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From:	General Secretariat of the Council
To:	Permanent Representatives Committee (Part 1)
No. Cion doc.:	12971/20
Subject:	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

Delegations will find in Annex the consolidated text[1] of the draft Regulation resulting from the third trilogue held on 28 October 2021.

If this text is approved by the Permanent Representatives Committee at its meeting on 10 November 2021, it will then be translated and, following legal-linguistic finalisation, adopted before 1 March 2022.

[1] This is the text referred to in points 9 and 16 of document 13505/21.

ANNEX

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[1],

After consulting the Committee of the Regions[2],

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.

[1] OJ C , , p. .
[2] OJ C , , p. .

(1a) The COVID-19 pandemic has highlighted the interconnectedness of human, animal, and ecosystem health and risks posed by the loss of biodiversity on earth. As recognised by the World Health Organization, many of the same microbes infect animals and humans, so efforts by just one sector cannot prevent or eliminate the problem. Diseases may be transmitted from humans to animals or vice versa and must therefore be tackled in both, taking advantage of potential synergies in research and treatments. Approximately 70 % of emerging diseases and almost all known pandemics (influenza, HIV/AIDS and COVID-19) are zoonosis. Those diseases have increased globally over the past 60 years. Changes in land use, deforestation, urbanisation, agricultural expansion and intensification, wildlife trafficking and consumption patterns are contributing factors. Zoonotic pathogens can be bacterial, viral or parasitic, or can involve unconventional agents, with the possibility of spreading to humans through direct contact or through food, water or the environment. The COVID-19 pandemic is a clear example of the need to reinforce the application of the One Health approach in the Union to achieve better public health outcomes, since, as stated in the EU4Health Programme established by Regulation (EU) 2021/522 of the European Parliament and of the Council[3], human health is connected to animal health and the environment and actions to tackle threats to health must take into account those three dimensions

[3] REGULATION (EU) 2021/522 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014, OJ L107, 26.3.2021, p.1

(2) The unprecedented experience of the COVID-19 pandemic has also highlighted the difficulties of the Union and the Member States to address such a public health emergency and has demonstrated the need to strengthen the Union's role in order to 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 from an early stage in a harmonised way ensuring cooperation and coordination between Union, national and regional competent authorities, industry and other actors of the pharmaceutical and medical devices supply chains, including healthcare professionals. The Union needs to give a higher priority to health, to ensure the continued provision of high quality healthcare services, and to be prepared to address epidemics and other health threats. 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, limited mandates and resources of its health agencies, and also by the limited degree of Union and Member States preparedness in case of a public health emergency impacting a majority of Member States.

(2a) Shortages have different and complex root causes which need to be further mapped, understood and analysed together with all different stakeholders in order to be comprehensively addressed. A better understanding of the shortages should include identification of vulnerabilities in the supply chain. In the specific case of the COVID-19 pandemic, the shortage of treatments for the disease had a variety of causes, ranging from production difficulties in third countries, to logistical or production difficulties within the Union, where the shortage of vaccines was due to inadequate manufacturing capacity.

(3) Disruptions to 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, uncertainty related to their supply and demand in the context of the COVID-19 pandemic, and the lack of production in the Union of certain medicinal products or active pharmaceutical ingredients 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, with serious consequences for its citizens.

(4) Addressing the issue of shortages of medicinal products has been a long-standing priority, but unresolved, for the Member States and European Parliament as illustrated by several reports from the European Parliament[4] as well as discussions under recent Presidencies of the Council of the European Union.

(4a) Shortages of medicinal products represent a growing threat to public health, with a serious impact on health care systems and on patients' right to access adequate medical treatment. Increased global demand exacerbated by the COVID-19 pandemic has led to further shortages of medicinal products, weakening the healthcare systems in Member States and posing significant risks to patients' health and care, particularly in terms of disease progression and worsening of symptoms, longer delays or interruptions in care or therapy, longer periods of hospitalisations, increased risk of exposure to falsified medicinal products, medication errors, adverse effects as a result of substitution of unavailable medicinal products with alternative ones, significant psychological distress for patients and increased costs for the healthcare systems.

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

(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 Union's external dependence in terms of domestic production of medicinal products and medical devices, the lack of coordination and the structural limitations in the Union's and Member States' ability to rapidly and effectively react to such challenges during public health crises, the need to support and strengthen the industrial fabric through appropriate policies, as well as the need for a more active and extended involvement of the Union institutions, bodies, offices and agencies addressing the health of the Union citizens.

(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 severe supply difficulties and, at certain times, serious shortages, and placed Member States in competition with each other to respond to the legitimate needs of their citizens, contributing to uncoordinated actions at national levels such as national hoarding and stockpiling. Those issues further resulted in new entities being involved in the expedited production of those products, which subsequently resulted in delays in conformity assessment, as well as the prevalence of over-priced, non-compliant, unsafe, and in some cases counterfeit products. It is therefore appropriate and urgent to establish long-term structures within an appropriate Union body to ensure a more solid and effective coordination and monitoring of shortages of medical devices that can occur during a public health emergency, as well as increased and early dialogue with the medical devices industry and healthcare professionals to prevent and mitigate those shortages

(6a) The COVID-19 outbreak and the subsequent health crisis revealed the need for a more coordinated Union approach in crisis management. Although the emergency of the situation explains the lack of an impact assessment accompanying the proposal, sufficient allocation of resources in terms of staff and funding should be secured, taking into account the specificities of the health sector in the different Member States.

(7) Uncertainty of supply and demand and the risk of shortages of 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 aggravating the consequences for public health, as well as lead to the need for temporary export transparency and export authorisation mechanisms. 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, adverse reactions and increased risk of fatalities 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 or being protected when doing so, as evidenced during the COVID-19 pandemic, with serious consequences for the health of health professionals. 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 have an appropriate framework at Union level to coordinate the EU response rto address the question of shortages and to reinforce and formalise monitoring of critical medicinal products and medical devices in the most efficient way and so as to avoid creating unnecessary burdens for stakeholders which may strain resources and cause additional delays.

(8) Safe and efficacious medicinal products that treat, prevent or diagnose diseases which cause public health emergencies, should be identified, developed, notably through joint efforts of public authorities, private sector and academia, and made available to Union citizens as soon as possible during such emergencies. The COVID-19 pandemic has also highlighted the need to coordinate assessments and conclusions on multinational clinical trials, in line with what was done on a voluntary basis by clinical trials experts of Member States, prior to the application of the Clinical Trials Regulation, 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 or other actors in the pharmaceutical supply chain 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.

(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 and strengthen 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, with a view to strategically complementing the efforts of the Commission, including HERA and Union agencies to that end.

(10a) In order to support the assessment of the crisis preparedness and management framework provided by this Regulation with regard to shortages of medicinal products and medical devices, the Commission should be able to use the outcomes of targeted stress tests performed by the Commission, the Agency, Member States or other relevant actors. Such stress tests entail a simulation exercise which mimics a major event or a public health emergency whereby segments of or the complete processes and procedures of this Regulation are tested.

(10b) In order to ensure a better functioning of the internal market of medicinal products and contribute to a high level of public health protection, it is appropriate for the Emergency Task Force to coordinate and provide advice to developers involved in the research and development of medicinal products, which may have the potential to treat, prevent, or diagnose diseases that cause a public health emergency.

(11) This Regulation aims to ensure a high level of human health protection by ensuring the smooth functioning of the internal market as regards medicinal products and medical devices. 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.

(11a) This Regulation establishes a framework to address the problem of shortages during public health emergencies and major events. However, shortages of medicinal products and medical devices are a persistent problem that has been increasingly affecting health and lives of Union citizens for decades. Therefore, this Regulation should be a first step towards improving the Union response to this long-lasting issue. The Commission should subsequently assess the expansion of this framework to ensure that the issue of shortages is broadly and permanently tackled.

(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 that have been proven effective, and on experience, best practices and examples in other countries, while remaining flexible enough to tackle any future health crisis in the most efficient way to the benefit of public health and patients.

(12a) It is understood that all recommendations, advice, guidance and opinions mentioned in this Regulation are inherently non-binding. Any of these acts allow the Commission, the Agency, the Steering Groups and the ETF to make their views known and to suggest a line of action without imposing any legal obligation on those to whom those acts are addressed.

(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 ,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 mitigate 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, while avoiding any duplication of the information requested and submitted. This should not interfere with the obligation of MAHs under Article 23a of the Directive 2001/83/EC[5] to notify Member States when the product ceases to be placed on the market of that Member State and the obligation under Article 81 of the Directive 2001/83/EC for MAH and wholesale distributors within the limits of their responsibilities, to ensure appropriate and continued supplies of that medicinal product entities and persons authorised and entitled to supply medicinal products so that the needs of patients in the Member State in question are covered.

(13a)

- In order to facilitate the prevention, monitoring and reporting of shortages of medicinal products, it would be necessary for the Agency to set up an electronic platform capable of processing information on supply and demand of critical medicines during major events and public health emergencies and outside of those times to allow for reporting on shortages of medicinal products that are likely to lead to major events or public health emergencies.

- To facilitate the development of such a platform, existing IT systems should be leveraged and used where possible.

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5 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 L311, 28.11.2001, p.67

- The platform should allow national competent authorities to submit and monitor information on unmet demands, including information received from marketing authorisation holders, wholesale distributors and other persons or entities entitled or authorised to supply public with medicinal products, to anticipate shortages of medicinal products. The platform could also process additional information received from marketing authorisation holders, wholesale distributors and other persons or entities entitled or authorised to supply public with medicinal products in order to prevent a major event or a public health emergency.

- The platform should also act as the sole portal for marketing authorisation holders to provide the information required during major events and public health emergencies once fully implemented, with a view to increasing efficiency, predictability during crises, and accelerate the decision-making process while avoiding duplication of efforts and an unjustified burden on all stakeholders.

- In order to facilitate the coordination role of the Agency, data interoperability with existing Member States' shortages monitoring platforms and other systems, as appropriate, should be a priority to allow the sharing of relevant information to the platform, managed by the Agency.

(13ab) In the event that the actual future demand is unknown due to a major event or public health emergency, it is important to make pragmatic predictions of demand for certain medicines through the use of best available information. In this context, planned minimum stocks and available stocks should be collected and taken into account in identifying the demand to the extent possible. This information is essential for correct adjustments in the manufacturing of medicinal products to avoid or at least mitigate the impact of shortages. However, when data on stocks are not available or cannot be provided due to national security interests, Member States should provide the Agency with estimated data on volumes of demand.

(13c) To facilitate appropriate communication between patients and consumers and the Medicines Shortages Steering Group, Member States could collect data on the impact of medicines shortages on patient and consumers, and share relevant information with the Medicines Shortages Steering Group in order to inform approaches to medicinal products shortage management.

(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 Decision No 1082/2013/EU[6] and, as regards the Medicines Shortages 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. In addition, such monitoring should take into consideration the One Health principles.

(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 and recommendations on the necessary action to take to safeguard the quality, safety, and efficacy of medicinal products as well as their supply and ensure a high level of human health protection.

(15a) In order to ensure the inclusivity and transparency of the work of the Medicines Shortages Steering Group, appropriate engagement with relevant third parties, including representatives of medicinal product interest groups, marketing authorisation holders, wholesale distributors, any other appropriate actor in the pharmaceutical supply chain, representatives of healthcare professionals and patients and consumers, needs to be ensured.

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6 DECISION No 1082/2013/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC, OJ L293, 5.11.2013, p.1

(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. Decisions on clinical trial applications should remain within the responsabilities of the Member States, in accordance with Regulation (EU) No 536/2014[7].

(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 advice and recommendations with regard to the use of medicinal products in the fight to overcome 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. The Medicines Shortage Steering Group could also draw on the work of the Emergency Task Force when developing the critical medicines lists.

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[7] REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, OJ L4, 7.1.2019, p.43

(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, while guaranteeing a high level of human health protection.

(19a) Experience with clinical trials during the COVID-19 pandemic revealed a tremendous amount of duplication of investigations on the same interventions, many small trials, under-representation of important population subgroups, based on gender, age, ethnicity or medical comorbidities, and a lack of collaboration, posing a risk of research waste. To improve the clinical research agenda, international regulators pointed out the need for robust evidence on quality, efficacy and safety of medicinal products. The main way to obtain reliable evidence is through coordinated, well-designed, adequately powered large randomised controlled trials. Clinical trial results and clinical data after marketing authorisation has been granted should be made publicly available in a timely manner after they become available. Publication of the protocol at the start of the clinical trial would allow public scrutiny.

(19ab) Whenever necessary and considering that human medicinal products may impact the veterinary sector, a close liaison with the national competent authorities for veterinary medicinal products should be envisaged.

(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. In that regard, a new Union wide and Union funded vaccine trial network called VACCELERATE was launched in light of the Commission communication of 17February 2021 entitled 'HERA Incubator: Anticipating together the threat of COVID-19 variants'. The Agency should 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 and coordinate the development of clinical trial protocols. 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.

(20a) The European Medicines Agency publishes a 'European Public Assessment Report' (EPAR) for products authorised in accordance with Regulation (EC) No 726/2004[8], which provides information on the related assessment by describing the data assessed and the reasons for recommending whether the medicine should be authorised or not. The report will include detailed information of all relevant pre-submission activities, including with regard to scientific advice provided by the Emergency Task Force the names of the coordinators and experts involved, and in case a medicine developer requested scientific advice during the pre-submission phase an overview of the scientific topics discussed during this advice.

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8 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 L136, 30.4.2004, p.1

(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.

To ensure such coordination, the Executive Steering group on Medical Devices should also liaise the Medical Devices Coordination Group, where appropriate. In that respect, Member States may appoint the same representatives to both the Executive Steering Group on Medical Devices and the Medical Device Coordination Group.

(21a) In order to establish the list of categories of critical medical devices and *in vitro* diagnostics and to facilitate the monitoring process, the manufacturers or their authorised representative and, where necessary, concerned notified bodies should provide the requested information. In specific situations, namely when a Member State considers the need to provide for temporary exemptions pursuant to Article 59(1) of Regulation (EU) 2017/745[9] or Article 54(1) of Regulation (EU) 2017/746[10] with a view to mitigating potential or actual shortages of medical devices and *in vitro* diagnostic medical devices, also the importer and distributor should play a relevant role in providing the requested information, if no authorised representative is designated by the non-EU manfacturer.

(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[11] to provide independent scientific and technical assistance to the Member States, the Commission, the MDCG, notified bodies and manufacturers, while upholding maximum transparency as a condition for fostering trust and confidence in the Union regulatory system.

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9 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 L117, 5.5.2017, p.1

10 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 L117, 5.5.2017, p.176

11 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

(22a) The Emergency Task Force should provide advice on clinical trial protocols and to developers of clinical trials that are conducted in the Union, providing guidance on clinically relevant endpoints and targets for vaccines and treatments in order to guide clinical trial design toward meeting the criteria for effective public health interventions.

(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[12] and Regulation (EU) 017/746[13] respectively, as well as providing opinions in response to consultation by manufacturers and notified bodies, the panels are to provide scientific, technical, and clinical assistance to the Member States, the Commission, and the 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. In this context, the expert panels could play a relevant role in the preparedness for and management of public health crises for medical devices, particularly those of high risk including those devices which have the potential to address public health emergencies without prejudice to tasks and obligations under Regulation (EU) 2017/745 and Regulation (EU) 2017/746.

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12 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.

13 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.

(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 suitable 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.

(24a) To ensure a smooth transition to the Agency, the support for the expert panels should be provided by the Commission, until the 1 March 2022.

(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 and systems under development, including the European data base on medical devices EUDAMED, alongside enhanced protection of data infrastructure and deterrence from possible cyberattacks.

In Eudamed, the European Medical Device Nomenclature (EMDN) system should help to gather relevant information on categorization of 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.

(25a) In order to ensure the completeness of information and data obtained by the Agency and considering the specific characteristics of the medical device sector, until Eudamed is fully functional, the list of single points of contact for monitoring the shortages of medical devices and *in vitro* diagnostic medical devices included on the public health emergency critical devices list may be obtained from relevant databases and medical device associations at EU or national level.

(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 Agency to use and facilitate such exchange and be part of the establishment and operation of the European Health Data Space interoperable infrastructure, taking advantage of all the potential of supercomputing, artificial intelligence and big data science to develop predicting models and take better and more timely-effective decisions, without compromising the privacy rights.

(26a) In order to facilitate the reliable exchange of medicinal product information in a robust and consistent manner, identification of human medicinal products will be based on International Organization for Standardization (ISO) for the identification of medicinal products for human use (IDMP) standards.

(26b) The handling of sensitive data, crucial for dealing with potential public health emergencies, requires a high level of protection against cyber-attacks. Health care organisations have been also facing heightened cyber-security threats in the midst of the COVID-19 pandemic. The Agency itself has been the target of a cyber-attack that resulted in some of the unlawfully accessed documents related to COVID-19 medicines and vaccines belonging to third parties being leaked on the internet. There is therefore the need for the Agency to be equipped with a high level of security against cyber-attacks to ensure the normal functioning of the Agency at all times and especially during public health emergencies. To that end, the Agency should establish a plan to prevent, detect, mitigate and respond to cyber-attacks so that its operation is secured at all times, while preventing any illegal access to documentation held by the Agency.

(26c) Due to the sensitive nature of health data, the Agency should safeguard and guarantee its processing operations respect the data protection principles of lawfulness, fairness and transparency, purpose limitation, data minimisation, accuracy, storage limitation, integrity and confidentiality. Where it is necessary for the purposes of this Regulation to process personal data, this should be done in accordance with Union law on the protection of personal data. Any processing of personal data based on this Regulation should take place in accordance with Regulations (EU) 2016/679[14]and (EU) 2018/1725[15]of the European Parliament and of the Council

(26d) It is imperative to have in place robust transparency measures and standards regarding the Agency's regulatory activities on medicinal products and medical devices falling under the scope of this Regulation. Those measures should include timely publication of all relevant information on approved products and clinical data, including clinical trial protocols. The Agency should apply high degree of transparency on the membership, recommendations, opinions and decisions of the newly established Steering Groups and the Emergency Task Force. Members of the Steering Groups and the Emergency Task Force should have no financial or other interests in the pharmaceutical or medical device industry which could affect their impartiality.

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

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).

(26e) Credibility of the Agency and public trust in its decisions relies on a high degree of transparency. Therefore, proactive engagement of adequate communication tools with the general public should be foreseen. In addition, strengthened and accelerated transparency standards and measures regarding the Agency's working bodies and clinical data assessed for the evaluation and surveillance of medicinal products and medical devices are paramount to gain and upheld public trust. This Regulation establishes a framework for those strengthened transparency standards and measures, based on the Agency's efforts, standards and measures put in place during the COVID-19 pandemic.

(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 Shortages Steering Group, and the Medical Devices Shortages Steering Group, as appropriate. This cooperation should also include strategic discussions with relevant entities of the Union in a position to assist the research and development of appropriate solutions and technologies to mitigate the effects of the public health emergency or major event, or prevent future similar public health emergencies or major events.

(27a) During a public health emergency or in relation to a major event, it should be possible for the Agency to enable regular exchanges of information with Member States, the industry, relevant actors of the pharmaceutical supply chain, representatives of healthcare professionals, patients and consumers, to guarantee early discussions on potential drug shortages in the market and supply constraints, so as to allow better coordination and synergies to mitigate and respond to the public health emergency or the major event.

(27b) Taking into account that the COVID-19 pandemic has not come to an end, and that the duration and evolution of health crises, such as pandemics, are uncertain, provision should be made for a review of the effectiveness of the functioning of the structures and mechanisms established in accordance with this Regulation. In light of that review, the structures and mechanisms should be amended, if 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.

(28a) In order to ensure that sufficient resources, including appropriate staffing and adequate expertise, 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. This expenditure should include remuneration to rapporteurs appointed to provide scientific services in relation to the Emergency Task Force and, in line with usual practice, reimbursement of travel, accommodation and subsistence expenses related to meetings of the Medicines Shortages Steering Group, Medical Devices Shortages Steering Groups, the Emergency Task Force and their working parties under this Regulation.

(29a) Moreover, the EU4Health programme or the Recovery and Resilience Facility, inter alia, are tools to provide additional support to national competent authorities in the area of shortages, including through the implementation of actions to mitigate shortages of medicines and improve the security of supply. Member States may request financial support from the Union specifically in view of the implementation of their obligations set out in this Regulation.

(30) The European Data Protection Supervisor has been consulted in accordance with Article 42(1) of Regulation (EU) No 2018/1725[16] and has adopted an opinion. [17]

(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,

(31a) One of the aims of this Regulation is to ensure a strengthened framework for reporting on and monitoring of shortages of medicinal products during major events and public health emergencies. As announced in the Pharmaceutical Strategy for Europe 2020[1] the Commission will propose to revise the pharmaceutical legislation to enhance the security of supply and address shortages through specific measures. This could cover a further co-ordinating role the EMA in monitoring and managing shortages of medicinal products. If as a result of this revision strengthened measures on the reporting on and monitoring of supply and demand of medicinal products at Union level are required, the ESMP should be considered as a suitable system to facilitate any new provisions relating to reporting and monitoring of shortages.

- As part of the reporting on this Regulation, the Commission should consider the need to extend the scope of this Regulation to include veterinary medicinal products and personal protective equipment, to adjust definitions and to introduce measures at EU or national level to strengthen compliance with the obligations set out in this regulation.

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16 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).

17 *[insert reference once available]*

- In addition it is necessary to include in that review consideration of the remit and functioning of the ESMP. The extension of the functioning of the ESMP and the need for national shortages monitoring systems should be considered if necessary.

- In preparation for and to support monitoring of shortages of medicinal products during major events and public health emergencies, capacity building, with support from EU funding mechanisms, should be considered to enhance cooperation among Member States. This could include exploration of best practice and coordination of the development of IT solutions to monitor and manage medicines shortages in Member States and connecting to the ESMP.

- To ensure the ESMP is used to its full potential and to identify and forecast problems with supply and demand of medicinal products, where appropriate, the ESMP should, facilitate the application of big data techniques and artificial intelligence.

(32) In order to allow for the prompt application of the measures provided for in this Regulation, it should enter into force on the day following that of its publication in the Official Journal of the European Union.

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:

(a) prepare for, prevent, coordinate 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 at Union level;

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

(ba) set up an interoperable and digital platform at Union level to monitor and report on shortages of medicinal products;

(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 Article 106(1) of Regulation (EU) 2017/745.

Article 2

Definitions

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

(a) ‘public health emergency’ means a public health emergency recognised by the European Commission in accordance with Decision No 1082/2013/EU;

(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;

(ba) 'veterinary medicinal product' means a veterinary medicinal product as defined in point (1) of Article 4 of Regulation (EU) 2019/6 of the European Parliament and the Council;

(c) ‘medical device’ means a medical device as defined in point (1) of Article 2 of Regulation (EU) 2017/745;

(ca) 'supply' refers to the total volume of stock of an individual medicinal product or medical device that is placed on the market by a marketing authorisation holder or a manufacturer;

(ca) ‘accessory’ for a medical device means an accessory as defined in point (2) of Article 2 of Regulation (EU) 2017/745 and for an *in vitro* medical device means accessory as defined in point (4) of Article 2 of regulation (EU) 2017/746;

(cb) 'demand' means the request for a medicinal product or a medical device by a healthcare professional or patient in response to clinical need. For demand to be satisfactorily met, the medicinal product or the medical device will need to be acquired in appropriate time and sufficient quantity to allow continuity of best care of patients;

(cb) ‘*in vitro* diagnostic medical device’ means 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 that is authorised and placed on the market in a Member State or of a CE-certified medical device does not meet demand for that medicinal product or medical device at a national level, whatever the cause;

(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 States. 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, demand 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.

2. For the purposes of this Regulation, references to “medical devices” and “*in vitro* medical devices” shall be understood as covering the medical devices and the *in vitro* medical devicesand their accessories in the meaning of paragraph 1.

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 Shortages Steering Group') is hereby established as part of the Agency. It shall meet regularly and in addition, whenever the situation requires, 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 Shortages Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one - appointed representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields.

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

   The list of the members of the Medicines Steering Group shall be transparent and made public on the Agency's web-portal.

3. The Medicines Shortages Steering Group shall be co-chaired by the Agency and by a representative of a Member State elected by and amongst its members.

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

3a. The Medicines Shortages Steering Group shall, in coordination with the national competent authorities, facilitate appropriate communication with marketing authorisation holders or their representatives, manufacturers, other relevant actors of the pharmaceutical supply chain, and representatives of healthcare professionals and patients and consumers with a view to receiving relevant information on potential or actual shortages of medicinal products considered as critical during a major event or a public health emergency as provided for in Article 6.

4. The Medicines Shortages 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 procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.

5. The Medicines Shortages 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 Shortages Steering Group shall be responsible for fulfilling the tasks referred to in Article 4(3), Article 4(4) and Articles 5 to 8.

6a. The Medicines Shortages Steering Group may consult with the Committee for Medicinal Products for Veterinary Use whenever it deems it necessary to deal with public health emergencies and major events related to zoonoses or diseases affecting only animals that have or may have a major impact on human health.

Article 4

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

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

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), or the platform referred to in Article 12a, once fully functional shall, based on the reporting criteria specified by the Agency pursuant to Article 9(1)(b), report in a timely manner to the Agency on any event, including an actual or a potential 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 such a shortage of a medicinal product, 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 raise the issue of concern to the Medicines Shortages Steering Group. Following a positive opinion of the Medicines Shortages Steering Group, the Commission may recognise the major event and trigger the actions foreseen in this regulation. The Commission or at least one member state may also raise the issue of concern to MSSG on their own initiative.

4. The Medicines Shortages 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 Shortages 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

1. Following the recognition of a public health emergency or a request for assistance referred to in Article 4(3), the Medicines Shortages 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.

2. The Medicines Shortages Steering Group shall provide recommendations 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.

2b (new) The Medicines Steering Group may consult with the Committee for Medicinal Products for Veterinary Use whenever it deems it necessary to deal with public health emergencies and major events related to zoonoses or diseases affecting only animals that have or may have a major impact on human health, or where the use of active ingredients of veterinary medicinal products may be useful to address the public health emergency or the major event, or otherwise whenever necessary.

Article 6

Lists of critical medicinal products and information to be provided

0. Without prejudice to paragraph 2, the Medicines Shortages Steering Group shall establish a list with the main therapeutic groups of medicinal products for ensuring emergency care, surgeries and intensive care, with a view to inform the preparation of the critical medicines lists as defined in Article 6(1) and Art 6(2), to respond to a public health emergency or major event. The list shall be established at the latest six months after the entry into force of the Regulation and updated annually and whenever necessary.

1. Following a request for assistance referred to in Article 4(3) and after consultation of its working party, the Medicines Shortages 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 and it has been confirmed that the assistance of the Medicines Steering Group is no longer needed as referred to in Article 4(4) of this Regulation.

2. Immediately following the recognition of a public health emergency and after consultation of its working party, the Medicines Shortages 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. The list may be updated in accordance with the outcomes of the review process under Article 16 of this Regulation, where appropriate, for which the Medicines Steering Group shall liaise with the Emergency Task Force.

3. The Medicines Steering Group shall adopt, and make publically available 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.

4a. The Agency shall establish a publicly accessible webpage with information on actual shortages of critical medicinal products, where EMA has assessed the shortage and has provided recommendations to patients and healthcare professionals. Reference to national registries on medicinal products shortages shall also be included. The webpage shall contain information on, but not limited to:

(a) trade name and international non-proprietary name;

(b) indication;

(c) reason for the shortage;

(d) start and end dates;

(e) Member States affected;

(f) information for healthcare professionals and patients, including if alternative treatments are available.

Article 7

Monitoring shortages of medicinal products on the critical medicines lists

Following the recognition of a public health emergency or a request for assistance referred to in Article 4(3,) on the basis of the critical medicines lists and the information and data provided in accordance with Articles 10 and 11, and the platform established in accordance with Article 12a, once fully functional, the Medicines Shortages 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 Decision No 1082/2013/EU and, in the case of a public health emergency, any other advisory committee on public health emergencies established pursuant to Union law as well as with the ECDC.

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 or any event that is likely to lead to a major event. Those reports may also be made available to other actors in the pharmaceutical supply chain, where relevant, and in accordance with relevant competition rules.

2. Where requested by the Commission or the sub-networks referred to in Article 9(2), the Medicines Shortages Steering Group shall provide aggregated data and forecasts of demand to substantiate its findings. In that regard, the Medicines Shortages Steering Group shall use data from the platform established in accordance with Article 12a, once fully functional, and shall liaise with the European Centre for Disease Prevention and Control to obtain epidemiological data, models and development scenarios 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.

The aggregated data and forecasts of demand may also be made available to other actors in the pharmaceutical supply chain, where relevant, and in accordance with competition rules with a view to better prevent or mitigate potential or actual shortages.

3. As part of that reporting, the Medicines Shortages Steering Group may also provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders and other entities, including representatives of healthcare professionals and patient organisations, to prevent or mitigate potential or actual shortages. Member States may request the Medicines Shortages Steering Group to provide recommendations on measures. In that regard the Group shall liaise, as relevant, with the Health Security Committee established in Decision No 1082/2013/EU and, in the case of a public health emergency, any other relevant advisory committee on public health emergencies established pursuant to Union law.

4. The Medicines Shortages Steering Group may, on its own initiative or upon request from the Commission or Member States, provide recommendations on measures, which may be taken by the Commission, Member States, marketing authorisation holders, representatives of healthcare professionals 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 Shortages Steering Group may upon request from the Commission coordinate measures, where relevant, between the national competent authorities, the marketing authorisation holders and other entities, including representatives of healthcare professionals and patient organisations 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

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

(a) specify the procedures and criteria for establishing and reviewing the critical medicines lists. Member States, healthcare professionals, patients, consumers, marketing authorisation holders and other relevant actors in the pharmaceutical supply chain may be consulted as necessary;

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

(c) develop streamlined electronic monitoring and reporting systems in coordination with the national competent authorities, facilitating the interoperability with other existing IT systems and systems under development until the platform provided for in Article 12a is fully functional, based on harmonised data fields across Member States;

(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)(i) 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;

(fa) publish information referred to in points (a), (b) and (f) of this paragraph on a dedicated space in its web-portal.

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 list 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 list referred to in point (a) and set a deadline for its submission if that information is not available in the platform provided for in Article 12a;

(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 Shortages Steering Group and set a deadline for its submission, if that information is not available in the platform provided for in Article 12a.

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;

(ba) Identification of active manufacturing sites of finished products and active substances;

(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;

(ea) available stocks;

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

(ec) information on the forecast of demand;

(f) details of available alternative medicinal products;

(g) prevention and mitigation plans, at least including information on production and supply capacity, production sites of the finished pharmaceutical product and of active pharmaceutical ingredients, potential alternative production sites or minimum stock levels.

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 to the database referred to in Article 57(1)(i) 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 requested by the Agency or the national competent authorities 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 or other relevant actors in the pharmaceutical supply chain 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 Shortages Steering Group of any measures taken and report on the monitoring and results of those measures, including information on the resolution of the potential or actual shortage.

6a. In order to supplement the shortage prevention and mitigation plans of critical medicinal products, the Agency and national competent authorities may request additional information from wholesale distributors and other relevant actors regarding any logistical challenges incurred by the wholesale supply chain.

Article 11

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

1. In order to facilitate the monitoring referred to in Article 7 and following a request from the Agency, Member States shall, by the deadline set by the Agency, submit the following information provided that it is not available in the platform established in Article 12a:

   (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, in accordance with Article 10(4);

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

2. Wholesale distributors and other legal entities or persons authorised or entitled to supply the public with medicinal products included on the critical medicines lists shall provide relevant information and data, including on stock levels, where necessary for Member States to fulfil their reporting obligations set out in paragraph 1.

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 Shortages 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 coordinate their actions related to any measures taken at Union level pursuant to Article 12(a);

(b) inform the Medicines Shortages 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. Where an alternative course of action has been taken at national level, the Member States where such alternative occurred, shall share, in a timely manner, the reasons to the Medicines Shortages Steering Group. The recommendations, guidelines and measures taken at Union level pursuant to Article 12(a) and a summary report of the lessons learned shall be made publicly available via the web-portal as referred to in Article 13.

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 Shortages 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;

(aa) facilitate the coordination between manufacturers and other relevant stakeholders to address demand surges, where necessary;

(b) consider the need for guidelines and recommendations addressed to Member States, marketing authorisation holders, and other entities, including from the pharmaceutical supply chain, where relevant.

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

(d) request the Medicines Shortages 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 Decision No 1082/2013/EU and other applicable Union legal acts;

(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, and report those actions as well as the results obtained to the Medicines Shortages Steering Group, where relevant.

Article 12a

1. The Agency shall set up, maintain, and manage an IT platform to be known as the European Shortages Monitoring Platform (The ESMP) linked to the database referred to in Article 57(1)(i) of Regulation (EC) No 726/2004. The ESMP shall be used to facilitate the collection of information on shortages, supply and demand of medicinal products, including if the product is placed or ceases to be placed on the market in a Member State.

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

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

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

3. To meet the objective of paragraph 2 during public health emergencies and major events, the ESMP, shall be used by,

(a) Marketing authorisation holders, to report to the Agency, through the single points of contact established in Article 9(2)(a), information relating to medicinal products on the critical medicines lists, in accordance with reporting obligations set out in Articles 9 and 10 of this Regulation.

(b) Member States, to report to the Agency, through the single points of contact established in Article 9(1)d, information relating to medicinal products on the critical medicines lists, in accordance with obligations set out in Articles 9 and 11 of this Regulation. That reporting shall include additional information received from marketing authorisation holders and wholesale distributors, or other legal entities or persons authorised or entitled to supply the public with medicinal products included on the critical medicines lists, where relevant.

4. To meet the objective of paragraph 2, to ensure preparedness for major events and public health emergencies, the ESMP shall be used by

(a) marketing authorisation holders to report to the Agency

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

ii. where appropriate, additional information based on the dataset set out in Article 9(3), relating to actual or potential shortages that are likely to lead to a major event or public health emergency.

(b) Member States to report to the Agency, through single points of contact established in Article 9(1)(d), on shortages of medicinal products that are likely to lead to a major event or a public health emergency in accordance with Article 4(2). This reporting:

i. shall include information referred to in Article 23a of the Directive 2001/83/EC reported to national competent authorities for authorisations granted in accordance with that Directive;

ii. may include additional information received from marketing authorisation holders, wholesalers and other persons or entities entitled or authorised to supply public with medicinal products.

5. To ensure the optimal use of the ESMP the Agency shall:

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

(b) Require that data submitted to the ESMP shall be compliant with the standards developed by the International Organisation for Standardization for the identification of medicinal products and be based on the four domains of master data in pharmaceutical regulatory processes: substance, product, organisation, and referential data, where relevant;

(c) Develop standardised reporting terminology, in collaboration with the Medicines Shortages Steering Group, to be used by marketing authorisation holders and Member States when reporting to the ESMP;

(d) Establish relevant guidance for reporting through the ESMP, in collaboration with the Medicines Shortages Steering Group;

(e) Ensure data interoperability between the ESMP, Member States' IT systems and other relevant IT systems and databases, with no duplication of reporting;

(f) Ensure appropriate levels of access to the information contained in the ESMP for the Commission, the Agency, national competent authorities reporting and the Medicines Shortages Steering Group;

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

(h) Ensure the ESMP is fully operational by 36 months after the date of entry into force of this Regulation and draw up a plan for the implementation of the ESMP.

Article 13

Communication on the Medicines Shortages Steering Group

1. The Agency shall, via a dedicated space on its web-portal and other appropriate means, in conjunction with national competent authorities, inform the public and interest groups in a timely manner with regard to the work of the Medicines Shortages Steering Group, and respond to disinformation targeting the work of the Medicines Shortage Steering Group as appropriate.

1a. Proceedings undertaken by the Medicines Shortages Steering Group shall be transparent. The summaries of the agenda and of the minutes of the Medicines Shortages Steering Group as well as the rules of procedure and recommendations shall be documented and made publicly available on the dedicated space on the Agency web portal. Where the rules of procedures referred to in Article 3(4) allow members of the MSSG to have divergent opinions recorded, the MSSG shall make such divergent opinions, and the grounds on which they are based, available to national competent authorities upon their request.

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 in preparation for and 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) in liaison with the scientific committees, working parties, and scientific advisory groups of the Agency, providing scientific advice and reviewing the available scientific data on medicinal products with the potential to address the public health emergency, including requesting data from developers and engaging with them in preliminary discussions;

   (b) providing advice on the main aspects of clinical trial protocols; and providing advice to developers on clinical trials for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency, in accordance with Article 15 without prejudice to the tasks of the Member States as regards assessment of submitted clinical trial applications to be conducted on their territories in accordance with Regulation (EU) No 536/2014[18];

[18] 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

(c) providing scientific support to facilitate clinical trials 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) in liaison with the scientific committees, working parties, and scientific advisory groups of the Agency, providing scientific recommendations with regard to the use of any medicinal product, which may have the potential to address public health emergencies, in accordance with Article 16;

(f) cooperating with national competent authorities, Union bodies and agencies, the World Health Organization, third countries, and international scientific organisations on scientific and technical issues 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, nominated by the scientific committees and working parties, including representatives of the PCWP and the HCPWP, (vice) Chairs of the scientific committees 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 as well as other clinical trial experts representing competent authorities of the Member States. External experts may be appointed and representatives of other Union bodies and agencies shall be invited on an ad hoc basis, as necessary, especially in cases of public health emergencies which affect also the veterinary medicinal products field in reference to Article 5 paragraph 2(b). It shall be chaired by the Agency and co-chaired by the chair or vice-chair of the Committee for Medicinal Products for Human Use. The Emergency Task Force composition should be publicly available.

4. The composition of the Emergency Task Force shall be approved by the Management Board of the Agency taking into account the specific expertise relevant for the therapeutic response to the public health emergency. The Executive Director of the Agency or their representative and representatives of the Commission and of the Management Board of the Agency shall be entitled to attend all meetings.

5. The Co-Chairs may invite other 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, independent clinical trial experts and researchers, 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 an advisory and support body separate from, and without prejudice to the tasks of the scientific committees of the Agency as regards the authorisation, supervision and pharmacovigilance of the concerned medicinal products and related regulatory actions to ensure the quality, safety and efficacy of those medicinal products. The Committee for Medicinal Products for Human Use or other relevant scientific committees of the Agency shall take the Emergency Task Force recommendations into consideration, when adopting their opinions. 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. Members of the Emergency Task Force shall update the annual declaration of their financial or other interests provided for in Article 63 of Regulation (EC) No 726/2004 whenever a relevant change occurs.

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. Without any undue delay and in any case prior to such publication, the Agency shall inform Member States and the Heath Security Committee, as appropriate.

Article 15

Advice on clinical trials

1. During a public health emergency, the Emergency Task Force shall provide advice on main aspects of clinical trial protocols submitted or intended to be submitted in a clinical trial application, without prejudice of the responsibility of the Member State(s) according to Regulation (EU) 536/2014, 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 and guidance 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. In preparation of the scientific advice, the Emergency Task Force shall involve representatives with clinical trial expertise of the Member States in particular of those where an application for authorisation of a clinical trial is submitted or is intended to be submitted.

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

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 15a

Public information about clinical trials and marketing authorisation decisions

1. For the duration of a public health emergency, the sponsors of clinical trials conducted in the Union shall, in particular:

   (a) make the clinical trial protocol publicly available at the start of the trial for all trials authorised under Regulation (EU) No 536/2014 that examine medicinal products which may have the potential to address the public health emergency, through the EU clinical trials register EU Portal and Database established by Articles 80 and 81 of that Regulation.

(b) make the summary of the results publicly available through the EU Portal and Database established by Articles 80 and 81 of Regulation (EU) No 536/2014 within a timeline set by the Agency that is shorter than the timeline laid down in Article 37 of Regulation (EU) No 536/2014.

2. Where a medicinal product receives a marketing authorisation relating to the public health emergency, the Agency shall publish, in particular:

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

(b) the European public assessment reports as soon as possible and, where possible, within seven days of marketing authorisation;

(c) the clinical data submitted to the Agency in support of the application where possible within two months of authorisation by the Commission, and after personal data have been anonymised and commercially confidential information redacted;

(d) the full body of the Risk Management Plan and any updated versions.

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 updated whenever needed during the public health emergency, including where agreed by the Emergency Task Force and the Committee for Medicinal Products for Human Use in preparation of the assessment of a marketing authorisation application.

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 health data generated outside of clinical studies taking into account their reliability. The Emergency Task Force may liaise with medicine agencies of third countries for additional information and data exchange.

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 its 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 available from 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.

Article 17

Communication on the Emergency Task Force

The Agency shall, via a dedicated space on its web-portal and other appropriate means and, in conjunction with national competent authorities, inform in a timely manner the public and relevant interest groups with regard to the work of the Emergency Task Force, and respond to disinformation targeting the work of the Emergency Task Force as appropriate.

The list of the members of the Emergency Task Force, the rules of procedure and the list of products under review regularly as well as the opinions adopted pursuant to Article 16 (4) shall be published on the Agency's web-portal.

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, including an interoperable and digitalised platform, for the submission of information and data, including electronic health data generated outside of clinical studies facilitating interoperability with other existing electronic tools, and tools under development, and providing the adequate support to Members States' competent authorities;

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

(ba) for vaccines, the coordination referred in point (b) 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 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 Shortages of Medical Devices

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

2. The Medical Devices Shortages Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one appointed representative per Member State. Each Member State shall appoint a representative with expertise in the field of medical devices or *in vitro* diagnostic medical devices, as relevant. These representatives may be the same as the one appointed for MDCG where appropriate. Members may be accompanied by experts in specific scientific or technical fields. Representatives of the PCWP and of the HCPWP may also attend the meetings of the Medical Devices Shortages Steering Group as observers. The list of members of the Medical Devices Shortages Steering Group shall be transparent and made public on the Agency's web-portal.

3. The Medical Devices Shortages Steering Group shall be co-chaired by the Agency and by a representative of a Member State elected by and amongst its members.

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

4. The Medical Devices Shortages 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 Shortages Steering Group shall be supported in its work by a working party comprised of single points of contact from national competent authorities responsible for shortage monitoring and management of medical devices and *in vitro* diagnostic medical devices established in accordance with Article 23(1).

6. The Medical Devices Shortages 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 Shortages Steering Group shall adopt a list of categories of critical medical devices and *in vitro* diagnostic medical devices which it considers as critical during the public health emergency ('the public health emergency critical devices list'). To the extent possible, relevant information on medical devices and *in vitro* diagnostics medical devices and related manufacturers shall be gathered from EUDAMED, when fully functional. The information shall also be gathered from importers and distributors, as appropriate. Until EUDAMED is fully functional, available information may be gathered also from national databases or other available sources. The list shall be updated whenever necessary until the termination of the recognition of the public health emergency.

2. The Medical Devices Shortages Steering Group shall adopt and make publically available a set of information necessary to monitor the supply and demand of medical devices and *in vitro* diagnostic 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 a dedicated space on its web-portal.

3a. The Agency shall report on the Agency's webpage information on actual shortages of critical medical devices included on the public health emergency critical devices list.

Article 21

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

1. During a public health emergency, and on the basis of the critical medical devices and *in vitro* diagnostic medical devices list and the information and data provided in accordance with Articles 24 and 25, the Medical Devices Shortages Steering Group shall monitor supply and demand of medical devices and *in vitro* diagnostic 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 Shortages Steering Group shall liaise, where relevant, with the MDCG, the Health Security Committee established in Decision No 1082/2013/EU and any other relevant advisory committee on public health emergencies established pursuant to Union law.

2. As part of the monitoring, the Medical Devices Shortages 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 Shortages Steering Group may take into account the data generated pursuant to Article 108 of Regulation (EU) 2017/745 and Article 101 of Regulation (EU) 2017/746.

Article 22

Reporting and recommendations on shortages of medical devices

1. For the duration of the public health emergency, the Medical Devices Shortages Steering Group shall regularly report the results of its monitoring to the Commission and the single points of contact referred to in Article 23(2)(a), and, in particular, signal any potential or actual shortages of medical devices and *in vitro* diagnostic medical devices included on the public health emergency critical devices list.

2. Where requested by the Commission, Member States or the single points of contact referred to in Article 23(2)(a), the Medical Devices Shortages Steering Group shall provide aggregated data and forecasts of demand to support its findings. In that regard, the Medical Devices Shortages 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 Shortages Steering Group referred to in Article 3 where medical devices and *in vitro* diagnostic medical devices included on the public health emergency critical devices list are used to jointly with a medicinal product. The findings and conclusions of the Medical Devices Shortages Steering Group may also be made available to other actors in the medical device and *in vitro* medical device sectors, where relevant, and in accordance with relevant competition rules.

3. As part of the reporting referred to in paragraphs 1 and 2, the Medical Devices Shortages 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 MDCG, the Health Security Committee established in Decision No 1082/2013/EU and any other relevant advisory committee on public health emergencies established pursuant to Union law.

4. The Medical Devices Shortages 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 and *in vitro* diagnostic medical devices caused by public health emergencies.

5. Where relevant, the Medical Devices Shortages Steering Group may, upon request from the Commission coordinate measures 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 and criteria for establishing and reviewing the critical devices lists. MDCG, healthcare professionals, patients, consumers, manufactures and other relevant actors in the medical and *in vitro* medical device sectors supply chain may be consulted as necessary;

   (b) develop streamlined electronic monitoring and reporting systems, in coordination with the national competent authorities, facilitate interoperability with existing electronic tools, namely EUDAMED and provide the adequate support to Members States' competent authorities for monitoring and reporting;

(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 responsible for shortage monitoring and management of medical devices and *in vitro* diagnostic medical devices;

(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 list of single points of contact from medical device manufacturers, or their authorised representatives, importers and notified bodies based on the medical devices and *in vitro* diagnostic medical devices included on the public health emergency critical devices list. Where relevant, national or EU databases, including Eudamed when fully functional, or medical device associations may be used to obtain information for the establishment and maintenance of the list of single points of contact;

(b) request relevant information from the single points of contact referred to in paragraph (a) based on the set of information agreed on by the Medical Devices Shortages Steering Group and set a deadline for its submission;

(c) request relevant 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 Shortages Steering Group and set a deadline for its submission;

(ca) other sources, including existing databases and databases in development, may also be used to gather part of the information required under paragraph 3.

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 *in vitro* diagnostic medical device and the intended purpose and where necessary, specific characteristics;

(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;

(ea) available stocks;

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

(ec) Qinformation on the forecast of demand;

(f) prevention and mitigation plans at least including information on production and supply capacity;

(g) information from concerned notified bodies about their resource capacity to process applications and carry out and complete, in an appropriate period of time considering the emergency, conformity assessments in relation to medical devices and *in vitro* diagnostic medical devices included in the public health emergency critical devices list. The notified body concerned shall communicate the date by which the assessment is expected to be completed. In this regard notified bodies shall prioritise the conformity assesment of medical devices and *in vitro* diagnostic 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 and *in vitro* diagnostic 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 and *in vitro* diagnostic medical devices included in the public health emergency critical devices list and possible critical issues that have impact on the final outcome of the assessment and which need to be considered in order to complete the conformity assessment process.

Article 24

Obligations on medical device manufacturers, authorised representatives, importers, distributors 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, or their authorised representatives, as applicable, and, if appropriate, importers and distributors of 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 or their authorised representatives, as applicable, notified bodies and, if appropriate, importers and distributors of medical devices shall justify the absence of any requested information and any delays in providing it by the deadline set by the Agency.

3. Where manufacturers, or their authorised representatives and, if appropriate, importers and distributors of medical devices and *in vitro* diagnostic 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 or their authorised representatives and, if appropriate, importers and distributors of medical devices and *in vitro* diagnostic 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 ~~or~~ their authorised representatives and, if appropriate, importers and distributors of medical devices and *in vitro* diagnostic 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) 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;

   (c) inform the Medical Devices Shortages 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 and *in vitro* diagnostic medical devices included on the public health emergency critical devices list are established outside the Union-, the information required- in accordance with this Article- shall be provided by the authorised representatives, or, if appropriate, importers and distributors.

Article 25

Role of Member States in the monitoring and mitigation of shortages of medical devices

1. In order to facilitate the monitoring referred to in Article 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 available information about needs related to the medical devices and *in vitro* diagnostic 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, in accordance with Article 24 (3);

   (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 and their authorised representatives, healthcare providers, importers, distributors, as applicable, and notified bodies on medical devices and *in vitro* diagnostic 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 Shortages 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:

(a) consider the need to provide for temporary exemptions at Member State level pursuant to Article 59(1) of Regulation (EU) 2017/745 or Article 54(1) of Regulation (EU) 2017/746 with a view to mitigating potential or actual shortages of medical devices and *in vitro* diagnostic medical devices included on the public health emergency critical devices list; while at the same time seeking to ensure a high level of patient and product safety;

(b) Take into account any recommendations and guidelines and coordinate their actions related to any measures taken at Union level pursuant to Article 12(a);

(c) inform the Medical Devices Shortages 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 medicinal products

The Commission shall take into account the information from and recommendations of the Medical Devices Shortages 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 and *in vitro* diagnostic medical devices included on the public health emergency critical devices list, including, where necessary, granting temporary exemptions at Union level pursuant to Article 59(3) of Regulation (EU) 2017/745 or Article 54(3) of Regulation (EU) 2017/746, while respecting the conditions set in those articles and at the same time seeking to ensure both patient and product safety;

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

(c) request the Medical Devices Shortages 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 Decision No 1082/2013/EU and other applicable Union legal acts;

(e) liaise with third countries and relevant international organisations, as appropriate, to mitigate potential or actual shortages of medical devices and *in vitro* diagnostic 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, and report these actions as well as the results obtained to the Medical Devices Shortages Steering Group, where relevant.

Article 27

Communication on the Medical Devices Shortages Steering Group

1. The Agency shall, via a dedicated space in its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups in a timely manner with regard to the work of the Medical Devices Shortages Steering Group and respond to disinformation targeting the work of the Medical Devices Shortages Steering Group as appropriate.

1a. Proceedings undertaken by the Medical Devices Shortages Steering Group shall be transparent. The summaries of the agenda and of the minutes of the Medical Devices Steering Group as well as the rules of procedure and recommendations shall be documented and made publicly available on the dedicated space on the Agency web portal. Where the rules of procedures referred to in Article 19 (4) allow members of the MDSG to have divergent opinions recorded, the MDSG shall make such divergent opinions, and the grounds on which they are based, available to national competent authorities upon their request.

Article 28

Support for the expert panels on medical devices

The Agency shall, on behalf of the Commission, from 1 March 2022 onward, provide the secretariat of the expert panels designated in accordance with Article 106(1) of Regulation (EU) 2017/745 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;

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

(d) maintain and regularly update a web-page for the expert panels and make publicly available on the web-page all information necessary not already publicly available in EUDAMED 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 Article 106(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 implementing acts adopted by the Commission pursuant to Article 106(1) of Regulation (EU) 2017/745;

(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 and the MDCG 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, Emergency Task Force and the expert panels

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

2. Members of the Medicines and Medical Devices Shortages 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 (Co-) Chairs, joint meetings of the Medicines and Medical Devices Steering Shortages Group may be held.

4. Where relevant, the Agency shall ensure cooperation between the Emergency Task Force and the expert panels in relation to preparedness and management of public health crises.

Article 29aa

Transparency and conflicts of interest

The Medicines Shortages Steering Group and the Medical Devices Shortages Steering Group shall carry out their activities in an independent, impartial and transparent manner. The members appointed to the Medicines Shortages Steering Group and the Medical Devices Shortages Steering Group and, where relevant, observers, shall not have any financial or other interests in the pharmaceutical or medical devices industry which could affect their independence or impartiality. The members appointed to the Medicines Shortages Steering Group and the Medical Devices Shortages Steering Group and, where relevant, observers shall make a declaration of their financial and other interests and update them annually and whenever necessary. The declaration of interests shall be made publicly available on the Agency's web-portal.

They shall disclose any other facts of which they become aware that might in good faith reasonably be expected to involve, or give rise to, a conflict of interest.

The members appointed to the Medicines Shortages Steering Group and the Medical Devices Shortages Steering Group and, where relevant, observers, who participate in meetings of the Medicines Shortages Steering Group and the Medical Devices Shortages Steering Group shall declare, before each meeting, any interests which could be considered to be prejudicial to their independence or impartiality with respect to the items on the agenda. Where the Agency decides that a declared interest constitutes a conflict of interest, that member or observer shall not take part in any discussions or decision-making, or obtain any information concerning that item of the agenda. Such declarations of members or observers and the decisions of the Agency shall be recorded in the summary minutes of the meeting. The members appointed to the Medicines Shortages Steering Group and the Medical Devices Shortages Steering Group and, where relevant, observers shall, even after their duties have ceased, be subject to a requirement of professional secrecy.

Article 29a

Protection against cyber-attacks

The Agency shall be equipped with a high level of security controls and processes against cyber-attacks, cyber-espionage and other data breaches to ensure the protection of health data and the normal functioning of the Agency at all times, and especially during public health emergencies or major events at Union level. To that end, the Agency shall actively pursue and implement best cybersecurity practices within Union institutions, bodies, offices and agencies to prevent, detect, mitigate, and respond to cyber-attacks.

Article 30

Confidentiality

1. Unless otherwise provided for in this Regulation and without prejudice to Regulation (EC) No 1049/2001[19] and Directive (EU) 2019/1937 of the European Parliament and of the Council[20], and existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect

[19] 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

[20] DIRECTIVE (EU) 2019/1937 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 October 2019 on the protection of persons who report breaches of Union law, OJ L305, 26.11.2019, p.17

(b) commercially confidential information and trade secrets of a natural or legal person in accordance with Directive (EU) 2016/943 of the European Parliament and of the Council[21], including intellectual property rights;

2. Without prejudice to paragraph 1, all parties involved in the application of this Regulation shall ensure that no commercially confidential information is shared in a way which has the potential to enable undertakings to restrict or distort competition 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 with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

[21] DIRECTIVE (EU) 2016/943 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure, OJ L157, 15.6.2016, p.1

Article 30a

Personal data protection

1. Transfers of personal data under this Regulation shall be subject to Regulations (EU) 2016/679[22] and (EU) 2018/1725[23] as applicable.

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

Article 30c

Reporting

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

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

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22 REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L119, 4.5.2016, p.1

23 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 L295, 21.11.2018, p.39

b. non-compliance with the obligations set out in Articles 10 and 24 of this Regulation by marketing authorisation holders and medical device manufacturers, authorised representatives, importers, distributors and notified bodies;

c. the remit and functioning of the ESMP.

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

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

a. the need to extend the scope of this Regulation to medicinal products for veterinary use and to personal protective equipment for medical use;

b. the need to adapt the definitions provided for in Article 2;

c. the need to introduce measures to strengthen at EU or national level the compliance with the obligations established in Articles 10 and 24 of this Regulation; and

d. the need to expand the remit of the ESMP, the need to further facilitate the ESMP interoperability with national and EU systems, the need for national shortages monitoring platforms, and the need to meet any additional requirements to address structural shortages of medicinal products, introduced as part of a revision of Directive 2001/83/EC and Regulation (EC) No 726/2004.

Article 30b

Union funding

1. The financing of the Agency's activities in support of the work of the Medicines Shortages and Medical Devices Shortages Steering Groups, the Emergency Task Force, their working parties and expert panels referred to in Article 106(1) of Regulation (EU) 2017/745 of the European Parliament and of the Council, involving its cooperation with the Commission and the European Centre for Disease Prevention and Control shall be ensured by the Union. The Union's financial assistance to the activities under this Regulation shall be implemented in accordance with Regulation (EU, Euratom) 2018/1046[24] of the European Parliament and of the Council.

2. The Agency shall remunerate the assessment activities of the rapporteurs in relation to the Emergency Task Force under this Regulation, in addition to reimbursing the expenses of the Member States' representatives and experts related to the meetings of the Medicines Shortages and Medical Devices Shortages Steering Groups, the Emergency Task Force and their working parties, in accordance with financial arrangements established by the Management Board. Such remuneration shall be paid to the relevant national competent authorities.

3. The Union contribution provided for in Article 67 of Regulation (EC) No 726/2004 shall cover the work of the Agency provided for under this Regulation, including for full remuneration paid to national competent authorities where fee exemptions apply in accordance with Regulation 297/95[25].

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24 REGULATION (EU, Euratom) 2018/1046 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012, OJ L193, 30.7.2018, p.1

25 COUNCIL REGULATION (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products, OJ L35, 15.2.95, p.1

Article 31

Entry into Force and date of application

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

2. It shall apply from 1 March 2022.

3. By way of derogation from paragraph 2, with the exception of Article 28, Chapter IV shall apply from... [date of entry into force + 12 months].

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