal/initiative does not require the use of human resources.

– X The proposal/initiative requires the use of human resources, as explained below:

Estimate to be expressed in full time equivalent units

		2021	2022	2023	2024	2025	2026	2027
• Establishment plan posts (officials and temporary staff)								
20 01 02 01 (Headquarters and Commission's Representation Offices)		38	59	82	82	82	82	82
20 01 02 03 (Delegations)								
01 01 01 01 (Indirect research)		6	6	7	7	7	7	7
01 01 01 11 (Direct research)								
Other budget lines (specify)								
• External staff (in Full Time Equivalent unit: FTE)[43]								
20 02 01 (AC, END, INT from the 'global envelope')			26	26	26	26	26	26
20 02 03 (AC, AL, END, INT and JPD in the delegations)								
XX 01 xx **yy zz** [44]	- at Headquarters							
	- in Delegations							
01 01 01 02 (AC, END, INT - Indirect research)		4	5	5	5	5	5	5
01 01 01 12 (AC, END, INT - Direct research)								
Other budget lines (specify)								
TOTAL		**48**	**96**	**120**	**120**	**120**	**120**	**120**

XX is the policy area or budget title concerned.

The appropriations required for human resources and other expenditure of an administrative nature will be met by appropriations from the Commission that are already assigned to management of the action and/or have been redeployed within the Commission, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Memorandum of Understanding will be signed between HERA and SANTE to ensure the adminsitrative support tasks of HERA. In this respect, 10 posts will be kept within DG SANTE (in addition to the 120 posts in HERA) for tasks that will be defined later in the domains of budget and financial management, document management, IT services, data protection and/or others.

43 AC= Contract Staff; AL = Local Staff; END= Seconded National Expert; INT = agency staff; JPD= Junior Professionals in Delegations.

44 Sub-ceiling for external staff covered by operational appropriations (former 'BA' lines).

Description of tasks to be carried out:

Officials and temporary staff	The HERA staffing need will be mainly consist of experts (AD level) in the following areas: clinical scientists, experts in infectious diseases, experts in virology, experts in epidemiology, data scientists, engineers, regulatory and quality specialists, experts in manufacturing, logistics and supply chain management, legal experts (e.g. procurement experts, EU legal pharmaceutical experts, etc.), project managers, experts in health emergencies, experts in public health, experts in global health policy, experts in healthcare systems, and communication experts. A specialised competition is ongoing for Health experts and will deliver laureates in 2022. In case an insufficient number of Officials can be found to fill the posts, a selection for temporary agents could be launched and/or temporary agents 2b will be hired on the permanent posts.
External staff	The HERA will need to collaborate closely with the Member States. The creation of 12 END positions will contribute to bringing to pass this collaboration and will also allow bringing in experts from national administrations. In addition, 20 Contract agents will ensure operational administrative and technical support tasks.

3.2.4. Compatibility with the current multiannual financial framework

The proposal/initiative:

– X can be fully financed through redeployment within the relevant heading of the Multiannual Financial Framework (MFF).

Redeployment of appropriations under the Horizon Health cluster, UCPM and EU4Health programmes; in addition, redeployments of a more limited magnitude in other programmes (to be further defined but could include the Digital Europe Programme, the Single Market Programme…).

– hand/or use of the special instruments as defined in the MFF Regulation.

In time of crisis, the Emergency Support Instrument could be mobilised and financed, inter alia, by the margin available under the relevant heading or special instruments.

– ☐ requires a revision of the MFF.

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

3.2.5. Third-party contributions

The proposal/initiative:

– ☑ does not provide for co-financing by third parties

– ☐ provides for the co-financing by third parties estimated below:

Appropriations in EUR million (to three decimal places)

	2021	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	Total
Specify the co-financing body								
TOTAL appropriations co-financed								

3.3. Estimated impact on revenue

– X The proposal/initiative has no financial impact on revenue.

– ☐ The proposal/initiative has the following financial impact:

  – ☐ on own resources

  – ☐ on other revenue

  – please indicate, if the revenue is assigned to expenditure lines ☐

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative[45]						
		2021	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**
Article …….								

For assigned revenue, specify the budget expenditure line(s) affected.

Other remarks (e.g. method/formula used for calculating the impact on revenue or any other information).

[45] As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 20 % for collection costs.