EUROPEAN
COMMISSION

Brussels, 11.11.2020
COM(2020) 725 final

2020/0321 (COD)

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

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

The unprecedented experience of the COVID-19 pandemic has demonstrated that the Union's ability to coordinate work to ensure the availability of medicinal products and medical devices and facilitate their development is currently limited.

During the COVID-19 crisis, ad hoc solutions needed to be found to contain the risk of shortages of medicines and medical devices such as ventilators, surgical masks and COVID-19 test kits. The operation of these mechanisms during the emergency was made possible by contingent arrangements between the actors involved (the Member States, the Commission, the European Medicines Agency ('the Agency'), the medicinal product marketing authorisation holders, and the medical device manufacturers and authorised representatives). This has in some cases required the Commission and the Agency to take on tasks requiring ad hoc working methods. For these solutions to become efficient and predictable, the respective roles and obligations of the different entities should be clarified and anchored in the relevant legislative framework.

Moreover, for, when a number of medicines purported to treat or prevent COVID-19, the Agency did not always have access to sufficient health data to formulate coordinated recommendations across the Union. The Agency provided scientific advice on their development and ability to fight COVID-19 to the utmost of its ability, but outside of a formal crisis management structure and without the benefit of fast-track scientific advice procedures and obligations on Member States and developers to cooperate. In particular, developers indicated a lack of harmonisation on aspects related to clinical trials, stemming mainly from the fact that each trial needs to be authorised separately in each Member State.

A suitable framework to support the work of the Expert Panels on medical devices as provided for in Regulation (EU) 2017/745[1] should also be provided for in order to ensure that those panels can efficiently and effectively provide scientific advice relevant for crisis preparedness and management, in addition to their core function to provide opinions on the verification by notified bodies of the clinical and performance assessments for certain high-risk medical devices, including certain *in vitro* diagnostic devices. This type of advice is essential for crisis preparedness and management, for example in the context of the COVID-19 pandemic, repurposing production lines for fast production of ventilators with the associated minimal technical and safety specifications.

Therefore, a clear framework for the activities to be deployed by the Agency in preparation for and during public health emergencies and other major events should be established in order to enhance the Union's capacity to react quickly, efficiently, and in a coordinated manner to such emergencies. To be effective and operational in

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC OJ L 117, 5.5.2017, p. 1 as amended by Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions, OJ L 130, 24.4.2020, p. 18.

times of public health emergencies, the approach should be based on strong preparedness. This preparedness can be achieved with the development of common tools and agreed methods for monitoring, reporting and data collection. Gathering data on key medicines and medical devices considered the most likely to be impacted by a health emergency or other major event is also a key priority. In doing so, the proposed Regulation builds on experience from the COVID-19 pandemic so far and on ad hoc solutions set up over the last months as well as the management of previous major events in the context of the established incident management plan. As part of this plan the EU Regulatory Network Incident Management Plan for medicines for human use was developed (Incident Review Network/IRN). [2] This structure is used to continuously monitor events and new information, to review their public health impact and to take the necessary routine measures to remedy the situation. The Incident Review Network will continue its activities taking into account the new management structure in times of crisis provided by the Medicines Steering Group established by the proposed Regulation. The proposed Regulation will complement and further develop the core tasks already given to the Agency in its founding Regulation[3], notably to provide scientific advice and to assess the quality, safety and efficacy of medicinal products as part of their authorisation process.

The general objectives of the proposal are to:

1. ensure a high level of human health protection by strengthening the Union's ability to manage and respond to public health emergencies, which have an impact on medicinal products and medical devices;
2. contribute to ensuring the smooth functioning of the internal market for such products during public health emergencies.

The specific objectives of the proposal are to:

1. monitor and mitigate potential and actual shortages of medicinal products and medical devices considered as critical in order to address a given public health emergency or, for medicinal products, other major events which may have a serious impact on public health;
2. ensure timely development of high quality, safe and efficacious medicinal products with a particular focus on addressing a given public health emergency;
3. ensure smooth functioning of expert panels for the assessment of some high-risk medical devices and avail of essential advice in crisis preparedness and management with regard to the use of medical devices.

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

As part of a package of closely associated measures, the proposal will form part of the Union's overall health response to the COVID-19 pandemic and enhanced crisis management framework. The recognition of a public health emergency in accordance

[2] https://www.ema.europa.eu/en/documents/other/european-union-regulatory-network-incident-management-plan-medicines-human-use_en.pdf

[3] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004, p. 1.

with the proposed Regulation on Cross-Border Health Threats would trigger the activation of the structures provided for within this proposal. The proposed monitoring of potential and actual shortages of medicines and medical devices would provide a clear evidence base, which would inform decisions on the need for medical countermeasures as provided for in that proposed Regulation.

The proposed measures would also complement the considerable body of current Union legislation in the fields of medicinal products and medical devices by supporting the continued implementation of that legislation during times of crisis. By facilitating the development of medicines, which have the potential to treat, prevent or diagnose a disease causing a public health crisis, the proposal will support the implementation of the current legislation on clinical trials. The Agency and Member States can use opinions and recommendations on such medicines in regulatory procedures leading to their authorisation for use within the EU. By providing a permanent structure within the Agency for the functioning of expert panels, the proposal will create the ability to quickly provide scientific advice and technical support on demand in case of crisis and to support the assessment of certain high-risk medical devices.

While not a central component of the proposed Regulation, it shall also contribute indirectly to the EU's international cooperation priorities in the area of global health. Through the work of the Emergency Task Force, the proposed Regulation will not only support Member States but also partner countries, to develop and access potential treatments and vaccines during public health crises, thus supporting the strengthening of health systems and global health security preparedness and response.

- **Consistency with other Union policies**

This proposal is in line with the obligations set out in the Union's Charter of Fundamental Rights and the EU's overarching objectives, including a stronger Health Union, a smooth functioning of the internal market, sustainable and resilient health systems, and an ambitious research and innovation agenda. In addition, the proposal will provide useful input to and synergies with the EU Digital Single Market agenda and in the context of the planned European Health Data Space, encouraging and supporting innovation and research, facilitating access to and analysis of data and information, including real world data (health data generated outside the scope of clinical studies), and by including the Agency in the European Health Data Space IT infrastructure, with the purpose, *inter alia*, of monitoring use and shortages of medicinal products and medical devices. While this proposal provides for a role for the Agency in the European Health Data Space, the details and procedures for processing personal data through that IT infrastructure, including the role of the Agency as a data controller and/or processor will be set out in the planned legislative proposal on that data space.

The proposal contributes to achieving a high level of human health protection and is thus consistent with the Charter of Fundamental Rights in this regard. Where personal data is processed to fulfil the provisions of the proposed Regulation, this will be done in line with the relevant Union legislation on personal data protection, namely Regulation (EU) 2018/1725[4] and Regulation (EU) 2016/679[5] (the General

[4] 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,

Data Protection Regulation (GDPR)) and build on existing procedures and processes within the Agency which are used to meet such requirements.

The proposal is a tailored approach for medicine and medical device management focusing on public health emergency preparedness. These measures will be complemented by additional actions under the Pharmaceutical Strategy for Europe to address structural challenges.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

The proposed Regulation would be based on Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union. Such an approach is based on the general and specific objectives of the proposal, namely to ensure the smooth functioning of the internal market, also during times of crisis, and to ensure the quality and safety of medicinal products and medical devices developed during such periods. This approach is also consistent with the legal basis generally used for Union legislation on medicinal products and medical devices[6].

- **Subsidiarity**

Public health emergencies of the magnitude of COVID-19 have an impact on all Member States, which, on their own are unable to provide a sufficient response. Potential or actual shortages of (nationally and centrally authorised) medicines and medical devices in times of crises can lead to the risk of disproportionate national stockpiling or restrictions to single market movements being placed on such goods. Such measures can have a negative impact on the free movement of goods. A coordinated response at Union-level to monitoring and mitigating the risk of shortages can help the Member States to be better prepared for a sudden increase in demand, avoid export restrictions within the EU or excessive and uncoordinated stockpiling, resulting in an effective allocation of resources at national and Union level, maintaining the smooth functioning of the single market and ensuring an overall positive impact on public health.

Providing scientific advice on medicinal products which have the potential to address public health emergencies at Union-level can facilitate their market entry, ensure a harmonised approach to their use across Member States, and help to ensure such products meet harmonised EU standards for their quality, safety and efficacy. Scientific advice can eliminate duplication of efforts and unnecessary research.

An uncoordinated approach to the development of medicines, which have the potential to treat, prevent, or diagnose diseases causing public health emergencies can cause delays in their development during periods where time is of the essence. Moreover, a lack of clear, Union-level advice on the use of medicines in national compassionate use programmes or outside of their authorised indications can lead to

---

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).

5 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

6 For example: Directive 2001/83/EC, Regulation (EC) No 726/2004, Regulation (EU) 2017/745, and Regulation (EU) 2017/746

a fragmented approach across the Union. In addition, regulators' access to EU-wide health data is limited and scattered across different partners leading to complex and slow analysis, undermining the optimal time window for certain interventions.

- **Proportionality**

The proposal constitutes a proportionate response to address the problems described in section 1. In particular, the proposed requirement of more structured monitoring at Union level will avoid duplication and provide a better overview of shortage issues of a Union-wide interest.

The proposal does not interfere with Member States' competences in decisions on the organisation of health care. The proposal does not interfere with notifications sent by marketing authorisation holders to the competent authorities when a product ceases to be on the market according to Article 23a of Directive 2001/83/EC[7].

- **Choice of the instrument**

The proposal takes the form of a new Regulation. This type of instrument is considered to be the most suitable considering that a key element of the proposal is the establishment of a framework at Union-level providing for coordinated action to address public health emergencies and major events and gives a number of tasks to the Agency. 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

- **Ex-post evaluations/fitness checks of existing legislation**

As part of a package of urgent measures based on lessons learnt so far from COVID-19, the initiative will be supported by an assessment of data collected and exchanges held with public and private stakeholders in the framework of the COVID-19 pandemic on issues encountered and possible means to address them. Considering that the initiative will enlarge the scope of existing legislation, it will not be based on an ex post evaluation, as the needs identified were not addressed by the existing framework.

- **Stakeholder consultations**

Shortages of medicines have been a priority for the Member States and European Parliament for many years as illustrated by several reports from the European Parliament as well as Council conclusions and discussions under recent Council Presidencies.

Following the COVID-19 pandemic, coordinating EU health policies, strengthening crisis management and increasing EU production of essential medicinal products and medical devices have also been identified as a priority by the Council. In addition, several Member States have called for coordination to ensure availability of critical medicines, including vaccines and medical devices during the COVID-19 and potential future health crises.

[7] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p.67

In its resolution on shortages of medicines of 17 September 2020[8], the European Parliament calls on the Commission to implement fast-track and innovative solutions to mitigate medicines shortages and calls on the Commission, the Agency and the national regulatory authorities to build on all the pragmatic efforts made during the COVID-19 crisis. The proposed Regulation would allow the Agency, to achieve part of the vision outlined in the European Parliament's resolution.

Medicinal product interest groups including associations representing respectively hospital pharmacists, community pharmacists, consumer associations, wholesale distributors, and medical doctors, have expressed concerns in relation to the recurrent problems of shortages of medicines in the EU. Such interest groups have renewed long-standing calls for action on this during the COVID-19 pandemic given the acute impact it has had on the supply of certain medicinal products during the current crisis.The COVID-19 pandemic has been extremely challenging for the medical devices industry, which has had to adapt to a sharp increase on demand in a climate of lack of coordination. Medical Device interest groups have recurrently requested a clearer view of EU demand in order to ensure that production capacity will meet the needs of Member States, which is essential to avoid shortages. The lack of EU-wide scientific advice on medical devices during the current crisis has also been highlighted as an area that the expert panels can contribute to in future crises.

- **Impact assessment**

Due to its urgent nature this proposal is not accompanied by an impact assessment. The initiative will enlarge the scope of the existing legislation. These changes are mainly based on an assessment of the data collected during the first months of the pandemic and exchanges held with public and private stakeholders in the framework of the COVID-19 pandemic on issues encountered and possible means to address them. As regards medical devices, the proposal takes into account the impact assessment undertaken in preparation for Regulation (EU) 2017/745 and Regulation (EU) 2017/746.

- **Fundamental rights**

The proposed Regulation contributes to achieving a high level of human health protection as set out in Article 35 of the EU Charter of Fundamental Rights. Where personal data is processed based on this proposal it will be done in line with the relevant Union legislation on personal data protection namely, Regulation (EU) 2018/1725 and Regulation (EU) 2016/679 (the General Data Protection Regulation (GDPR)).

4. BUDGETARY IMPLICATIONS

The implementation of this proposal has no impact on the current Multiannual Financial Framework 2014-2020.

The financial impact on the EU budget post-2020 will be part of the next Multiannual Financial Framework.

The budgetary implications are mainly related to:

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

– administrative support (e.g. to ensure the secretariat of the Executive Steering Groups for medicinal products and medical devices, and the Emergency Task Force, establish and maintain networks of single points of contacts, provide the secretariat for the medical device expert panels, coordinate independent vaccines effectiveness and safety monitoring studies using relevant data held by public authorities);

– scientific support (e.g. provide scientific advice on medicines which have the potential to treat, prevent or diagnose diseases and technical assessments and advice on medical devices by expert panels;

– IT support (e.g. establish, host, and maintain streamlined electronic monitoring and reporting tools);

– remuneration in the form of a special allowance to national experts involved in expert panels on medical devices.

5. OTHER ELEMENTS

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

The proposal aims to complement the measures directed at improving the overall EU crisis management framework by addressing the specific issues related to medicinal product and medical device sectors and the tasks of the Agency. It would thus introduce new rules for the Agency with the objective to provide mechanisms within the Agency to:

– Monitor and mitigate potential and actual shortages of medicinal products and medical devices considered as critical in order to address a given public health emergency or, for medicinal products, major event;

– Provide advice on medicinal products, which have the potential to treat, prevent or diagnose the disease in question. Such advice would cover both medicinal products under development, those used under national compassionate use programmes, and those already authorised for a different indication but with the potential to also treat, prevent or diagnose the disease in question (repurposed medicines).

– Provide a well-managed and sustainable structure to coordinate the expert panels on medical devices, which will be involved in the assessment of specific high-risk medical devices and device types relevant for health crisis management and provide scientific advice essential in crisis preparedness and crisis management.

The proposal also seeks to ensure inter-Agency cooperation during such emergencies, most notably with the European Centre for Disease Prevention and Control (ECDC).

2020/0321 (COD)

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

After consulting the European Economic and Social Committee[9],

After consulting the Committee of the Regions[10],

Acting in accordance with the ordinary legislative procedure,

Whereas:

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

(2) The unprecedented experience of the COVID-19 pandemic has demonstrated that the Union should be more effective in managing the availability of medicinal products and medical devices and in developing medical countermeasures to address the threats posed to public health. The Union's ability to do so has been severely impeded by the absence of a clearly defined legal framework for managing its response to the pandemic, and also by the limited degree of Union preparedness in case of a public health emergency impacting a majority of Member States.

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

(4) Dealing with the issue of shortages of medicinal products has been a long-standing priority for the Member States and European Parliament as illustrated by several

[9] OJ C , , p. .
[10] OJ C , , p. .

reports from the European Parliament[11] as well as discussions under recent Presidencies of the Council of the European Union.

(5) The COVID-19 pandemic has exacerbated the problem of shortages for certain medicinal products considered as critical in addressing the pandemic, and has highlighted the structural limitations in the Union's ability to rapidly and effectively react to such challenges during public health crises.

(6) The rapid evolution of COVID-19 and the spread of the virus led to a sharp increase in demand for medical devices such as ventilators, surgical masks, and COVID-19 test kits while disruption of production or limited capacity to rapidly increase production and the complexity and global nature of the supply chain for medical devices, led to a negative impact on supply. Those issues resulted in new entities being involved in the production of those products, which subsequently resulted in bottlenecks in conformity assessment, as well as the prevalence of non-compliant, unsafe, and in some cases counterfeit products. It is therefore appropriate to establish long-term structures within an appropriate Union body to ensure monitoring of shortages of medical devices resulting from a public health emergency.

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

(8) Safe and efficacious medicinal products that treat, prevent or diagnose diseases which cause public health emergencies, should be developed and made available within the Union as soon as possible during such emergencies. The COVID-19 pandemic has also highlighted sub-optimal coordination and decision-making as regards multinational clinical trials, and Union-level advice on the use of medicinal products in national compassionate use programmes or outside of their authorised indications in the Union, causing delays in the adoption of research outcomes and in the development and availability of new or repurposed medicines.

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

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

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

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

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

(13) A harmonised system of monitoring of shortages of medicinal products and medical devices should be established, which will facilitate appropriate access to critical medicinal products and medical devices during public health emergencies and major events, which may have a serious impact on public health. That system should be complemented with improved structures to ensure appropriate management of public health crises and coordinate and provide advice on the research and development of medicinal products which may have the potential to address public health emergencies. In order to facilitate the monitoring and reporting on potential or actual shortages of medicinal products and medical devices, the Agency should be able to ask and obtain information and data from the concerned marketing authorisation holders, manufacturers and Member States through designated points of contact.

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

(15) With respect to medicinal products, an executive steering group should be established within the Agency to ensure a robust response to major events and to coordinate urgent actions within the Union in relation to the management of issues relating to the supply of medicinal products. The Steering Group should establish lists of critical medicinal products to ensure monitoring of those products and it should be able to provide advice on the necessary action to take to safeguard the quality, safety, and efficacy of medicinal products and ensure a high level of human health protection.

(16) The Executive Steering Group on Shortages and Safety of Medicinal Products should benefit from the Agency's extensive scientific expertise as regards the evaluation and

supervision of medicinal products and should further develop the Agency's leading role in coordinating and supporting the response to shortages during the COVID-19 pandemic.

(17) In order to ensure that safe, high quality, and efficacious medicinal products, which have the potential to address public health emergencies, can be developed and made available within the Union as soon as possible during public health emergencies, an emergency task force should be established within the Agency to provide advice on such medicinal products. The Emergency Task Force should provide advice free of charge on scientific questions related to the development of treatments and vaccines and on clinical trial protocols, to those organisations involved in their development, such as marketing authorisation holders, clinical trial sponsors, public health bodies, and academia, irrespective of their exact role in the development of such medicinal products.

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

(19) The establishment of the Emergency Task Force should build on the support provided by the Agency during the COVID-19 pandemic, notably as regards scientific advice on clinical trials design and product development as well as the 'rolling' review i.e. on an on-going basis, of emerging evidence to allow a more efficient assessment of medicinal products including vaccines during public health emergencies.

(20) Individual research entities may agree together, or with another party, to act as a sponsor in order to prepare one harmonised Union-wide clinical trial protocol, yet experience during the COVID-19 pandemic has shown that initiatives to set up large multinational trials struggle to materialise due to the lack of a single entity that can undertake all the responsibilities and activities of a sponsor within the Union, while interacting with multiple Member States. It is therefore appropriate for the Agency to identify and facilitate such initiatives by giving advice on the possibilities to act as a sponsor or, where applicable, to define respective responsibilities as co-sponsors in accordance with Article 72 of Regulation (EU) 536/2014. Such an approach would strengthen the research environment in the Union, and promote harmonisation and avoid subsequent delays in integrating the results of research to a marketing authorisation. A Union sponsor could benefit from Union research funding available at the time of the public health emergency as well as existing clinical trial networks to facilitate the development, application, submission, and running of the trial. This may be particularly valuable for trials established by Union or international public health or research organisations.

(21) With respect to medical devices, an executive steering group on medical devices should be established to coordinate urgent actions within the Union in relation to the management of supply and demand issues of medical devices, and to establish a list of critical devices in the case of a public health emergency.

(22) This Regulation also provides the Agency with a role to support the expert panels on medical devices designated under Commission Implementing Decision (EU)

2019/1396[12] to provide independent scientific and technical assistance to the Member States, the Commission, the Medical Device Coordination Group (MDCG), notified bodies and manufacturers.

(23) In addition to their role in clinical evaluation assessments and performance evaluations of certain high risk medical devices and *in vitro* diagnostic medical devices in accordance with Regulation (EU) 2017/745[13] and Regulation (EU) 2017/746[14] respectively, as well as providing opinions in response to consultation by manufacturers and notified bodies, the expert panels should play an essential role in the preparedness for and management of public health crises for medical devices, including those devices which have the potential to address public health emergencies. The panels are to provide scientific, technical, and clinical assistance to the Member States, the Commission, and the Medical Device Coordination Group (MDCG). In particular the panels are to contribute to the development of guidance on a number of points including clinical and performance aspects for specific devices, categories, or groups of devices or specific hazards related to a category or group of devices, develop clinical evaluation and performance evaluation guidance in line with the state of the art, and contribute to the identification of concerns and emerging issues on safety and performance.

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

(25) In order to facilitate the work and the exchange of information under this Regulation, provision should be made for the establishment and management of IT infrastructures and synergies with other existing IT systems or systems under development, including the EUDAMED IT platform for medical devices. That work should also be facilitated by, where appropriate, emerging digital technologies such as computational models and simulations for clinical trials, as well as data from the EU Space Programme such as the Galileo geolocation services, and Copernicus earth observation data.

(26) Rapid access and exchange of health data, including real world data i.e. health data generated outside of clinical studies, is essential to ensure effective management of public health emergencies and other major events. This Regulation should allow the

---

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

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

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

Agency to use and facilitate such exchange and be part of the establishment and operation of the European Health Data Space infrastructure.

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

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

(29) In order to ensure that sufficient resources are available for the work provided for under this Regulation, expenditure of the Agency should be covered by the contribution from the Union to the Agency's revenue.

(30) The European Data Protection Supervisor has been consulted in accordance with Article 42(1) of Regulation (EU) No 2018/1725[15] and has adopted an opinion.[16]

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

HAVE ADOPTED THIS REGULATION:

Chapter I

General Provisions

Article 1

Subject Matter

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

[15] 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).

[16] *[insert reference once available]*

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

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

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

(d) provide support for the expert panels designated in accordance with Implementing Decision (EU) 2019/1396.

Article 2

Definitions

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

(a) *'public health emergency'* means a public health emergency at Union level recognised by the European Commission in accordance with Article 23(1) of Regulation (EU) 2020/[…][17];

(b) *'medicinal product'* means a medicinal product as defined in point (2) of Article 1 of Directive 2001/83/EC of the European Parliament and of the Council;

(c) *'medical device'* means both a medical device as defined in point (1) of Article 2 of Regulation (EU) 2017/745, read in conjunction with point (a) of Article 1(6) of that Regulation, and an *in vitro* diagnostic medical device as defined in point (2) of Article 2 of Regulation (EU) 2017/746;

(d) *'shortage'* means that supply of a medicinal product for human use or a medical device does not meet demand for that medicinal product or medical device;

(e) *'developer'* means any legal or natural person seeking to generate scientific data with regard to the quality, safety and efficacy of a medicinal product as part of that product's development;

(f) *'major event'* means an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State. Such an event concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin or incident that can affect the supply or quality, safety, and efficacy of medicinal products. Such an event may lead to shortages of medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection.

[17] [*insert reference to the Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU]* OJ C […], […], p. […].

Chapter II

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

Article 3

The Executive Steering Group on Shortages and Safety of Medicinal Products

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

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

3. The Medicines Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medicinal product interest groups and marketing authorisation holders to attend its meetings.

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

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

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

Article 4

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

1. The Agency shall continuously monitor any event that is likely to lead to a major event or a public health emergency.

2. To facilitate the monitoring task referred to in paragraph 1, the national competent authorities, through the single points of contact referred to in Article 3(5), shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report to the Agency on any event, including a shortage of a medicinal product in a given Member State, that is likely to lead to a major event or a public health emergency. Where a national competent authority informs the Agency of a shortage of a medicinal product in a given Member State, it shall provide the Agency with any information received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC. Based on a report of an event from a national competent

authority and in order to understand the impact of the event in other Member States, the Agency may request information from the national competent authorities, through the working party referred to in Article 3(5).

3. Where the Agency considers that an actual or imminent major event needs to be addressed, it shall inform the Commission and the Member States thereof. The Commission, on its own initiative or following a request from one or more Member States, or the Executive Director of the Agency may request the assistance of the Medicines Steering Group to address the major event.

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

5. In the case of a major event or public health emergency, Articles 5 to 12 shall apply as follows:

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

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

Article 5

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

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

The Medicines Steering Group shall provide advice to the Commission and Member States on any appropriate action it believes should be taken at Union level on the medicinal products concerned in accordance with the provisions of Directive 2001/83/EC or Regulation (EC) No 726/2004.[18]

Article 6

Lists of critical medicinal products and information to be provided

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

[18] Regulation (EC) No 726/2004

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

3. The Medicines Steering Group shall adopt a set of information necessary to monitor the supply and demand of medicinal products included on the lists referred to in paragraphs 1 and 2 ('the critical medicines lists') and inform its working party thereof.

4. The Agency shall immediately publish the critical medicines lists and any updates to those lists on its web-portal referred to in Article 26 of Regulation (EC) No 726/2004.

Article 7

Monitoring shortages of medicinal products on the critical medicines lists

On the basis of the critical medicines lists and the information and data provided in accordance with Articles 10 and 11, the Medicines Steering Group shall monitor supply and demand of medicinal products included on those lists with a view to identifying any potential or actual shortages of those medicinal products. As part of that monitoring, the Medicines Steering Group shall liaise, where relevant, with the Health Security Committee established in Article 4 of Regulation (EU) 2020/[…][19] and, in the case of a public health emergency, the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation.

Article 8

Reporting and recommendations on shortages of medicinal products

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

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

3. As part of that reporting, the Medicines Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities to prevent or mitigate

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

potential or actual shortages. In that regard the Group shall liaise, as relevant, with the Health Security Committee and, in the case of a public health emergency, the Advisory Committee on public health emergencies.

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

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

Article 9

Working methods and provision of information on medicinal products

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

   (a) specify the procedures for establishing the critical medicines lists;

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

   (c) develop streamlined electronic monitoring and reporting systems;

   (d) establish and maintain membership of the working party referred to in Article 3(5) comprised of single points of contacts from national competent authorities for medicinal products;

   (e) establish and maintain a list of single points of contact from marketing authorisation holders for all medicinal products for human use authorised in the Union, through the database provided for in Article 57(1)(l) of Regulation 726/2004;

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

2. Following the recognition of a public health emergency or a request for assistance referred to in Article 4(3) the Agency shall:

   (a) establish and maintain for the duration of the public health emergency or major event, a sub-network of single points of contact from marketing authorisation holders based on the medicinal products included on the critical medicines lists;

   (b) request information from the points of contact included in the sub-network referred to in point (a) and set a deadline for its submission;

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

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

   (a) the name of the marketing authorisation holder;

(b) the name of the medicinal product;

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

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

(e) sales and market share data;

(f) details of available alternative medicinal products;

(g) mitigation plans including production and supply capacity;

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

Article 10

Obligations on marketing authorisation holders

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

2. Marketing authorisation holders of medicinal products authorised in the Union shall, within 6 months from the date of application of this Regulation, provide the information required pursuant to Article 9(1)(e) in the form of an electronic submission in the database referred to in Article 57(1)(l) of Regulation (EC) No 726/2004. Those marketing authorisation holders shall update their submission wherever necessary.

3. Marketing authorisation holders shall justify the absence of any requested information and any delays in providing it by the deadline set by the Agency.

4. Where marketing authorisation holders for medicinal products included on the critical medicines lists indicate that the submitted information contains information of a commercially confidential nature, they shall identify the relevant parts and clarify the reasons for such an indication. The Agency shall assess the merits of each request and protect commercially confidential information against unjustified disclosure.

5. Where marketing authorisation holders for medicinal products included on the critical medicines lists are in possession of any additional information, which provides evidence of a potential or actual shortage they shall immediately provide such information to the Agency.

6. Following the reporting on the results of the monitoring and any recommendations on preventive or mitigating measures in accordance with Article 8, marketing authorisation holders for medicinal products included on the critical medicines list shall:

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

(b) take into account any recommendations and guidelines and comply with any measures taken at Union and Member State-level pursuant to Articles 11 and 12;

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

Article 11

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

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

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

   (b) indicate the existence of any commercially confidential information and clarify the reasons for such an indication;

   (c) indicate the absence of any requested information, and any delays in providing requested information by the deadline set by the Agency.

2. Where necessary to fulfil their reporting obligations set out in paragraph 1, Member States, with the support of the Agency, shall gather information and data on stock levels from wholesale distributors and other legal entities entitled to supply the public with medicinal products included on the critical medicines lists.

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

4. Following the reporting on the results of the monitoring and any recommendations on preventive or mitigating measures in accordance with Article 8, Member States shall:

   (a) take into account any recommendations and guidelines and comply with any measures taken at Union-level pursuant to Article 12;

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

Article 12

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

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

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

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

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

(d) request the Medicines Steering Group to provide recommendations or coordinate measures as provided for in Article 8(3), (4) and (5);

(e) consider the need for medical countermeasures in accordance with Articles 12 and 25(b) of Regulation (EU) 2020/[…];[20]

(f) liaise with third countries and relevant international organisations, as appropriate, to mitigate potential or actual shortages of medicinal products included on the critical medicines list or their active pharmaceutical ingredients, where those products or ingredients are imported into the Union and where such potential or actual shortages have international implications.

Article 13

Communication on the Medicines Steering Group

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

Chapter III

Medicinal Products with the potential to address public health emergencies

Article 14

The Emergency Task Force

1. The Emergency Task Force is hereby established as part of the Agency. It shall be convened during public health emergencies, either in person or remotely. The Agency shall provide its secretariat.

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

   (a) providing scientific advice and reviewing the available scientific data on medicinal products with the potential to address the public health emergency, including requesting data from developers and engaging with them in preliminary discussions;

   (b) reviewing clinical trial protocols and providing advice to developers on clinical trials to be conducted in the Union for medicinal products intended to treat,

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

prevent, or diagnose the disease causing the public health emergency, in accordance with Article 15;

(c) providing scientific support to facilitate clinical trials to be conducted in the Union for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency. Such support shall include advice to sponsors of similar or linked planned clinical trials on the establishment, in their place, of joint clinical trials and may include advice on establishing agreements to act as a sponsor or as co-sponsor in accordance with Articles 2(14) and 72 of Regulation (EU) 536/2014;

(d) contributing to the work of the scientific committees, working parties and scientific advisory groups of the Agency;

(e) providing scientific recommendations with regard to the use of any medicinal product, which may have the potential to address public health emergencies, in accordance with Article 16;

(f) cooperating with Union bodies and agencies, the World Health Organization, third countries, and international scientific organisations on scientific and technical issues relating to the public health emergency and to medicinal products which may have the potential to address public health emergencies, as necessary.

3. The Emergency Task Force shall be composed of representatives of the scientific committees, working parties, and staff members of the Agency, the coordination group established in accordance with Article 27 of Directive 2001/83/EC, and the Clinical Trials Coordination and Advisory Group established in accordance with Article 85 of Regulation (EU) 536/2014.[21] External experts may be appointed and representatives of other Union bodies and agencies be invited on an ad hoc basis, as necessary. It shall be chaired by the Agency.

4. The composition of the Emergency Task Force shall be approved by the Management Board of the Agency. The Executive Director of the Agency or their representative and representatives of the Commission shall be entitled to attend all meetings.

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

6. The Emergency Task Force shall establish its rules of procedure including rules on the adoption of recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.

7. The Emergency Task Force shall perform its tasks as a body separate from, and without prejudice to the tasks of the scientific committees of the Agency as regards

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

the authorisation, supervision and pharmacovigilance of the concerned medicinal products and related regulatory actions to ensure the quality, safety and efficacy of those medicinal products. The Emergency Task Force shall take account of any scientific opinion issued by those committees in accordance with Regulation (EC) No 726/2004 and Directive 2001/83/EC.

8. Article 63 of Regulation (EC) No 726/2004 shall apply to the Emergency Task Force as regards transparency and the independence of its members.

9. The Agency shall publish information about the medicinal products that the Emergency Task Force considers may have the potential to address public health emergencies and any updates on its web-portal.

Article 15

Advice on clinical trials

1. During a public health emergency, the Emergency Task Force shall review clinical trial protocols submitted or intended to be submitted in a clinical trial application by developers of medicinal products as part of an accelerated scientific advice process.

2. Where a developer engages in an accelerated scientific advice process, the Emergency Task force shall provide such advice free of charge at the latest 20 days following the submission to the Agency of a complete set of requested information and data by the developer. The advice shall be endorsed by the Committee for Medicinal Products for Human Use.

3. The Emergency Task Force shall establish procedures for the request and submission of the set of information and data required, including information on the Member State or States where an application for authorisation of a clinical trial is submitted or is intended to be submitted.

4. The Emergency Task Force shall involve representatives of the Member State or States where an application for authorisation of a clinical trial is submitted or is intended to be submitted in the preparation of the scientific advice.

5. When authorising a clinical trial application for which scientific advice has been given, Member States shall take that advice duly into account.

6. Where a developer is the recipient of scientific advice, the developer shall subsequently submit the data resulting from clinical trials to the Agency following a request made pursuant to Article 16.

7. Without prejudice to the provisions of this Article, the scientific advice shall otherwise be provided to those developers in accordance with the procedures established pursuant to Article 57 of Regulation EC (No) 726/2004.

Article 16

Review of medicinal products and recommendations on their use

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

2. In preparation of the review, the Emergency Task Force may request information and data from marketing authorisation holders and from developers and engage with them in preliminary discussions. The Emergency Task Force may also, where available, make use of observational studies of health data generated outside of clinical studies taking into account their reliability.

3. Based on a request from one or more Member States, or the Commission, the Emergency Task Force shall provide recommendations to the Committee for Medicinal Products for Human Use for an opinion in accordance with paragraph 4 on the following:

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

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

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

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

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

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

Article 17

Communication on the Emergency Task Force

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

Article 18

IT tools and data

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

(a) develop and maintain electronic tools for the submission of information and data, including electronic health data generated outside the scope of clinical studies;

(b) coordinate independent vaccine effectiveness and safety monitoring studies using relevant data held by public authorities. Such coordination shall be conducted jointly with the European Centre for Disease Prevention and Control and notably through a new vaccine monitoring platform;

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

(d) provide access to the Emergency Task Force to external sources of electronic health data including, health data generated outside the scope of clinical studies, to which the Agency has access.

Chapter IV

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

Article 19

The Executive Steering Group on Medical Devices

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

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

3. The Medical Devices Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medical device interest groups to attend its meetings.

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

5. The Medical Devices Steering Group shall be supported in its work by a working party comprised of single points of contact from national competent authorities for medical devices established in accordance with Article 23(1).

6. The Medical Devices Steering Group shall be responsible for fulfilling the tasks referred to in Articles 20, 21, and 22.

Article 20

List of critical medical devices and information to be provided

1. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medical Devices Steering Group shall adopt a list of medical devices which it considers as critical during the public health emergency ('the public health emergency critical devices list'). The list shall be updated whenever necessary until the termination of the recognition of the public health emergency.

2. The Medical Devices Steering Group shall adopt a set of information necessary to monitor the supply and demand of medical devices included on the public health emergency critical devices list and inform its working party thereof.

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

Article 21

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

1. On the basis of the public health emergency critical devices list and the information and data provided in accordance with Articles 24 and 25, the Medical Devices Steering Group shall monitor supply and demand of medical devices included on that list with a view to identifying any potential or actual shortages of those medical devices. As part of that monitoring, the Medical Devices Steering Group shall liaise, where relevant, with the Health Security Committee established in Article 4 of Regulation (EU) 2020/[…][22] and the Advisory Committee on public health emergencies established pursuant to Article 24 of that Regulation.

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

Article 22

Reporting and recommendations on shortages of medical devices

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

2. Where requested by the Commission or the sub-network referred to in Article 23(2)(b), the Medical Devices Steering Group shall provide aggregated data and forecasts of demand to support its findings. In that regard, the Steering Group shall liaise with the European Centre for Disease Prevention and Control to obtain epidemiological data to help forecast medical device needs, and with the Medicines Steering Group referred to in Article 3 where medical devices included on the public health emergency critical devices list are used to jointly with a medicinal product.

3. As part of the reporting referred to in paragraphs 1 and 2, the Medical Devices Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, medical device manufacturers, notified bodies and other entities to prevent or mitigate potential or actual shortages. In that regard the Group shall liaise, where relevant, with the Health Security Committee and the Advisory Committee on public health emergencies.

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

4. The Medical Devices Steering Group may, on its own initiative or upon request from the Commission, provide recommendations on measures which may be taken by the Commission, Member States, medical device manufacturers, notified bodies and other entities to ensure preparedness to deal with potential or actual shortages of medical devices caused by public health emergencies.

5. The Medical Devices Steering Group may, upon request from the Commission coordinate measures, where relevant, between the national competent authorities, manufacturers of medical devices, notified bodies, and other entities to prevent or mitigate potential or actual shortages in the context of a public health emergency.

Article 23

Working methods and provision of information on medical devices

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

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

   (b) develop streamlined electronic monitoring and reporting systems;

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

   (d) establish and maintain a list of single points of contact from medical device manufacturers, authorised representatives and notified bodies;

   (e) specify the methods for the provision of recommendations and coordination of measures provided for in Article 22.

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

   (a) establish and maintain for the duration of the public health emergency, a sub-network of single points of contact from medical device manufacturers and notified bodies based on the medical devices included on the public health emergency critical devices list;

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

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

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

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

   (b) identification of the medical device and the intended purpose;

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

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

(e) sales and market share data;

(f) mitigation plans including production and supply capacity;

(g) information from concerned notified bodies about their resource capacity to process applications and carry out and complete conformity assessments in relation to medical devices included in the public health emergency critical devices list;

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

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

Article 24

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

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

2. Medical device manufacturers and notified bodies shall justify the absence of any requested information and any delays in providing it by the deadline set by the Agency.

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

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

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

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

(b)

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

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

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

Article 25

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

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

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

(b) indicate the existence of any commercially confidential information, and, clarify the reasons for such an indication;

(c) indicate the absence of any requested information, and any delays in providing requested information by the deadline set by the Agency.

2. Where necessary to fulfil their reporting obligations set out in paragraph 1, Member States shall gather information from manufacturers, importers, distributors and notified bodies on medical devices included on the public health emergency critical devices list.

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

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

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

(c) take into account any recommendations and guidelines and comply with any measures taken at Union-level pursuant to Article 26;

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

Article 26

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

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

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

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

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

(d) consider the need for medical countermeasures in accordance with Articles 12 and 25(b) of Regulation (EU) 2020/[…];[23]

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

Article 27

Communication on the Medical Devices Steering Group

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

Article 28

Support for the expert panels on medical devices

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

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

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

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

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

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

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

(f) ensure that remuneration and expenses are provided to the experts in accordance with Article 11 of Implementing Decision (EU) 2019/1396;

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

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

Chapter V

Final Provisions

Article 29

Cooperation between Steering Groups

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

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

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

Article 30

Confidentiality

1. Unless otherwise provided for in this Regulation and without prejudice to Regulation (EC) No 1049/2001[24] and existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation

[24] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.05.2001, p. 43

shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:

(a) personal data in accordance with Article 32;

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

(c) the effective implementation of this Regulation.

2. All parties involved in the application of this Regulation shall ensure that no commercially confidential information is shared in a way which has the potential to enable undertakings to restrict or distort competition in the meaning of Article 101 TFEU.

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

4. Paragraphs 1, 2, and 3 shall not affect the rights and obligations of the Commission, the Agency, Member States and other actors identified in this Regulation with regard to the exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

5. The Commission, the Agency, and Member States may exchange commercially confidential information and, where necessary to protect public health, personal data, with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

Article 31

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

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE 35
1.1. Title of the proposal/initiative 35
1.2. Policy area(s) concerned 35
1.3. The proposal relates to 35
1.4. Objective(s) 35
1.4.1. General objective(s) 35
1.4.2. Specific objective(s) 35
1.4.3. Expected result(s) and impact 36
1.4.4. Indicators of performance 36
1.5. Grounds for the proposal/initiative 37
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 37
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. 37
1.5.3. Lessons learnt from similar experiences in the past 38
1.5.4. Compatibility with the Multiannual Financial Framework and possible synergies with other appropriate instruments 39
1.5.5. Assessment of the different available financing options, including scope for redeployment 39
1.6. Duration and financial impact of the proposal/initiative 40
1.7. Management mode(s) planned 40
2. MANAGEMENT MEASURES 41
2.1. Monitoring and reporting rules 41
2.2. Management and control system(s) 41
2.2.1. Justification of the management mode(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed 41
2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them 41
2.3. Measures to prevent fraud and irregularities 42
3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE 42
3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected 42
3.2. Estimated impact on expenditure 43

3.2.1. Summary of estimated impact on expenditure 43
3.2.2. Estimated impact on EMA's appropriations 45
3.2.3. Estimated impact on EMA's human resources 47
3.2.4. Compatibility with the current multiannual financial framework 51
3.2.5. Third-party contributions 51
3.3. Estimated impact on revenue 52

LEGISLATIVE FINANCIAL STATEMENT 'AGENCIES'

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

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

1.2. Policy area(s) concerned

Policy area: Cohesion, Resilience and Values

Activity: Health

1.3. The proposal relates to

X a new action

☐ a new action following a pilot project/preparatory action[25]

X the extension of an existing action

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

1.4. Objective(s)

1.4.1. General objective(s)

The proposal aims to:

– ensure a high level of human health protection by strengthening the Union's ability to respond to and manage public health emergencies, which have an impact on medicinal products and medical devices;

– contribute to ensuring the smooth functioning of the internal market for such products during public health emergencies.

1.4.2. Specific objective(s)

Specific objectives

1. Monitor and mitigate potential and actual shortages of medicinal products and medical devices considered as critical in order to address a given public health emergency or, for medicinal products, other major events which may have a serious impact on public health;

2. Ensure the quality, safety and efficacy of medicinal products which may have the potential to address a given health emergency;

3. Ensure smooth functioning of expert panels for the assessment of some high-risk medical devices and avail of essential advice in crisis preparedness and management with regard to the use of medical devices.

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

1.4.3. Expected result(s) and impact

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

The initiative should contribute to ensuring that shortages of medicinal products and medical devices considered as critical in addressing a given health emergency and, for medicinal products, a major event, are avoided across the Union. By doing so, those products should ultimately remain available to patients in sufficient numbers even during such emergencies.

Member States and medicines and medical device manufacturers should benefit from a coordinated approach at Union level. A permanently established mechanism to be used during emergencies within the Agency to monitor and report on potential and actual shortages, should allow for a better and more timely flow of information between authorities and manufacturers. This should allow for necessary action to be taken by the Commission, Member State authorities and manufacturers to mitigate potential or actual shortages. Such a framework should reduce the risk of uncoordinated stockpiling of such products and allow for the continued flow of goods across the single market so that they reach the areas that need them most as the impact of public health emergencies peaks at different times across the Union.

The initiative should also contribute to ensuring that medicines which may have the potential to treat, prevent or diagnose diseases which result in public health emergencies are identified early on, benefit from timely scientific advice, and are subject to a robust assessment of their quality, safety and efficacy. By doing so, those products should ultimately reach the market in a timely manner and provide safe and effective treatment and prevention options for patients.

In the context of the European Health Data Space, the initiative should also contribute to providing access to health data for research and regulatory purposes, supporting better decision-making (regulators and policy makers) throughout the product lifecycle on medicines with timely, valid and reliable data from real world healthcare settings. This should integrate the Agency into the future infrastructure for a European Health Data Space, allowing for the use of data for research, policy-making and evidence-based tools.

Member States and manufacturers should benefit from a coordinated approach at Union level on the advice given on clinical trial protocols and the use of such medicines in national indications – so-called ‘off-label use’.

1.4.4. Indicators of performance

Specify the indicators for monitoring progress and achievements.

Detailed objectives and expected results including performance indicators will be established by the annual work programme, while the Single Programming Document will set out overall strategic objectives, expected results and set of performance indicators. The key performance indicators for the Agencies as well as the guidelines for the Single Programming Document and the Consolidated Annual Activity Report developed by the Commission should be respected.

For work on shortages of medicines and medical devices:

– Number of medicines at risk of shortages or in shortages in the EU Member States

For the work on medicines which may have the potential to address public health emergencies:

– Number of recommendations and amount of advice issued by the Emergency Task Force.

For the expert panels:

– Number of opinions issued annually.

For the Agency's participation in the European Health Data Space digital infrastructure that supports the use of health data for better decision-making:

– Number of studies enabled, using the future infrastructure of the European Health Data Space

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

Upon the entry into force of the Regulation, the Agency should put in place the framework which will be used to manage future public health emergencies (crisis preparedness and response) including the development of procedures for data submission, reporting and monitoring tools, and rules of procedure and working methods for the Steering Groups and Emergency Task Force. This will allow for the immediate operationalisation of those groups as soon as a public health emergency has been recognised (crisis management).

From March 2022 at the latest the Agency should begin to host the secretariat of and ensure support for the medical device expert panels on a permanent basis.

The building and deployment of European Health Data Space infrastructure within the Agency will enable the Agency to access or query real world data to better support decision-making throughout the product lifecycle on medicines should begin in 2021, and progress in full alignment with the establishment of the overall European Health Data Space.

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)

Public health emergencies of the magnitude of COVID-19 have an impact on all Member States, which, on their own are unable to provide a sufficient response. Potential or actual shortages of medicines and medical devices in times of crises can lead to the risk of national stockpiling or restrictions to single market movements being placed on such goods, which can have a negative impact on the free movement of goods. An uncoordinated approach to the development of medicines, which may have the potential to treat, prevent, or diagnose diseases causing public health emergencies can cause delays in their development during periods where time is of the essence. Moreover, a lack of clear, Union-level advice on the use of medicines in national compassionate use programmes or outside of their authorised indications can lead to a fragmented approach across the Union. Additionally, regulators access to EU-wide health data is limited and scattered across different partners leading to complex and slow analysis undermining the optimal time window for certain interventions.

Expected generated Union added value (ex-post)

A coordinated response at Union-level to monitoring and mitigating the risk of shortages can help to avoid actions such as uncoordinated stockpiling being taken and therefore have both a

positive impact on public health and maintain the smooth functioning of the single market. In the same vein, providing scientific advice on medicinal products which have the potential to address public health emergencies at Union-level can facilitate their market entry, ensure a coordinated approach to their use across Member States, and help to ensure such treatments meet harmonised Union standards for their quality, safety and efficacy, whilst avoiding duplication of efforts and unnecessary research. Integrating the Agency into the European Health Data Space digital health infrastructure can support better decision-making throughout the product lifecycle on medicines and can facilitate access and analysis of real world health data in a timely and reliable manner. This would support health policy making including: legislative development, impact and monitoring of implementation, design of healthcare systems and more informed decision-making on cost-effectiveness. Ultimately, this action can benefit patients with a faster access to innovative medicines and safe and effective use.

1.5.3. Lessons learnt from similar experiences in the past

The unprecedented experience of the COVID-19 pandemic has demonstrated that the Union's ability to coordinate work to ensure availability of medicinal products and medical devices and facilitate the development of medical countermeasures is limited, among other things, by the absence of a structured mechanism to monitor and quickly address shortages of such products.

During the COVID-19 crisis, ad hoc solutions had to be found to contain the risk of shortages of medicines and medical devices such as ventilators and the medicines used with them (such as the EU Executive Steering Group and the Clearing House). The operation of these mechanisms during the emergency was made possible by contingent arrangements between the actors involved (the Commission, the Agency, the Member States). For these solutions to become efficient and predictable, it has become apparent that the respective roles and obligations of the different actors should be clarified and solidly anchored in the legislative framework that applies to their operations.

Equally, when a number of medicines were purported to treat or prevent COVID-19, EMA provided scientific advice on their development and ability to fight COVID-19 to the utmost of its ability, but outside of a formal crisis management structure and without the benefit of fast-track scientific advice procedures and obligations on Member States and developers to cooperate. In particular, developers indicated a lack of harmonisation on aspects related to clinical trials, stemming mainly from the fact that each trial needs to be authorised separately in each Member State.

Integrating the Agency into the European Health Data Space digital health infrastructure to support better decision-making throughout the product lifecycle on medicines should leverage on the lessons learnt from other equivalent initiatives (e.g. FDA/Sentinel, Health Canada/CNODES, PMDA) as well as from the knowledge advances achieved by complementary initiatives (e.g. EHDEN, ELIXIR, VAC4EU, OHDSI).

These lessons learnt thus provide a solid basis for the establishment of a clear framework for the activities to be deployed by the Agency during public health emergencies, in order to enhance the Union's capacity to react quickly, efficiently and in a coordinated manner to such emergencies.

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

The Agency should cooperate and promote synergies with other Union bodies and decentralised agencies, such as the European Centre for Disease and Control (ECDC), European Food Safety Authority (EFSA) and take full advantage and ensure consistency with the EU4Health programme and other EU programmes financing actions in the domain of public health.

As from 2022, the Agency would take over some tasks currently performed by the Commission under the Health programme Expert panels (JRC).

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

The European Commission has no expertise to assess medicinal products with the potential to treat public health emergencies. The European Medicines Agency is the suitable body to conduct the proposed tasks. Nevertheless, the European Commission will participate in the management of the Executive Steering Groups without additional resources.

Involvement of Member States' national authorities will also be a crucial factor since access to health data may require strict requirements to be fulfilled at national level by participating health data providers.

1.6. Duration and financial impact of the proposal/initiative

☐ **limited duration**

– ☐ Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY

– ☐ Financial impact from YYYY to YYYY

✓ **unlimited duration**

– Implementation with a start-up period from Jan 2021 to Dec 2021,

– followed by full-scale operation.

1.7. Management mode(s) planned[26]

☐ **Direct management** by the Commission through

– ☐ executive agencies

☐ **Shared management** with the Member States

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

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

☐the EIB and the European Investment Fund;

✓ bodies referred to in Articles 70 and 71;

☐ 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.

Comments

[26] 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.

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

All Union agencies work under a strict monitoring system involving an internal control coordinator, the Internal Audit Service of the Commission, the Management Board, the Commission, the Court of Auditors and the Budgetary Authority. This system is reflected and laid down in the EMA's founding regulation.

In accordance with the Joint Statement on the EU decentralised agencies (the 'Common Approach'), the framework financial regulation (2019/715) and related Commission Communication C(2020)2297, the annual work programme and Single Programming Document of the Agency shall comprise detailed objectives and expected results including set of performance indicators. The Agency will accompany its activities included in its working programme by key performance indicators. The activities of the Agency will be then measured against these indicators in the Consolidated Annual Activity Report. The annual work programme shall be coherent with the multi-annual work programme and both shall be included in an annual Single Programming Document which shall be submitted to the European Parliament, the Council, and the Commission. The Management Board of Agency will be responsible for supervision of the administrative, operational and budgetary efficient management of the Agency.

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 annual EU subsidy is transferred to the Agency in accordance with its payment needs and upon its request.

The Agency will be subject to administrative controls including budgetary control, internal audit, annual reports by the European Court of Auditors, the annual discharge for the execution of the EU budget and possible investigations conducted by OLAF to ensure, in particular, that the resources allocated to agencies are put to proper use. The activities of the Agency will also be subject to the supervision of the Ombudsman in accordance with Article 228 of the Treaty. These administrative controls provide a number of procedural safeguards to ensure that account is taken of the interests of the stakeholders.

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

The main risk relates to under- or non-implementation of the tasks foreseen. In order to mitigate this, sufficient resources should be made available in both financial and staffing terms.

2.3. Measures to prevent fraud and irregularities

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

Anti-fraud measures are provided for in Article 69 of Regulation (EC) No 726/2004 and the framework financial Regulation (2019/715). The Executive Director and the Management Board of the Agency will take the appropriate measures in accordance with the Internal Control Principles applied across all EU institutions. In line with the Common Approach and Article 42 of the framework financial Regulation, an anti-fraud strategy has been developed and is followed by the Agency.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

Given the on-going reflection on the creation of an 'EU BARDA', the Commission retains the right to adjust the proposed resources and staff allocation when a precise proposal for an 'EU BARDA' is tabled.

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 of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff.[27]	from EFTA countries[28]	from candidate countries[29]	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation
2	06.100301	Diff.	YES	NO	NO	NO

- New budget lines requested

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./non-diff.	from EFTA countries	from candidate countries	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation
	[XX.YY.YY.YY]		YES/NO	YES/NO	YES/NO	YES/NO

[27] Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.

[28] EFTA: European Free Trade Association.

[29] Candidate countries and, where applicable, potential candidates from the Western Balkans.

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

EUR million (to three decimal places)

Heading of multiannual financial framework	Number	Heading 2 : Cohesion, Resilience and Values

[Body]: EMA			Year **2021**	Year **2022**	Year **2023**	Year **2024**	Year **2025**	Year **2026**	**Year 2027 et seqq.**	**TOTAL**
Title 1:	Commitments	(1)	3.065	3.315	3.800	4.300	4.300	4.300	**4.300**	**27.380**
	Payments	(2)	3.065	3.315	3.800	4.300	4.300	4.300	**4.300**	**27.380**
Title 2:	Commitments	(1a)	0.725	0.775	0.900	1.000	1.000	1.000	**1.000**	**6.400**
	Payments	(2a)	0.725	0.775	0.900	1.000	1.000	1.000	**1.000**	**6.400**
Title 3:	Commitments	(3a)	24.000	18.000	18.000	10.000	10.000	10.000	**10.000**	**100.000**
	Payments	(3b)	24.000	18.000	18.000	10.000	10.000	10.000	10000	**100.000**
TOTAL appropriations for EMA	Commitments	=1+1a +3a	**27.790**	**22.090**	**22.700**	**15.300**	**15.300**	**15.300**	**15.300**	**133.780**
	Payments	=2+2a +3b	**27.790**	**22.090**	**22.700**	**15300**	**15.300**	**15300**	**15.300**	**133.780**

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

EUR million (to three decimal places)

		Year **2021**	Year **2022**	Year **2023**	Year **2024**	Year **2025**	Year **2026**	**Year 2027 et seqq.**	**TOTAL**
DG: <…….>									
• Human Resources									
• Other administrative expenditure									
TOTAL DG <…….>	Appropriations								

TOTAL appropriations under HEADING 7 of the multiannual financial framework	(Total commitments = Total payments)								

EUR million (to three decimal places)

		Year **2021**	Year **2022**	Year **2023**	Year **2024**	Year **2025**	Year **2026**	**Year 2027 et seqq.**	**TOTAL**
TOTAL appropriations under HEADINGS 1 to 7 of the multiannual financial framework	Commitments	**27.790**	**22.090**	**22.700**	**15.300**	**15.300**	**15300**	**15.300**	**133.780**
	Payments	**27.790**	**22.090**	**22.700**	**15.300**	**15.300**	**15.300**	**15.300**	**133.780**

3.2.2. Estimated impact on EMA's appropriations

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

– ✓ The proposal/initiative requires the use of operational appropriations, as explained below:

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs			Year **2021**		Year **2022**		Year **2023**		Year **2024**		Year **2025**		Year **2026**		**Year 2027 et seqq.**		**TOTAL**	
	OUTPUTS																	
⇩	Type[30]	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No	Total cost
SPECIFIC OBJECTIVE No 1 Monitor and mitigate potential and actual shortages of medicines and medical devices considered as critical in order to address a given public health emergency																		
Medicines Steering Group				5.000		1.000		1.000		1.000		1.000		1.000		1.000		11.000
Devices Steering Group				5.000		1.000		1.000		1.000		1.000		1.000		1.000		11.000
Expert Panels				0		2.000		2.000		2.000		2.000		2.000		2.000		12.000
Subtotal for specific objective No 1				10.000		4.000		4.000		4.000		4.000		4.000		4.000		34.000
SPECIFIC OBJECTIVE No 2 Ensure the quality, safety and efficacy of medicinal products which may have the potential to address a given health emergency																		

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

Emergency Task				5.000		1.000		1.000		1.000		1.000		1.000		1.000		11.000
vaccine platform				5.000		5.000		5.000		5.000		5.000		5.000		5.000		35.000
Subtotal for specific objective No 2				10.000		6.000		6.000		6.000		6.000		6.000		6.000		46.000
SPECIFIC OBJECTIVE No 3 Allow timely access and analysis of EU-wide health data to support better decision-making throughout the product lifecycle on medicines (development, authorisation, performance monitoring) with valid and reliable real world evidence																		
Node Reuse data				4.000		8.000		8.000		0		0		0		0		20.000
Subtotal for specific objective No 3				4.000		8.000		8.000		0		0		0		0		20.000
TOTAL COST				**24.000**		**18.000**		**18.000**		**10.000**		**10.000**		**10.000**		**10.000**		**100.000**

3.2.3. Estimated impact on EMA's human resources

3.2.3.1. Summary

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

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

EUR million (to three decimal places)

	Year **2021**	Year **2022**	Year **2023**	Year **2024**	Year **2025**	Year **2026**	**Year 2027 et seqq.**	**TOTAL**
Temporary agents (AD Grades)	2.700	3.000	3.450	3.750	3.750	3.750	**3.750**	**24.150**
Temporary agents (AST grades)	0.450	0.450	0.450	0.750	0.750	0.750	**0.750**	**4.350**
Contract staff	0.640	0.640	0.800	0.800	0.800	0.800	**0.800**	**5.280**
Seconded National Experts	0	0	0	0	0	0	**0**	**0**
TOTAL	**3.790**	**4.090**	**4.700**	**5.300**	**5.300**	**5.300**	**5.300**	**33.780**

Staff requirements (FTE):

	Year **2021**	Year **2022**	Year **2023**	Year **2024**	Year **2025**	Year **2026**	**Year 2027 et seqq.**	**TOTAL**
Temporary agents (AD Grades)	18	20	23	25	25	25	**25**	**25**
Temporary agents (AST grades)	3	3	3	5	5	5	**5**	**5**
Contract staff	8	8	10	10	10	10	**10**	**10**
Seconded National Experts								
TOTAL	**29**	**31**	**36**	**40**	**40**	**40**	**40**	**40**

Please indicate the planned recruitment date and adapt the amount accordingly (if recruitment occurs in July, only 50 % of the average cost is taken into account) and provide further explanations.

3.2.3.2. Estimated requirements of human resources for the parent DG

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

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

Estimate to be expressed in full amounts (or at most to one decimal place)

	Year **2021**	Year **2022**	Year **2023**	Year **2024**	Year **2025**	Year **2026**	**Year 2027 et seqq.**
• **Establishment plan posts (officials and temporary staff)**							
XX 01 01 01 (Headquarters and Commission's Representation Offices)							
XX 01 01 02 (Delegations)							
XX 01 05 01 (Indirect research)							
10 01 05 01 (Direct research)							
• **External staff (in Full Time Equivalent unit: FTE)**[31]							
XX 01 02 01 (AC, END, INT from the 'global envelope')							
XX 01 02 02 (AC, AL, END, INT and JPD in the Delegations)							
XX 01 04 ***yy***[32] - at Headquarters[33]							
XX 01 04 ***yy***[32] - in Delegations							
XX 01 05 02 (AC, END, INT – Indirect research)							
10 01 05 02 (AC, END, INT – Direct research)							
Other budget lines (specify)							
TOTAL							

XX is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary

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

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

33 Mainly for the Structural Funds, the European Agricultural Fund for Rural Development (EAFRD) and the European Fisheries Fund (EFF).

with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

Officials and temporary staff	Staff at EMA to perform analysis of regulatory questions from the development, authorisation and supervision of medicines by EMA and NCA committees, scientific overview of the studies, integration of study results into the core medicinal product assessment work of the EMA, contract management, legal, administration and IT support.
External staff	

Description of the calculation of cost for FTE units should be included in the Annex V, section 3.

3.2.4. Compatibility with the current multiannual financial framework

– ✓ The proposal/initiative is compatible the current multiannual financial framework.

– ✓The proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

The proposed additional budget for EMA may be financed by a reduction of the EU4Health budget in future years.

– ☐ The proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework[34].

3.2.5. Third-party contributions

– The proposal/initiative does not provide for co-financing by third parties.

– The proposal/initiative provides for the co-financing estimated below:

EUR million (to three decimal places)

	Year **2021**	Year **2022**	Year **2023**	Year **2024**	Year **2025**	Year **2026**	**Year 2027 et seqq.**	Total
Specify the co-financing body	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.
TOTAL appropriations co-financed	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.

[34] See Articles 11 and 17 of Council Regulation (EU, Euratom) No 1311/2013 laying down the multiannual financial framework for the years 2014-2020.

3.3. Estimated impact on revenue

– ✓ 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[35]						
		Year **2021**	Year **2022**	Year **2023**	Year **2024**	Year **2025**	Year **2026**	**Year 2027 et seqq.**
Article …….		p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	

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

Specify the method for calculating the impact on revenue.

[35] 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.