REPORT


Committee on the Environment, Public Health and Food Safety

Rapporteur: Véronique Trillet-Lenoir
Symbols for procedures

* Consultation procedure
*** Consent procedure
***I Ordinary legislative procedure (first reading)
***II Ordinary legislative procedure (second reading)
***III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in **bold italics** in the left-hand column. Replacements are indicated in **bold italics** in both columns. New text is indicated in **bold italics** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in **bold italics**. Deletions are indicated using either the **symbol** or strikeout. Replacements are indicated by highlighting the new text in **bold italics** and by deleting or striking out the text that has been replaced.

By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.
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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION


(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2020)0727),
– having regard to Article 294(2) and Article 168(5) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0367/2020),
– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
– after consulting the European Economic and Social Committee,
– having regard to the opinion of the Committee of the Regions of 7 May 2021¹,
– having regard to Rule 59 of its Rules of Procedure,
– having regard to the opinion of the Committee on the Internal Market and Consumer Protection,
– having regard to the report of the Committee on the Environment, Public Health and Food Safety (A9-0247/2021),

1. Adopts its position at first reading hereinafter set out;
2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Amendment 1

Proposal for a regulation

¹ OJ C ... / Not yet published in the Official Journal.
Recital 1 a (new)

*Text proposed by the Commission*

(1a) Health provisions of the Treaties are still largely under-used in terms of the purposes they were designed to achieve. This Regulation should therefore be aimed at making the best possible use of such health provisions, in order to demonstrate the strength of the Union’s health policy, while preserving the normal functioning of the single market in the event serious cross-border threats to health arise.

Amendment 2

Proposal for a regulation

Recital 2

*Text proposed by the Commission*

(2) In light of the lessons learnt during the ongoing COVID-19 pandemic and in order to facilitate adequate Union-wide preparedness and response to all cross-border threats to health, the legal framework for epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, as set out in Decision No 1082/2013/EU, needs to be broadened with regard to additional reporting requirements and analysis on health systems indicators, and cooperation *by* Member States *with* the European Centre for Disease Prevention and Control (ECDC). Moreover, in order to ensure effective Union response to novel cross-border threats to health, the legal framework to combat serious cross-border threats to health should enable to immediately adopt case definitions for the surveillance of novel threats and should provide for the establishment of a network of EU reference laboratories and a network to support monitoring of disease outbreaks that are relevant to substances of human

*Amendment*

(2) In light of the lessons learnt during the ongoing COVID-19 pandemic and in order to facilitate adequate Union-wide *prevention*, preparedness and response to all cross-border threats to health, including *zoonotic-related threats*, the legal framework for epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, as set out in Decision No 1082/2013/EU, needs to be broadened with regard to additional reporting requirements and analysis on health systems indicators, and cooperation *between* Member States, *and* Union agencies, particularly the European Centre for Disease Prevention and Control (ECDC) *and* the European Medicines Agency (EMA), *and* international organisations, namely the *World Health Organization (WHO)*. Moreover, in order to ensure effective Union response to novel cross-border threats to health, the legal framework to combat serious cross-border threats to health should enable to immediately adopt
origin. The capacity for contact tracing should be strengthened via the creation of an automated system, using modern technologies.

case definitions for the surveillance of novel threats and should provide for the establishment of a network of EU reference laboratories and a network to support monitoring of disease outbreaks that are relevant to substances of human origin. The capacity for contact tracing should be strengthened via the creation of an automated system that uses modern technologies, while respecting Regulation (EU) 2016/679 of the European Parliament and of the Council (‘GDPR’) 1a.


Amendment 3

Proposal for a regulation
Recital 3

Text proposed by the Commission

(3) An important role in the coordination of preparedness and response planning for serious cross-border threats to health is being played by the Health Security Committee (HSC), as formally established by Decision No 1082/2013/EU. This Committee should be given additional responsibilities with regard to the adoption of guidance and opinions to better support Member States in the prevention and control of serious cross-border threats to health.

Amendment

(3) An important role in the coordination of prevention, preparedness and response planning for serious cross-border threats to health is being played by the Health Security Committee (HSC), as formally established by Decision No 1082/2013/EU. This Committee should be given additional responsibilities with regard to the adoption of guidance and opinions to better support Member States in the prevention and control of serious cross-border threats to health and support better coordination between Member States to address those threats. Representatives designated by the European Parliament should be able to
participate in the HSC as observers.

Amendment 4

Proposal for a regulation
Recital 4 a (new)

Text proposed by the Commission

(4a) Prevention and promotion strategies concern all sectoral policies including fiscal, commercial, economic, agro-environmental, educational, housing, cultural and relating to social assistance. Health in all Policies should be a principle of all public policies. An instrument already used at the national level to assess the health impact of the different sectoral policies is the so-called Health Test. A Health impact assessment should be undertaken for all programmes managed by the Union.

Amendment 5

Proposal for a regulation
Recital 5

Text proposed by the Commission

(5) This Regulation should apply without prejudice to other binding measures concerning specific activities or quality and safety standards for certain goods, which provide for special obligations and tools for monitoring, early warning and combatting specific threats of a cross-border nature. Those measures include, in particular, relevant Union legislation in the area of common safety concerns in public health matters, covering goods such as pharmaceutical products, medical devices and foodstuffs, substances of human origin (blood, tissues and cells, organs), and exposure to ionising radiation.

Amendment

(5) This Regulation should apply without prejudice to other binding measures concerning specific activities or quality and safety standards for certain goods, which provide for special obligations and tools for monitoring, early warning and combatting specific threats of a cross-border nature, such as the International Health Regulations (IHR) of the World Health Organization (WHO). Those measures include, in particular, relevant Union legislation in the area of common safety concerns in public health and environmental matters, covering goods such as pharmaceutical products, medical devices, in vitro
diagnostic medical devices, and foodstuffs, substances of human origin (blood, plasma, tissues and cells, organs), and exposure to ionising radiation.

Amendment 6

Proposal for a regulation

Recital 6

Text proposed by the Commission

(6) The protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health. In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States through the Early Warning and Response System (‘EWRS’) set up by Decision No 2119/98/EC.

Amendment

(6) In line with the “One Health” and “Health in all policies” approaches, the protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. The Union should support Member States in reducing health inequalities, within and between Member States, in achieving universal health coverage and in addressing the challenges of vulnerable groups. The Union should also urge Member States to implement the health-specific country-specific recommendations and support Member States in strengthening the resilience, responsiveness and readiness of healthcare systems to address future challenges, including pandemics. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, and all relevant stakeholders, such as health professionals, patient associations, industry and supply chain actors, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and
Proposed for a regulation

Recital 7

Text proposed by the Commission

(7) Preparedness and response planning are essential elements for effective monitoring, early warning of and combating serious cross-border threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States’ preparedness and response plans so as to ensure they are compatible within the regional level structures. To support Member States in this endeavour, targeted training and knowledge exchange activities for healthcare staff and public health staff should be provided by the Commission and Union Agencies. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-action and after-action reviews with Member States. These plans should be coordinated, be functional and updated, and have sufficient resources for their operationalisation. Following stress tests

Amendment

(7) Prevention, preparedness and response planning are essential elements for effective monitoring, early warning of and combating serious cross-border threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States’ prevention, preparedness and response plans so as to ensure they are compatible within the regional level structures. The plans should be implemented through interregional crisis anticipation planning with particular attention paid to cross-border regions to enhance their health cooperation. Where appropriate, regional authorities should participate in the drawing up of these plans. To support Member States in this endeavour, the Commission and Union agencies should provide targeted training and facilitate the sharing of best practices for healthcare staff and public health staff to improve their knowledge and ensure necessary skills. To ensure the putting into operation
and reviews of the plans, corrective actions should be implemented and the Commission should be kept informed of all updates.

Amendment 8

Proposal for a regulation
Recital 8

Text proposed by the Commission

(8) To this end, Member States should provide the Commission with an update on the latest situation with regard to their preparedness and response planning and implementation at national level. Information provided by the Member States should include the elements that Member States are obliged to report to the World Health Organization (WHO) in the context of the International Health Regulations (IHR). In turn, the Commission should report to the European Parliament and to the Council on the state of play and progress with preparedness, response planning and implementation at Union level, including on corrective actions, every 2 years to ensure that

Amendment

(8) To this end, Member States should provide the Commission with an update on the latest situation with regard to their prevention, preparedness and response planning and implementation at national level, and regional level where applicable. Information provided by the Member States should include the elements that Member States are obliged to report to the World Health Organization (WHO) in the context of the International Health Regulations (IHR). Access to timely and complete data is a precondition for rapid risk assessments and crisis mitigation. To avoid duplication of efforts and diverging recommendations, standardised definitions, where possible, and fluid
national preparedness and response plans are adequate. In order to support the assessment of these plans, EU audits in Member States should be conducted, in coordination with the ECDC and Union agencies. Such planning should include in particular adequate preparedness of critical sectors of society, such as energy, transport, communication or civil protection, which rely, in a crisis situation, on well-prepared gender-sensitive public health systems that are also in turn dependent on the functioning of those sectors and on maintenance of essential services at an adequate level. In the event of a serious cross-border threat to health originating from a zoonotic infection, it is important to ensure the interoperability between health and veterinary sectors for preparedness and response planning.

information exchanges should take place between Union agencies, the WHO and national agencies. In turn, the Commission should report to the European Parliament and to the Council on the state of play and progress with prevention, preparedness, response planning and implementation at Union level, including on corrective actions, every year to ensure that national preparedness and response plans are adequate. In order to support the assessment of these plans, EU audits in Member States should be conducted, in coordination with the ECDC and Union agencies. Such planning should include in particular adequate preparedness of critical long-term healthcare and critical sectors of society, such as agriculture, energy, transport, communication or civil protection, which rely, in a crisis situation, on well-prepared gender-sensitive public health systems that are also in turn dependent on the functioning of those sectors and on maintenance of essential services at an adequate level. In the event of a serious cross-border threat to health originating from a zoonotic infection, it is important to ensure the interoperability between health and veterinary sectors for preparedness and response planning.

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https://www.who.int/ihr/publications/9789241596664/en/

Amendment 9

Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission

(8a) Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firmer action at Union level to support cooperation and coordination among the Member States,
in particular between neighbouring border regions. The national plans of Member States sharing a border with at least one other Member State should therefore include plans to improve the preparedness for, prevention of and response to health crises in border areas in neighbouring regions, including through mandatory cross-border training for healthcare staff and coordination exercises for the medical transfer of patients. The Commission should regularly report on the state of play of cross-border crisis preparation in neighbouring regions.

Amendment 10
Proposal for a regulation
Recital 8 b (new)

Text proposed by the Commission

(8b) The role of frontline health professionals has also become apparent during the pandemic as they have been key to ensuring access to medicine and continuity of care, providing moral support and being a source of trusted information against false information. For future emergencies, it is necessary to strengthen the knowledge of health professionals by laying down rules to provide training for workers in the fields of health care and public health. It is also necessary to integrate them through their professional organisations in the definition of public health policies as well as in the digital transformation in order to improve the quality and efficiency of health systems and ensure their sustainability for the health, social and territorial cohesion work they carry out.

Amendment 11
Proposal for a regulation
Recital 8 c (new)

Text proposed by the Commission

(8c) Health literacy plays a fundamental role in preventing and mitigating the impact of cross-border threats and contributing to a better understanding on the part of the population of the countermeasures and risk assessment of different threats. Respiratory etiquette, correct hand washing, avoiding unnecessary close contact with anyone with flu-like symptoms, and avoiding unprotected contact with wild animals should be part of health education campaigns to improve the population's behaviour, based on the latest available evidence.

Amendment 12

Proposal for a regulation
Recital 8 d (new)

Text proposed by the Commission

(8d) Building on lessons learnt from the COVID-19 pandemic, this Regulation should create a more robust mandate for coordination at Union level. The declaration of a Union emergency situation would trigger increased coordination and allow for timely development, stockpiling and joint procurement of medical countermeasures.

Amendment 13

Proposal for a regulation
Recital 8 e (new)

Text proposed by the Commission

(8e) This Regulation also ensures coordinated action at Union level, in
order to ensure that the internal market functions properly, and to ensure that basic supplies, including medicines, medical products and personal protective equipment (PPE) circulate freely.

Amendment 14
Proposal for a regulation
Recital 8 f (new)

Text proposed by the Commission

Amendment


Amendment 15
Proposal for a regulation
Recital 9

Text proposed by the Commission

Amendment

(9) As serious cross-border threats to

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health are not limited to Union borders, joint procurement of medical countermeasures should be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union legislation. The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU, should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the EU. The Commission should ensure coordination and information exchange between the entities organizing any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council.\(^\text{16}\)

Joint procurement of medical countermeasures would strengthen the negotiating position of participating countries, improve the security of supply and ensure equitable access to medical countermeasures.

The functioning of the Joint Procurement Agreement and rescEU should abide by high standards of transparency, including in relation to the disclosure of the amounts ordered by and delivered to each participating country and details of their liabilities.

The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU, should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint
procurement procedure, to allow for better coordination within the EU. The **exclusivity clause should entail that countries participating in the joint procurement procedure do not negotiate and sign parallel contracts with producers, and define clear consequences for those that do. The Commission should ensure coordination and information exchange between the entities organizing and participating in any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council**\(^{16}\).

The Member States should ensure a sufficient reserve of critical medical products to counter the risk of shortages of critical products.

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**Amendment 16**

**Proposal for a regulation**

**Recital 9 a (new)**

*Text proposed by the Commission*

(9a) Joint procurement should be based on shared responsibilities and a fair approach with rights and obligations for all parties involved. Clear commitments should be provided and respected with manufacturers delivering the agreed production levels and the authorities purchasing their agreed reserved volumes;
Amendment 17
Proposal for a regulation
Recital 9 b (new)

Text proposed by the Commission

(9b) In times of crisis, temporary measures should be introduced by the Commission to mitigate shortages and facilitate the circulation of medicines between Member States, including the acceptance of different packaging formats, a reuse procedure to enable marketing authorisation holders to obtain approval in another Member State, extending the validity of good manufacturing practices certificates, longer expiry periods, and the use of veterinary medicinal products. The Commission should strictly monitor the use of such measures, to ensure that patient safety is not compromised and to keep medicines available in the event of difficulties or shortages.

Amendment 18
Proposal for a regulation
Recital 9 c (new)

Text proposed by the Commission

(9c) Joint procurement should be carried out in a transparent, timely and effective way. In this respect, clear and transparent stages for the process, scope, tender, specifications, timelines and formalities should be defined. A preliminary consultation phase, subject to adequate safeguards against conflict of interest and asymmetry of information, involving relevant actors should be guaranteed, as well as two-way communication throughout the procedure;
Amendment 19
Proposal for a regulation
Recital 9 d (new)

Text proposed by the Commission

Amendment

(9d) The Commission should pay special attention to ensuring that joint procurement of medical countermeasures within the meaning of Article 12 also includes procurement of orphan drugs.

Amendment 20
Proposal for a regulation
Recital 9 e (new)

Text proposed by the Commission

Amendment

(9e) If joint procurement is deployed, the awarding process should take into account qualitative criteria such as the ability of the manufacturer to ensure security of supply during a health crisis, as well as price;

Amendment 21
Proposal for a regulation
Recital 9 f (new)

Text proposed by the Commission

Amendment

(9f) In order to achieve transparency, the European Parliament should scrutinise contracts concluded under the Joint Procurement Procedure. The Commission should provide to the Parliament complete, timely and accurate information on the ongoing negotiations and give access to the tender documents as well as to the contracts concluded.
Amendment 22
Proposal for a regulation
Recital 9 g (new)

Text proposed by the Commission

Amendment

(9g) Where a joint procurement procedure has not been used to purchase medical countermeasures, the Commission should encourage Member States to exchange information on pricing and delivery dates of medical countermeasures, to provide an increased level of transparency and thus allow Member States to access and negotiate medical countermeasures in more equitable conditions.

Amendment 23
Proposal for a regulation
Recital 9 h (new)

Text proposed by the Commission

Amendment

(9h) In times of crisis, other mechanisms should be used to enable global response and crises mitigation. Such mechanisms could, for example, include a Union export control mechanism, enhanced cooperation agreements on the production of medical countermeasures, pre-allocating part of the Union joint procurement, and both voluntary and compulsory technology know-how pools and licensing agreements between companies, which should facilitate access to counter-measures for people, including those in Eastern Partnership and low- and middle-income countries.

Amendment 24
Proposal for a regulation
Recital 10

**Text proposed by the Commission**

(10) Unlike for communicable diseases, the surveillance of which at Union level is carried out on a permanent basis by the ECDC, other potentially serious cross-border threats to health do not currently necessitate monitoring by EU Agencies. A risk-based approach, whereby monitoring is carried out by Member States and available information is exchanged through EWRS, is therefore more appropriate for such threats.

**Amendment**

(10) Unlike for communicable diseases, the surveillance of which at Union level is carried out on a permanent basis by the ECDC, other potentially serious cross-border threats to health do not currently necessitate monitoring by EU Agencies. A risk-based approach, whereby monitoring is carried out by Member States and available information is exchanged through EWRS, is therefore more appropriate for such threats. *Nevertheless, the ECDC should have the ability to monitor the impact of communicable diseases on major non-communicable diseases, including mental diseases, assessing the continuity of screening, diagnosis, monitoring, treatment and care in the healthcare system, in coordination with existing data sets, tools and registers.*

Amendment 25

Proposal for a regulation
Recital 11

**Text proposed by the Commission**

(11) The Commission should strengthen cooperation and activities with the Member States, the ECDC, the European Medicines Agency (‘EMA’), other Union Agencies, research infrastructures and the WHO to improve the prevention of communicable diseases, such as vaccine preventable diseases, as well as other health issues, such as antimicrobial resistance.

**Amendment**

(11) The Commission should strengthen cooperation and activities with the Member States, the ECDC, the European Medicines Agency (‘EMA’), other Union Agencies, research infrastructures and the WHO to improve, *through the One Health approach*, the prevention of communicable diseases, such as vaccine preventable diseases, as well as other health issues, such as antimicrobial resistance, *and other major non-communicable diseases*. During health crises, particular attention should be paid to the continuity of screening, diagnosis, monitoring, treatment and care for other diseases and conditions, and to the mental health
implications of the crisis and psychosocial needs of the population.

Amendment 26
Proposal for a regulation
Recital 12

Text proposed by the Commission

(12) In case of cross-border health threats due to a communicable disease, the blood and transplant services in the Member States can provide a means for rapid testing of the donor population and assessing exposure to and immunity from the disease in the general population. These services in return are dependent on rapid risk assessments by the ECDC to safeguard patients, in need of a therapy from a substance of human origin, from a transmission of such communicable disease. Such risk assessment serves then as basis to allow for the appropriate adaptation of measures setting standards for quality and safety of such substances of human origin. The ECDC should therefore set up and operate a network of national blood and transplant services and their authorities to serve this dual purpose.

Amendment

(12) In case of cross-border health threats due to a communicable disease, the blood and transplant services, pharmacies and other licensed health care establishments in the Member States can provide a means for rapid testing of the donor population and assessing exposure to and immunity from the disease in the general population. These services in return are dependent on rapid risk assessments by the ECDC to safeguard patients, in need of a therapy from a substance of human origin or undergoing a process of medically assisted reproduction from a transmission of such communicable disease. Such risk assessment serves then as basis to allow for the appropriate adaptation of measures setting standards for quality and safety of such substances of human origin. The ECDC should therefore set up and operate a network of national blood and transplant services and their authorities, as well as pharmacy services and other licensed health services and establishments, to serve this dual purpose.

Amendment 27
Proposal for a regulation
Recital 12 a (new)

Text proposed by the Commission

(12a) In order to improve early preparedness for and response to the emergence of cross-border health threats, it is crucial to enable continuous and
rapid access to data on the availability of
the necessary medical countermeasures
Therefore, a network of Member States' services providing up-to-date information on national strategic stockpiles and the availability of medical countermeasures, stockpiles of medical products, essential health products and diagnostic tests should be established, operated and coordinated at Union level. Strengthening coordination and information with Member States on strategic stockpiles and medical countermeasures available is necessary to enhance the collection, modelling and use of prospective data that allow early alert notifications in the Union.

Amendment 28

Proposal for a regulation
Recital 13

Text proposed by the Commission

(13) A system enabling the notification at Union level of alerts related to serious cross-border threats to health has been put in place by Decision No 2119/98/EC in order to ensure that competent public health authorities in Member States and the Commission are duly informed in a timely manner. All serious cross-border threats to health covered by this Regulation are covered by the EWRS. The operation of the EWRS should remain within the remit of the ECDC. The notification of an alert should be required only where the scale and severity of the threat concerned are or could become so significant that they affect or could affect more than one Member State and require or could require a coordinated response at the Union level. To avoid duplication and ensure coordination across Union alert systems, the Commission and ECDC should ensure that alert notifications under the EWRS and other rapid alert systems at Union level are

Amendment

(13) A system enabling the notification at Union level of alerts related to serious cross-border threats to health has been put in place by Decision No 2119/98/EC in order to ensure that competent public health authorities in Member States and the Commission are duly informed in a timely manner. All serious cross-border threats to health covered by this Regulation are covered by the EWRS. The operation of the EWRS should remain within the remit of the ECDC. The notification of an alert should be required only where the scale and severity of the threat concerned are or could become so significant that they affect or could affect more than one Member State and require or could require a coordinated response at the Union level. To avoid duplication and ensure coordination across Union alert systems, the Commission and ECDC should ensure that alert notifications under the EWRS and other rapid alert systems at Union level are
linked to each other to the extent possible so that the competent authorities of the Member States can avoid as much as possible notifying the same alert through different systems at Union level and can benefit from receiving all-hazard alerts from a single coordinated source.

Amendment 29

Proposal for a regulation
Recital 14

Text proposed by the Commission

(14) In order to ensure that the assessment of risks to public health at the Union level from serious cross-border threats to health is consistent as well as comprehensive from a public health perspective, the available scientific expertise should be mobilised in a coordinated manner, through appropriate channels or structures depending on the type of threat concerned. That assessment of risks to public health should be developed by means of a fully transparent process and should be based on principles of excellence, independence, impartiality and transparency. The involvement of Union agencies in these risk assessments needs to be broadened according to their speciality in order to ensure an all hazard approach, via a permanent network of agencies and relevant Commission services to support the preparation of risk assessments.

Amendment

(14) In order to ensure that the assessment of risks to public health at the Union level from serious cross-border threats to health is consistent as well as comprehensive from a public health perspective, the available scientific expertise should be mobilised in a coordinated and multidisciplinary manner, through appropriate channels or structures depending on the type of threat concerned. That assessment of risks to public health should be developed by means of a fully transparent process and should be based on principles of excellence, independence, impartiality and transparency. The involvement of Union agencies and bodies in these risk assessments needs to be broadened according to their speciality in order to ensure an all hazard approach, via a permanent network of agencies and relevant Commission services to support the preparation of risk assessments. In order to achieve a sufficient degree of expertise and effectiveness, the financial and human resources of Union agencies and bodies should be increased.

Amendment 30
Proposal for a regulation
Recital 14 a (new)

Text proposed by the Commission

(14a) Member States, the Commission and Union agencies, while applying the One Health approach, should identify recognised public health organisations and experts, both in the area of communicable and major non-communicable diseases, and other relevant stakeholders across sectors, available to assist in Union responses to health threats. Such experts and stakeholders, including civil society organisations, should be structurally engaged throughout all crisis response activities and contribute to the decision-making processes. National authorities should also consult and involve representatives of patient organisations and national social partners in the healthcare and social services sector in the implementation of this regulation where appropriate. It is essential that there be full compliance with transparency and conflict of interest rules for stakeholder engagement.

Amendment 31

Proposal for a regulation
Recital 14 b (new)

Text proposed by the Commission

(14b) Green lanes should only be considered as an appropriate tool for pandemic situations of a declared public health emergency where they are aimed at ensuring that essential goods, medical countermeasures and cross border workers circulate freely and safely within the internal market. The creation of green lanes in such situations should not affect the relevant Treaty provisions or
Amendment 32
Proposal for a regulation
Recital 15 a (new)

Text proposed by the Commission

(15a) The Commission should ensure that, at the time of the declaration of a state of emergency, the number of accommodation facilities in hospitals in the Member States, as well as the number of available accommodation units in intensive care units in the Member States, are known, for the purpose of cross-border movement of patients.

Amendment 33
Proposal for a regulation
Recital 16 a (new)

Text proposed by the Commission

(16a) Regular dialogue and exchange of information between authorities, industry, relevant entities of the pharmaceutical supply chain, healthcare professionals' and patients' organisations should also be ensured in order to start early discussions about expected potential serious cross-border threats to health in the market, by way of sharing information about expected supply constraints or raising specific clinical needs, thereby allowing better coordination, synergies and appropriate reaction when needed.

Amendment 34
Recital 17

Text proposed by the Commission

(17) Inconsistent communication with the public and stakeholders such as healthcare professionals can have a negative impact on the effectiveness of the response from a public health perspective as well as on economic operators. The coordination of the response within the HSC, assisted by relevant subgroups, should, therefore, encompass rapid information exchange concerning communication messages and strategies and addressing communication challenges with a view to coordinating risk and crisis communication, based on robust and independent evaluation of public health risks, to be adapted to national needs and circumstances. Such exchanges of information are intended to facilitate the monitoring of the clarity and coherence of messages to the public and to healthcare professionals. Given the cross-sectoral nature of this type of crises, coordination should also be ensured with other relevant constituencies, such as the Union Civil Protection Mechanism established by Decision (EU) 2019/420 of the European Parliament and of the Council\(^{17}\).

Amendment

(17) Inconsistent communication with the public and stakeholders such as healthcare and public health professionals can have a negative impact on the effectiveness of the response from a public health perspective as well as on economic operators. The coordination of the response within the HSC, assisted by relevant subgroups, should, therefore, encompass rapid information exchange concerning communication messages and strategies and addressing communication challenges with a view to coordinating risk and crisis communication, based on holistic, robust and independent evaluation of public health risks, to be adapted to national and regional needs and circumstances. In those Member States with regions having health competences, those regions should provide this information. Such exchanges of information are intended to facilitate the monitoring of the clarity and coherence of messages to the public and to healthcare professionals. Following its recommendations to Member States and healthcare professionals, the ECDC should broaden its communication activity to include the general public by establishing and managing an online portal to share verified information and fight against disinformation. Given the cross-sectoral nature of this type of crises, coordination should also be ensured with other relevant constituencies, such as the Union Civil Protection Mechanism established by Decision (EU) 2019/420 of the European Parliament and of the Council\(^{17}\).

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\(^{17}\) Decision (EU) 2019/420 of the European Parliament and of the Council of 13 March 2019 amending Decision No 1313/2013/EU on a Union Civil Protection
Amendment 35

Proposal for a regulation
Recital 18

Text proposed by the Commission
(18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at Union level, and advise on public health response measures and on the termination of this emergency recognition. The advisory committee should consist of independent experts, selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the ECDC, of the EMA, and of other Union bodies or agencies as observers. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as ‘EU Health Task Force’.

Amendment
(18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at Union level, and advise on public health response measures and on the termination of this emergency recognition. The advisory committee should consist of independent experts, representatives of health and care workers, including nurses and medical doctors, and representatives of civil society, selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the ECDC, of the EMA, and of other Union bodies or agencies as observers. All members of the Advisory Committee should provide declarations of interest. The advisory committee should work in close cooperation with national advisory bodies. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, Union export control mechanisms, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and
deploy outbreak assistance teams, known as ‘EU Health Task Force’.

Amendment 36

Proposal for a regulation
Recital 20

*Text proposed by the Commission*

(20) The occurrence of an event that corresponds to serious cross-border threats to health and is likely to have Union-wide consequences should require the Member States concerned to take particular control or contact-tracing measures in a coordinated manner in order to identify people already contaminated and those persons exposed to risk. Such cooperation could require the exchange of personal data through the system, including sensitive information related to health and information about confirmed or suspected human cases of the disease, between those Member States directly involved in the contact-tracing measures. The exchange of personal data concerning health by the Member States has to comply with Article 9(2)(i) of Regulation (EU) 2016/679 of the European Parliament and of the Council.

*Amendment*

(20) The occurrence of an event that corresponds to serious cross-border threats to health and is likely to have Union-wide consequences should require the Member States concerned or potentially concerned to take particular control or contact-tracing measures in a coordinated manner in order to identify people already contaminated and those persons exposed to risk. Such cooperation could require the exchange of personal data through the system, including sensitive information related to health and information about confirmed or suspected human cases of the disease or infection, between those Member States directly involved in the contact-tracing measures. The exchange of personal data concerning health by the Member States has to comply with Article 9(2)(i) of Regulation (EU) 2016/679 of the European Parliament and of the Council.

Proposal for a regulation

Recital 21

Text proposed by the Commission

(21) Cooperation with third countries and international organisations in the field of public health should be fostered. It is particularly important to ensure the exchange of information with the WHO on the measures taken pursuant to this Regulation. This reinforced cooperation is also required to contribute to EU’s commitment to strengthening support to health systems and reinforcing partners’ preparedness and response capacity. The Union could benefit from concluding international cooperation agreements with third countries or international organisations, including the WHO, to foster the exchange of relevant information from monitoring and alerting systems on serious cross-border threats to health. Within the limits of the Union’s competences, such agreements could include, where appropriate, the participation of such third countries or international organisations in the relevant epidemiological surveillance monitoring network and the EWRS, exchange of good practice in the areas of preparedness and response capacity and planning, public health risk-assessment and collaboration on response coordination, including the research response.

Amendment

(21) Cooperation with third countries and international organisations in the field of public health should be fostered. It is particularly important to ensure the exchange of information with the WHO on the measures taken pursuant to this Regulation. This reinforced cooperation is also required to contribute to EU’s commitment to strengthening support to health systems and reinforcing partners’ preparedness and response capacity. The Union could benefit from concluding international cooperation agreements with third countries or international organisations, including the WHO, to foster the exchange of relevant information from monitoring and alerting systems on serious cross-border threats to health. Within the limits of the Union’s competences, such agreements could include, where appropriate, the participation of such third countries or international organisations in the relevant epidemiological surveillance monitoring network, such as the European Surveillance System (TESSy), and the EWRS, exchange of good practice in the areas of preparedness and response capacity and planning, public health risk-assessment and collaboration on response coordination, including the research response. The Commission and the Member States should actively work towards the establishment of a WHO framework convention on pandemic preparedness and response, which should lay down principles and priorities for pandemic preparedness and response. Such a framework convention should facilitate the implementation of the International Health Regulations (2005) and should support the strengthening of the international health framework and improving cooperation with regard to
early detection, prevention, response and resilience in respect of future pandemics.

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World Health Organisation
International Health Regulations (2005)
Third Edition available at https://www.who.int/publications/i/item/9789241580496

Amendment 38
Proposal for a regulation
Recital 22

*Text proposed by the Commission*

(22) The processing of personal data for the purpose of implementing this Regulation should comply with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 of the European Parliament and of the Council\(^\text{19}\). In particular, the operation of the EWRS should provide for specific safeguards for the safe and lawful exchange of personal data for the purpose of contact tracing measures implemented by Member States at national level. In this regard, the EWRS includes a messaging function in which personal data, including contact and health data, can be communicated to relevant authorities involved in contact tracing measures.

*Amendment*

(22) **Due to the sensitive nature of the health data, Member States, the Commission and Union agencies should safeguard and guarantee that their processing operations respect the data protection principles in accordance with Article 5 of the GDPR.** The processing of personal data for the purpose of implementing this Regulation should comply with the GDPR and Regulation (EU) 2018/1725 of the European Parliament and of the Council\(^\text{19}\). In particular, the operation of the EWRS should provide for specific safeguards for the safe and lawful exchange of personal data for the purpose of contact tracing measures implemented by Member States at national level. In this regard, the EWRS includes a messaging function in which personal data, including contact and health data, can be communicated to relevant authorities involved in contact tracing. **Regulation (EU) 2018/1725 of the European Parliament and of the Council should be strictly respected and appropriate technical and organisational security measures, in accordance with that Regulation, should be put in place.**

\(^{19}\) Regulation (EU) 2018/1725 of the

Amendment 39

Proposal for a regulation
Recital 25

Text proposed by the Commission

(25) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt implementing acts in relation to: templates to be used when providing the information on preparedness and response planning; organisation of the training activities for health care and public health staff; the establishment and update of a list of communicable diseases and related special health issues subject to the network of epidemiological surveillance and the procedures for the operation of such a network; the adoption of case definitions for those communicable diseases and special health issues covered by the epidemiological surveillance network and, where necessary, for other serious cross-border threats to health subject to ad hoc monitoring; the procedures for the operation of the EWRS; the functioning of the surveillance platform; the designation of EU reference laboratories to provide support to national and regional reference laboratories; the procedures for the information exchange on and the coordination of the responses of the Member States; the recognition of situations of public health emergency at Union level and the termination of such a recognition and procedures necessary to ensure that the operation of the EWRS and the processing of data are in accordance with the data protection legislation.

Amendment

(25) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt implementing acts in relation to: templates to be used when providing the information on preparedness and response planning; organisation of the training activities for health care and public health staff; the establishment and update of a list of communicable diseases and related special health issues subject to the network of epidemiological surveillance and the procedures for the operation of such a network; the adoption of case definitions for those communicable diseases and special health issues covered by the epidemiological surveillance network and, where necessary, for other serious cross-border threats to health subject to ad hoc monitoring; the procedures for the operation of the EWRS; the functioning of the surveillance platform; the designation of EU reference laboratories to provide support to national and regional reference laboratories; the procedures for the information exchange on and the coordination of the responses of the Member States; the recognition of situations of public health emergency at Union level and the termination of such a
recognition and procedures necessary to ensure that the operation of the EWRS and the processing of data are in accordance with the data protection legislation.

Amendment 40

Proposal for a regulation
Recital 28

Text proposed by the Commission

(28) In order to ascertain the state of implementation of the national preparedness plans and their coherence with the Union plan, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of procedures, standards and criteria for the audits aimed at the assessment of preparedness and response planning at national level. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Amendment

(28) In order to supplement certain aspects of this Regulation and to ascertain the state of implementation of the national and regional preparedness plans and their coherence with the Union plan, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of: the establishment and updating of a list of communicable diseases and related special health issues subject to the network of epidemiological surveillance; the adoption of case definitions for those communicable diseases and special health issues covered by the epidemiological surveillance network and, where necessary, for other serious cross-border threats to health that are the subject of ad hoc monitoring; the requirements necessary to ensure the compliance of the operation of the EWRS and the processing of data with the relevant Regulations; the establishment and updating of a list of relevant health data to be automatically collected by a digital platform, subject to human oversight; the functioning of the surveillance platform; and the procedures, standards and criteria for the audits aimed at the assessment of preparedness and response planning at national and regional level. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be
conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016\textsuperscript{21}. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

\textsuperscript{21} OJ L 123, 12.5.2016, p. 1.

Amendment 41
Proposal for a regulation
Recital 28 b (new)

\textit{Text proposed by the Commission}

\textit{(28b) In respect of the establishment and updating of a list of communicable diseases and related special health issues subject to the network of epidemiological surveillance and the procedures for the operation of such a network, the adoption of case definitions for those communicable diseases and special health issues, covered by the epidemiological surveillance network and the case definitions to be used for ad hoc monitoring, the Commission should adopt delegated acts under the urgency procedure where duly justified imperative grounds of urgency related to the severity or novelty of a serious cross-border threat to health or to the rapidity of its spread between the Member States so require.}

Amendment 42
Proposal for a regulation
Article 1 – paragraph 1 – point c

Text proposed by the Commission

(c) joint procurement of medical countermeasures;

Amendment

(c) joint procurement, management and deployment of medical countermeasures;

Amendment 43
Proposal for a regulation
Article 1 – paragraph 2 – point b a (new)

Text proposed by the Commission

(ba) a network of national strategic stockpiles and available medical countermeasures;

Amendment 44
Proposal for a regulation
Article 1 – paragraph 3

Text proposed by the Commission

3. The implementation of this Regulation shall be supported by funding from relevant Union programmes and instruments.

Amendment

3. In keeping with the “One Health” and “Health in all policies” approaches, the implementation of this Regulation shall be supported by funding from relevant Union programmes and instruments. The strengthened Union health framework addressing serious cross-border health threats shall work in synergy with and in a manner that is complementary to other Union policies and funds, such as actions implemented under the EU4Health programme, the European Structural and Investment Funds (ESIF), Horizon Europe, the Digital Europe Programme, rescEU reserve, the European Social Fund Plus (ESF+), the Emergency Support Instrument (ESI) and the Single Market Programme (SMP).
Amendment 45
Proposal for a regulation
Article 1 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. This Regulation shall ensure that in future health emergencies, the detection of, health interventions concerning and treatment of other serious diseases are not halted.

Amendment 46
Proposal for a regulation
Article 1 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

3b. This Regulation shall be implemented with full respect for the dignity and fundamental rights and freedoms of persons.

Amendment 47
Proposal for a regulation
Article 2 – paragraph 2

Text proposed by the Commission

Amendment

2. This Regulation shall also apply to the epidemiological surveillance of communicable diseases and of related special health issues.

2. This Regulation shall also apply to the epidemiological surveillance of communicable diseases, the monitoring of the impact of such diseases on major non-communicable diseases and on related special health issues, such as mental health, and the impact on deferred screening, diagnosis, monitoring, treatment and care for other diseases and conditions.

Amendment 48
Proposal for a regulation
Article 2 – paragraph 3 a (new)

Text proposed by the Commission

3a. This Regulation shall promote the implementation of the International Health Regulations, reduce administrative burden and duplication of resources, and strengthen the gaps exposed during the COVID-19 pandemic in the prevention of, preparedness for and response to public health threats.

Amendment 49

Proposal for a regulation
Article 2 – paragraph 4

Text proposed by the Commission

4. In exceptional emergency situations, a Member State or the Commission may request the coordination of response within the HSC as referred to in Article 21, for serious cross-border threats to health other than those referred to in Article 2(1), if it is considered that public health measures taken previously have proven insufficient to ensure a high level of protection of human health.

Amendment 50

Proposal for a regulation
Article 2 – paragraph 5

Text proposed by the Commission

5. The Commission shall, in liaison with the Member States, ensure

Justification

The current situation proves that in times of pandemics there are more problems with chronic diseases, including mental diseases, as for example the access to treatment is limited.
coordination and information exchange between the mechanisms and structures established under this Regulation and similar mechanisms and structures established at Union level or under the Euratom Treaty whose activities are relevant for preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health.

Justification

*Links with WHO have to established as well to ensure synergies and avoid duplication of efforts.*

**Amendment 51**

**Proposal for a regulation**

**Article 2 – paragraph 6**

**Text proposed by the Commission**

6. Member States shall retain the right to maintain or introduce additional arrangements, procedures and measures for their national systems in the fields covered by this Regulation, including arrangements provided for in existing or future bilateral or multilateral agreements or conventions, on condition that such additional arrangements, procedures and measures do not impair the application of this Regulation.

**Amendment**

6. Member States shall retain the right to maintain or introduce additional arrangements, procedures and measures for their national systems in the fields covered by this Regulation, including arrangements provided for in existing or future bilateral or multilateral agreements or conventions, on condition that such additional arrangements, procedures and measures do not impair the application of this Regulation. *The Union shall call for the establishment of a WHO framework convention on pandemic preparedness and response. That convention shall be such as to facilitate the implementation of the International Health Regulation (2005)¹ and resolve the weaknesses of that Regulation, identified during the COVID-19 crisis.*

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¹ World Health Organization. *International Health Regulation (IHR, 2005)*
Amendment 52

Proposal for a regulation
Article 2 – paragraph 6 a (new)

Text proposed by the Commission

6a. This Regulation shall also apply, where appropriate, to regional competent authorities, systems and programmes in the fields covered by this Regulation.

Amendment 53

Proposal for a regulation
Article 3 – paragraph 1 – point 3

Text proposed by the Commission

(3) ‘contact tracing’ means measures implemented in order to trace persons who have been exposed to a source of a serious cross-border threat to health, and who are in danger of developing or have developed a disease, through manual or other technological means;

Amendment

(3) ‘contact tracing’ means measures to identify, assess and manage persons who have been exposed to a source of a serious cross-border threat to health, and who are in danger of being infected or being infectious or who have developed a communicable disease, through manual or other technological means, with the sole objective of rapidly identifying potentially newly infected persons who may have come into contact with existing cases, in order to reduce further onward transmission;

Amendment 54

Proposal for a regulation
Article 3 – paragraph 1 – point 4

Text proposed by the Commission

(4) ‘epidemiological surveillance’ means the systematic collection, recording,

Amendment

(4) ‘epidemiological surveillance’ means the systematic collection, recording,
analysis, interpretation and dissemination of data and analysis on communicable diseases and related special health issues; analysis, interpretation and dissemination of data and analysis on communicable diseases, the monitoring of the impact of such diseases on major non-communicable diseases, such as those relating to mental health, and on related special health issues;

Amendment 55

Proposal for a regulation
Article 3 – paragraph 1 – point 5 a (new)

Text proposed by the Commission

Amendment

(5a) ‘One Health approach’ means a multisectoral approach which recognises that human health is connected to animal health and to the environment, and that actions to tackle threats to health must take into account those three dimensions;

Amendment 56

Proposal for a regulation
Article 3 – paragraph 1 – point 5 b (new)

Text proposed by the Commission

Amendment

(5b) ‘Health in All Policies’ means an approach to the development, implementation and review of public policies, regardless of the sector, whereby the health implications of decisions are taken into account, and which seeks to achieve synergies and to avoid harmful health impacts being caused by such policies, in order to improve the health of the population and health equity;

Amendment 57

Proposal for a regulation
Article 3 – paragraph 1 – point 7 a (new)

Text proposed by the Commission

(7a) ‘major non-communicable disease’ means a disease as defined in point (4a) of Article 2 of Regulation (EU) [ECDC regulation, correct reference to be inserted];

Amendment

Amendment 58

Proposal for a regulation
Article 3 – paragraph 1 – point 8

Text proposed by the Commission


Amendment


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Amendment 59
Proposal for a regulation
Article 3 – paragraph 1 – point 8 a (new)

Text proposed by the Commission

Amendment


Amendment 60

Proposal for a regulation
Article 3 – paragraph 1 – point 8 b (new)

Text proposed by the Commission

Amendment

(8b) “medical device” means both a medical device as defined in point (1) of Article 2 of Regulation (EU) 2017/745, read in conjunction with point (2) of Article 1 and point (a) of Article 1(6) of that Regulation, and an in vitro diagnostic medical device as defined in point (2) of Article 2 of Regulation (EU) 2017/746.

Amendment 61

Proposal for a regulation
Article 3 – paragraph 1 – point 8 c (new)

Text proposed by the Commission

Amendment

(8c) ‘green lanes’ means passable and safe transit corridors that preserve supply chains in the event of a declared public health emergency at Union level in a pandemic situation by ensuring that essential goods, medical countermeasures and cross border workers can circulate freely and safely within the internal market, while fully respecting Article 77 (2)(e) TFEU.

Amendment 62
Proposal for a regulation
Article 4 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Representatives of relevant Union agencies shall participate in HSC meetings as observers.

Amendment 63

Proposal for a regulation
Article 4 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) coordination in liaison with the Commission of the preparedness and response planning of the Member States in accordance with Article 10;

(b) coordination in liaison with the Commission and relevant Union agencies of the prevention, preparedness and response planning of the Member States in accordance with Article 10;

Amendment 64

Proposal for a regulation
Article 4 – paragraph 2 – point c

Text proposed by the Commission

Amendment

(c) coordination in liaison with the Commission of the risk and crisis communication and responses of the Member States to serious cross-border threats to health, in accordance with Article 21;

(c) coordination in liaison with the Commission and relevant Union agencies of the risk and crisis communication and responses of the Member States to serious cross-border threats to health, in accordance with Article 21;

Amendment 65

Proposal for a regulation
Article 4 – paragraph 2 – point d a (new)

Text proposed by the Commission

Amendment

(da) adoption, on an annual basis, of
an action programme to clearly set its priorities and objectives at the high level working group and the technical working group levels.

Amendment 66
Proposal for a regulation
Article 4 – paragraph 4

Text proposed by the Commission

4. The HSC shall be chaired by a representative of the Commission. The HSC shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State.

Amendment

4. The HSC shall be chaired by a representative of the Commission without the right to vote. The HSC shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State.

Amendment 67
Proposal for a regulation
Article 4 – paragraph 5 a (new)

Text proposed by the Commission

5a. Members of the HSC and the Commission shall ensure thorough consultation with relevant Union agencies, public health experts, international organisations and stakeholders, including healthcare professionals.

Amendment

7a. The European Parliament shall designate representatives to participate in the Health Security Committee (‘HSC’) as observers.
Amendment 69
Proposal for a regulation
Article 4 – paragraph 7 b (new)

Text proposed by the Commission

Amendment

7b. The list of members of the HSC at both the political and technical levels shall be made public on the Commission and Council websites. Members of the Committee shall have no financial or other interests that could affect their impartiality. They shall act in the public interest and in an independent manner and make an annual declaration of their financial interests. All direct interests which could relate to the medical or another relevant sector shall be entered in a register held by the Commission and be accessible to the public, upon request.

Amendment 70
Proposal for a regulation
Article 4 – paragraph 7 c (new)

Text proposed by the Commission

Amendment

7c. The rules of procedure, guidance, agendas and minutes of the meetings of the HSC shall be published on the Commission’s web-portal.

Amendment 71
Proposal for a regulation
Chapter II – title

Text proposed by the Commission

Amendment

II PREPAREDNESS AND RESPONSE PLANNING

II PREVENTION, PREPAREDNESS AND RESPONSE PLANNING
Justification

Cross-border threats from within the EU need to be prevented where possible. "Preparedness and Response" planning is too reactive and not sufficiently proactive.

Amendment 72

Proposal for a regulation
Article 5 – title

Text proposed by the Commission

Amendment

Union preparedness and response plan

Union prevention, preparedness and response plan

Amendment 73

Proposal for a regulation
Article 5 – paragraph 1

Text proposed by the Commission

Amendment

1. The Commission, in cooperation with Member States and the relevant Union agencies, shall establish a Union health crisis and pandemic plan (‘the Union prevention, preparedness and response plan’) to promote effective and coordinated response to cross-border health threats at Union level.

Amendment 74

Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission

Amendment

2. The Union prevention, preparedness and response plan shall complement the national preparedness and response plans established in accordance with Article 6.
Amendment 75

Proposal for a regulation
Article 5 – paragraph 3 – introductory part

Text proposed by the Commission

3. The Union preparedness and response plan shall, in particular, include arrangements for governance, capacities and resources for:

Amendment

3. The Union *prevention*, preparedness and response plan shall, in particular, include arrangements for governance, capacities and resources for:

Amendment 76

Proposal for a regulation
Article 5 – paragraph 3 – point c

Text proposed by the Commission

(c) the epidemiological surveillance and monitoring;

Amendment

(c) the epidemiological surveillance and monitoring, *as well as the impact of communicable diseases on major non-communicable diseases*;

Amendment 77

Proposal for a regulation
Article 5 – paragraph 3 – point e

Text proposed by the Commission

(e) the risk and crisis communication;

Amendment

(e) the risk and crisis communication, *aimed at health professionals and at citizens*;

Amendment 78

Proposal for a regulation
Article 5 – paragraph 3 – point f a (new)

Text proposed by the Commission

(fa) the mapping of the production capacities of medical products in the Union as a whole;

Amendment
Amendment 79
Proposal for a regulation
Article 5 – paragraph 3 – point f b (new)

Text proposed by the Commission

Amendment

(fb) the establishment of a Union stock of critical medicinal products, medical countermeasures and personal protective equipment as part of the rescEU emergency reserve;

Amendment 80
Proposal for a regulation
Article 5 – paragraph 3 – point g a (new)

Text proposed by the Commission

Amendment

(ga) the criteria for activating and deactivating the actions;

Amendment 81
Proposal for a regulation
Article 5 – paragraph 3 – point g b (new)

Text proposed by the Commission

Amendment

(gb) ensuring that healthcare services, including the screening, diagnosis, monitoring, treatment and care for other diseases and conditions, are provided without disruption during health emergencies;

Amendment 82
Proposal for a regulation
Article 5 – paragraph 3 – point g c (new)

Text proposed by the Commission

Amendment

(gc) ensuring that national health systems are inclusive and provide equal access to health and related services, and that quality treatments are available without delays;

Amendment 83

Proposal for a regulation
Article 5 – paragraph 3 – point g d (new)

Text proposed by the Commission

Amendment

(gd) an adequate and needs-oriented staffing level;

Amendment 84

Proposal for a regulation
Article 5 – paragraph 3 – point g e (new)

Text proposed by the Commission

Amendment

(ge) monitoring whether adequate risk assessments, preparedness plans and training courses are foreseen for health and social care professionals;

Amendment 85

Proposal for a regulation
Article 5 – paragraph 4

Text proposed by the Commission

Amendment

4. The Union preparedness and response plan shall include interregional preparedness elements to establish coherent, multi-sectoral, cross-border public health measures, in particular

4. The Union prevention, preparedness and response plan shall include cross-border and interregional preparedness plans to establish coherent, multi-sectoral, cross-border public health
considering capacities for testing, contact tracing, laboratories, and specialised treatment or intensive care across neighbouring regions. The plans shall include preparedness and response means to address the situation of those citizens with higher risks.

Amendment 86
Proposal for a regulation
Article 5 – paragraph 4 a (new)

Text proposed by the Commission

4a. The Union preparedness and response plan shall also provide for measures to ensure that the single market functions normally in the event serious cross-border threats to health arise.

Amendment 87
Proposal for a regulation
Article 5 – paragraph 5

Text proposed by the Commission

5. In order to ensure the operation of the Union prevention, preparedness and response plan, the Commission shall conduct stress tests, exercises and in-action and after-action reviews with Member States, and update the plan as necessary.

The prevention, preparedness and response plan shall take into account health systems data and relevant data to be collected at national or regional level.

Amendment 88
### Proposal for a regulation

**Article 5 – paragraph 5 a (new)**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5a. In order to respond to public health emergencies, the European Commission may issue recommendations, based on Union health systems data, on the minimum resources needed, in relation, among other things, to each Member State’s population, for the provision of baseline universal health coverage of adequate quality, including on the option of pooling resources at Union level.</strong></td>
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</tbody>
</table>

#### Amendment 89

**Proposal for a regulation**

**Article 5 – paragraph 5 b (new)**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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</thead>
<tbody>
<tr>
<td><strong>5b. The reviews and any subsequent adjustments to the plan shall be published to increase the transparency of the process of prevention, preparedness and response planning.</strong></td>
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</tbody>
</table>

#### Amendment 90

**Proposal for a regulation**

**Article 6 – title**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tbody>
<tr>
<td>National preparedness and response plans</td>
<td>National prevention, preparedness and response plans</td>
</tr>
</tbody>
</table>

#### Amendment 91
Proposal for a regulation
Article 6 – paragraph 1

Text proposed by the Commission

1. When preparing national prevention, preparedness and response plans each Member State shall consult patients’ organisations, healthcare professionals’ organisations, industry and supply chain stakeholders, and national social partners, coordinate with the Commission in order to reach consistency with the Union prevention, preparedness and response plan, which shall be in accordance with arrangements for governance, capacities and resources referred to in Article 5(3), including with regard to national stockpiling requirements and the management of Union strategic reserves, and inform without delay the Commission and the HSC of any substantial revision of the national plan.

Amendment 92

Proposal for a regulation
Article 6 – paragraph 1a (new)

Text proposed by the Commission

1a. National prevention, preparedness and response plans shall include arrangements for governance and information on capacities and resources referred to in Article 5(3).

Amendment 93

Proposal for a regulation
Article 7 – title

Text proposed by the Commission

Reporting on preparedness and response

Amendment

Reporting on prevention, preparedness and
Amendment 94

Proposal for a regulation
Article 7 – paragraph 1 – subparagraph 1

Text proposed by the Commission

1. Member States shall by the end of November 2021 and every 2 years thereafter provide the Commission with a report on their preparedness and response planning and implementation at national level.

Amendment

1. Member States shall within 6 months of the entry into force of this regulation and every 2 years thereafter provide the Commission with an updated report on their prevention, preparedness and response planning and implementation at national and, where appropriate, regional and cross-border levels.

Amendment 95

Proposal for a regulation
Article 7 – paragraph 1 – subparagraph 2 – introductory part

Text proposed by the Commission

That report shall cover the following:

Amendment

That report shall be succinct, based on common indicators, give an overview of the actions implemented in the Member States, and shall cover the following:

Amendment 96

Proposal for a regulation
Article 7 – paragraph 1 – subparagraph 2 – point a

Text proposed by the Commission

(a) identification of, and update on the status of the implementation of the capacity standards for preparedness and response planning as determined at national level for the health sector, as provided to the WHO in accordance with the IHR;

Amendment

(a) identification of, and update on the status of the implementation of the capacity standards for prevention, preparedness and response planning as determined at national and appropriate, regional level for the health sector, as provided to the WHO in accordance with the IHR;
Amendment 97

Proposal for a regulation
Article 7 – paragraph 1 – subparagraph 2 – point a a (new)

Text proposed by the Commission

Amendment

(aa) a description of the measures or arrangements aimed at ensuring interoperability between the health sector and other sectors that are critical in the case of an emergency.

Amendment 98

Proposal for a regulation
Article 7 – paragraph 1 – subparagraph 2 – point a b (new)

Text proposed by the Commission

Amendment

(ab) a description of the business continuity plans, measures or arrangements aimed at ensuring the continuous delivery of critical services and products;

Amendment 99

Proposal for a regulation
Article 7 – paragraph 1 – subparagraph 2 – point b

Text proposed by the Commission

Amendment

(b) elements of emergency preparedness, in particular:

(b) an update, if needed, on the elements of emergency prevention, preparedness and response, in particular:

Amendment 100
Proposal for a regulation
Article 7 – paragraph 1 – subparagraph 2 – point b – point i

Text proposed by the Commission

(i) governance: including national policies and legislation that integrate emergency preparedness, response and recovery coordination mechanisms;

Amendment

(i) governance: including national and, if appropriate, regional policies and legislation that integrate emergency prevention and preparedness; plans for emergency prevention, preparedness, response and recovery coordination mechanisms at national and, where relevant, regional and cross-border levels; continuity of critical long-term healthcare;

Amendment 101

Proposal for a regulation
Article 7 – paragraph 1 – subparagraph 2 – point b – point ii

Text proposed by the Commission

(ii) capacities: including assessments of risks and capacities to determine priorities for emergency preparedness; surveillance and early warning, information management; access to diagnostic services during emergencies; basic and safe gender-sensitive health and emergency services; risk communications; research development and evaluations to inform and accelerate emergency preparedness;

Amendment

(ii) capacities: including assessments of risks and capacities to determine priorities for emergency preparedness; surveillance and early warning, information management; the capacities to produce medicinal products; stocks of medical countermeasures including personal protective equipment of the highest quality; equitable access to diagnostic services and tools, and medical products during emergencies; information relevant for the internal market and Union strategic reserves of medical products; equitable, high-quality; basic and safe gender-sensitive health and emergency services that take account of the needs of populations at higher risk; continuity of screening, diagnosis, monitoring, treatment for care in relation to other diseases and conditions, in particular critical long-term healthcare; risk communications; research development and evaluations to inform and accelerate
emergency preparedness;

Amendment 102

Proposal for a regulation
Article 7 – paragraph 1 – subparagraph 2 – point b – point iii

_text proposed by the Commission_ (iii) resources: including financial resources for emergency preparedness and contingency funding for response; logistics mechanisms and essential supplies for health; and dedicated, trained and equipped human resources for emergencies; and

 Amend

_text proposed by the Commission_ (iii) resources: including financial resources for emergency preparedness and contingency funding for response; logistics mechanisms and essential supplies for health; _measures to ensure continuity of critical long-term healthcare; and health and social services with an adequate number of_ dedicated, trained and equipped human resources for emergencies; and

Amendment 103

Proposal for a regulation
Article 7 – paragraph 1 – subparagraph 2 – point b – point iii a (new)

_text proposed by the Commission_ (iiiia) strategic stockpile: each Member State shall provide information on the number and availability of medical countermeasures and other essential medicinal products and critical medical devices for the control of the threats set out in Article 2(1), as well as the capacity for their safekeeping and storage. In order to have a greater response capacity, storage shall be carried out in the premises closest to and most accessible for the population centres, without compromising the accessibility of those products for people in remote, rural and outermost regions, which meet the necessary requirements to provide the service in accordance with the regulations applicable to medicinal products, medical devices and other medical countermeasures._

 Amend

_text proposed by the Commission_ (iiiia) strategic stockpile: each Member State shall provide information on the number and availability of medical countermeasures and other essential medicinal products and critical medical devices for the control of the threats set out in Article 2(1), as well as the capacity for their safekeeping and storage. In order to have a greater response capacity, storage shall be carried out in the premises closest to and most accessible for the population centres, without compromising the accessibility of those products for people in remote, rural and outermost regions, which meet the necessary requirements to provide the service in accordance with the regulations applicable to medicinal products, medical devices and other medical countermeasures.
Amendment 104

Proposal for a regulation
Article 7 – paragraph 1 – subparagraph 2 – point c a (new)

Text proposed by the Commission

(ca) the consultation with relevant partners that has taken place to ensure risk assessments, prevention, preparedness and response plans and implementation are broadly shared and supported and in line with applicable labour legislation and collective agreements;

Amendment 105

Proposal for a regulation
Article 7 – paragraph 1 – subparagraph 2 – point c b (new)

Text proposed by the Commission

(cb) gaps found in the implementation and any necessary actions that will be taken by the Member States to improve their preparedness and response capacity.

Amendment 106
Proposal for a regulation
Article 7 – paragraph 1 – subparagraph 3

Text proposed by the Commission

The report shall include, whenever relevant, interregional preparedness and response elements in line with the Union and national plans, covering in particular the existing capacities, resources and coordination mechanisms across neighbouring regions.

Amendment

For Member States sharing a land border with at least one other Member State, the report shall include cross-border, interregional and intersectoral prevention, preparedness and response plans with neighbouring regions including coordination mechanisms for all elements listed in points (a), (b) and (c), cross-border training and sharing of best practices for healthcare staff and public health staff and coordination mechanisms for the medical transfer of patients. Union or national entities that are engaged in stockpiling of medical products shall engage with the Commission and Member States in reporting of stocks that are available and taken into account in both Union and national preparedness and response planning.

Amendment 107

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 3 a (new)

Text proposed by the Commission

The report shall also include, as far as feasible, information on the impact of communicable diseases on major non-communicable diseases.

Amendment

The latest available version of the prevention, preparedness and response plans shall be attached to the report.

Amendment 108
Amendment 109

Proposal for a regulation
Article 7 – paragraph 2 – subparagraph 4

Text proposed by the Commission

The recommendations of the report shall be published on at the website of the Commission.

Amendment

The recommendations of the report shall be published on the websites of the Commission and the ECDC.

Amendment 110

Proposal for a regulation
Article 8 – title

Text proposed by the Commission

Auditing on preparedness and response planning

Amendment

Auditing on prevention, preparedness and response planning

Amendment 111

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission

1. Every 3 years, the ECDC shall conduct audits in the Member States aimed at ascertaining the state of implementation of the national plans and their coherence with the Union plan. Such audits shall be implemented with the relevant Union agencies, aiming at the assessment of preparedness and response planning at national level with regard to the information referred to in Article 7(1).

Amendment

1. Every 2 years, the ECDC shall conduct audits in the Member States aimed at ascertaining the state of implementation of the national plans and their coherence with the Union plan. Such audits shall be based on a set of indicators and implemented in cooperation with the relevant Union agencies, aiming at the assessment of prevention, preparedness and response planning at national level with regard to the information referred to in Article 7(1).

Amendment 112
Proposal for a regulation
Article 8 – paragraph 2 – introductory part

Text proposed by the Commission
2. Member States shall present an action plan addressing the proposed recommendations of the audit and the corresponding corrective actions and milestones.

Amendment
2. In the event the audit identifies deficiencies, the Member State shall, within six months of receipt of its conclusions, present an action plan addressing the proposed recommendations of the audit and setting out the corresponding corrective actions and milestones.

Amendment 113
Proposal for a regulation
Article 8 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission
If a Member State decides not to follow a recommendation, it shall state its reasons for doing so.

Amendment

Justification
Clearly, the recommendations cannot be binding on Member States. However, in case a Member State finds it is not suitable to follow recommendations, it should be obliged to state the reasons, especially that it may be a mutually beneficial exercise by which both sides better understand its respective circumstances.

Amendment 114
Proposal for a regulation
Article 9 – title

Text proposed by the Commission
Commission report on preparedness planning

Amendment
Commission report on prevention, preparedness planning

Amendment 115
Proposal for a regulation
Article 9 – paragraph 1

Text proposed by the Commission

1. On the basis of the information provided by the Member States in accordance with Article 7, and of the results of the audits referred to in Article 8, the Commission shall by July 2022 and every 2 years afterwards, transmit to the European Parliament and to the Council a report on the state of play and progress on preparedness and response planning at Union level.

Amendment

1. On the basis of the information provided by the Member States in accordance with Article 7, and of the results of the audits referred to in Article 8, the Commission shall by July 2022 and every 2 years afterwards, transmit to the European Parliament and to the Council a report on the state of play and progress on prevention, preparedness and response planning at Union level.

Amendment 116
Proposal for a regulation

Article 9 – paragraph 1 a (new)

Text proposed by the Commission

1a. The Commission report shall include the state of cross-border preparedness and response planning in neighbouring regions.

Amendment

Amendment 117
Proposal for a regulation

Article 9 – paragraph 2

Text proposed by the Commission

2. The Commission may adopt recommendations on preparedness and response planning addressed to Member States based on the report referred to in paragraph 1.

Amendment

2. The Commission may adopt recommendations on prevention, preparedness and response planning addressed to Member States based on the report referred to in paragraph 1. Those recommendations may cover, inter alia, the minimum resources needed to respond to public health emergencies in relation to, among other things, population size and they shall be developed on the basis of good practice and policy assessments.
Amendment 118
Proposal for a regulation
Article 10 – title

Text proposed by the Commission
Coordination of preparedness and response planning in the HSC

Amendment
Coordination of *prevention*, preparedness and response planning in the HSC

Amendment 119
Proposal for a regulation
Article 10 – paragraph 1 – subparagraph 1

Text proposed by the Commission
1. The Commission and the Member States shall work together within the HSC to coordinate their efforts to develop, strengthen and maintain their capacities for the monitoring, early warning and assessment of, and response to serious cross-border threats to health.

Amendment
1. The Commission, *relevant Union agencies* and the Member States shall work together within the HSC to coordinate their efforts to develop, strengthen and maintain their capacities for the monitoring, *prevention*, early warning and assessment of, and response to serious cross-border threats to health.

Amendment 120
Proposal for a regulation
Article 10 – paragraph 1 – subparagraph 2 – point a

Text proposed by the Commission
(a) sharing best practice and experience in preparedness and response planning;

Amendment
(a) sharing best practice and experience in *prevention*, preparedness and response planning;

Amendment 121
Proposal for a regulation
Article 10 – paragraph 1 – subparagraph 2 – point b

Text proposed by the Commission
(b) promoting the interoperability of

Amendment
(b) promoting the interoperability of
national preparedness planning and the intersectoral dimension of preparedness and response planning at Union level;

Amendment 122

Proposal for a regulation
Article 10 – paragraph 1 – subparagraph 2 – point e

*Text proposed by the Commission*  
(e) monitoring progress, identifying gaps and actions to strengthen preparedness and response planning, including in the field of research, at national and at Union levels.

*Amendment*

(e) monitoring progress, identifying gaps and actions to strengthen prevention, preparedness and response planning, including in the field of research, at regional, national and at Union levels;

Amendment 123

Proposal for a regulation
Article 10 – paragraph 1 a (new)

*Text proposed by the Commission*  
1a. The Commission and the Member States shall, where appropriate, conduct a dialogue with stakeholders, including health and care workers’ organisations, industry and supply chain stakeholders, and patient and consumer organisations. That dialogue shall include regular exchanges of information between authorities, industry and relevant actors in the pharmaceutical supply chain to identify expected supply constraints so as to allow better coordination, development of synergies and appropriate responses;

Amendment 124
Proposal for a regulation
Article 11 – paragraph 1 – subparagraph 1

**Text proposed by the Commission**

1. The Commission may organise training activities for healthcare staff and public health staff in the Member States, including preparedness capacities under the International Health Regulations.

**Amendment**

1. The Commission may organise training activities, supported by the relevant Union agencies, in close cooperation with medical associations and patient organisations, for healthcare staff, social service staff and public health staff in the Member States in particular interdisciplinary One Health training, including preparedness capacities under the International Health Regulations.

Amendment 125

Proposal for a regulation
Article 11 – paragraph 1 – subparagraph 2

**Text proposed by the Commission**

1. The Commission shall organise those activities in cooperation with the Member States concerned.

**Amendment**

1. The Commission shall organise those activities in cooperation with the Member States concerned or potentially concerned, and in coordination, where possible, with the WHO to avoid duplication of activities, including preparedness capacities under the International Health Regulations.

Amendment 126

Proposal for a regulation
Article 11 – paragraph 1 – subparagraph 2 a (new)

**Text proposed by the Commission**

In cross-border regions, joint cross-border training and sharing of best practices for healthcare staff and public health staff shall be promoted and familiarity with public health systems shall be mandatory.
Amendment 127

Proposal for a regulation
Article 11 – paragraph 1 – subparagraph 2 b (new)

Text proposed by the Commission

The Commission shall use the fullest potential of distance learning to broaden the number of trainees.

Amendment

Amendment 128

Proposal for a regulation
Article 11 – paragraph 2

Text proposed by the Commission

2. The training activities referred to in paragraph 1 shall aim to provide staff referred to in that paragraph with knowledge and skills necessary in particular to develop and implement the national preparedness plans referred to in Article 6, implement activities to strengthen crisis preparedness and surveillance capacities including the use of digital tools.

Amendment

2. The training activities referred to in paragraph 1 shall aim to provide staff referred to in that paragraph with knowledge and skills necessary in particular to develop and implement the national preparedness plans referred to in Article 6, implement activities to strengthen crisis preparedness and surveillance capacities including the use of digital tools, ensure the continuity of critical long-term healthcare services and be consistent with the One Health approach.

Amendment 129

Proposal for a regulation
Article 11 – paragraph 3

Text proposed by the Commission

3. The training activities referred to in paragraph 1 may be open to staff of the competent authorities of third countries and may be organised outside the Union.

Amendment

3. The training activities referred to in paragraph 1 may be open to staff of the competent authorities of third countries and may be organised outside the Union in coordination, where possible, with ECDC activities in this area.
**Amendment 130**

Proposal for a regulation  
Article 11 – paragraph 5

*Text proposed by the Commission*

5. The Commission may support organising programmes, in cooperation with the Member States, for the exchange of healthcare staff and public health staff between two or more Member States and for the temporary secondment of staff from one Member State to the other.

*Amendment*

5. The Commission may support organising programmes, in cooperation with the Member States, for the exchange of healthcare staff and public health staff between two or more Member States and for the temporary secondment of staff from one Member State to the other. In organising those programmes, account shall be taken of the contribution made by professional health organisations in each of the Member States.

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**Amendment 131**

Proposal for a regulation  
Article 12 – paragraph 1

*Text proposed by the Commission*

1. The Commission and any Member States which so desire may engage in a joint procurement procedure conducted pursuant to Article 165(2) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council with a view to the advance purchase of medical countermeasures for serious cross-border threats to health.

*Amendment*

1. The Commission and any Member States may engage in a joint procurement procedure as contracting parties conducted pursuant to Article 165(2) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council with a view to the advance purchase of medical countermeasures for serious cross-border threats to health within a reasonable time frame.

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Amendment 132

Proposal for a regulation
Article 12 – paragraph 2 – point a

**Text proposed by the Commission**

(a) participation in the joint procurement procedure shall be open to all Members States, European Free Trade Association (EFTA) States and Union candidate countries in accordance with Article 165(2) of Regulation (EU, Euratom) 2018/1046;

**Amendment**

(a) participation in the joint procurement procedure shall be open to all Members States, European Free Trade Association (EFTA) States, Union candidate countries in accordance with Article 165(2) of Regulation (EU, Euratom) 2018/1046, and to the Principality of Andorra, the Principality of Monaco, the Republic of San Marino and the Vatican City State;

Amendment 133

Proposal for a regulation
Article 12 – paragraph 2 – point c

**Text proposed by the Commission**

(c) **Member States, EFTA States and Union candidate** countries participating in a joint procurement shall procure the medical countermeasure in question through that procedure and not through other channels, and shall not run parallel negotiation processes for that product;

**Amendment**

(c) **countries participating in a joint procurement** shall procure the medical countermeasure in question through that procedure and not through other channels, and shall not run parallel negotiation processes for that product from that moment onwards. **Countries that engage in parallel negotiation processes from that moment onwards shall be excluded from the group of participating countries, irrespective of whether those processes have reached the signature stage**;

Amendment 134
Proposal for a regulation
Article 12 – paragraph 2 – point c a (new)

Text proposed by the Commission

Amendment

(ca) the joint procurement shall define clear procedural steps for the process, scope, tender specifications and timelines and it shall require all parties to deliver and respect clear commitments, including manufacturers delivering agreed production quantities and authorities purchasing agreed reserved volumes. The precise amounts ordered by and provided to each participating country and details of their liabilities shall be disclosed.

Amendment 135

Proposal for a regulation
Article 12 – paragraph 2 – point c b (new)

Text proposed by the Commission

Amendment

(cb) A high degree of transparency shall be applied to all joint procurement activities and related purchase agreements. The European Court of Auditors shall have full access to all relevant documents to provide accurate annual scrutiny of signed contracts and the public investment involved;

Amendment 136

Proposal for a regulation
Article 12 – paragraph 2 – point c c (new)

Text proposed by the Commission

Amendment

(cc) if joint procurement is deployed, qualitative criteria shall be considered in the award process, in addition to cost. Such criteria shall also take into consideration, for example, the ability of the manufacturer to ensure security of
supply during a health crisis;

Amendment 137

Proposal for a regulation
Article 12 – paragraph 2 – point c d (new)

Text proposed by the Commission

Amendment

(cd) the joint procurement shall be conducted in such a way so as to strengthen the purchasing power of participating countries, improve the security of supply and ensure equitable access to medical countermeasures against serious cross-border threats to health;

Amendment 138

Proposal for a regulation
Article 12 – paragraph 3 – introductory part

Text proposed by the Commission

Amendment

3. The Commission shall, in liaison with the Member States, ensure coordination and information exchange between the entities organizing any action, including, but not limited to joint procurement procedures, stockpiling and donation of medical countermeasures under different mechanisms established at Union level, in particular under:

3. The Commission shall, in liaison with the Member States, ensure coordination and information exchange between the entities organizing and participating in any action, including, but not limited to joint procurement procedures, development, stockpiling in facilities that meet the specific legal requirements for the storage of medical countermeasures and having the greatest proximity to and accessibility for the greatest number of population centres, without compromising the accessibility of those products for people in remote, rural and outermost regions, distribution and donation of medical countermeasures, which shall be of benefit to low- and middle-income countries, under different mechanisms established at Union level, in particular under:
Amendment 139
Proposal for a regulation
Article 12 – paragraph 3 – point a

Text proposed by the Commission
(a) stockpiling under the rescEU referred to in Article 12 of Decision No 1313/2013/EU;

Amendment
(a) stockpiling under the rescEU referred to in Article 23 of Decision No 1313/2013/EU;

Amendment 140
Proposal for a regulation
Article 12 – paragraph 3 – point f

Text proposed by the Commission
(f) other instruments supporting biomedical research and development at Union level for enhanced capacity and readiness to respond to cross-border threats and emergencies.

Amendment
(f) other programmes and instruments supporting biomedical research and development at Union level for enhanced capacity and readiness to respond to cross-border threats and emergencies.

Amendment 141
Proposal for a regulation
Article 12 – paragraph 3 a (new)

Text proposed by the Commission
3a. Participating countries shall ensure that there is adequate stockpiling and distribution of procured medical countermeasures. The main details and characteristics of that stockpiling and distribution shall be set out in national plans.

Amendment
3a. Participating countries shall ensure that there is adequate stockpiling and distribution of procured medical countermeasures. The main details and characteristics of that stockpiling and distribution shall be set out in national plans.

Amendment 142
Proposal for a regulation
Article 12 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

3b. In accordance with the principle of transparency, the Commission shall regularly inform the European Parliament about negotiations concerning the joint procurement of medical countermeasures.

Amendment 143
Proposal for a regulation

Article 12 – paragraph 3 c (new)

Text proposed by the Commission

Amendment

3c. The European Parliament reserves at all times the right to scrutinize, under existing confidentiality rules, the uncensored content of all contracts concluded in proceedings under this Article.

Amendment 144
Proposal for a regulation

Article 12 – paragraph 3 d (new)

Text proposed by the Commission

Amendment

3d. The Commission and Member States shall provide up-to-date, accessible and clear information to consumers on their rights and duties regarding jointly procured medical countermeasures, including details on liability for damages, and access to legal protection and to consumer representation.

Amendment 145
Proposal for a regulation
Article 12 – paragraph 3 e (new)

Text proposed by the Commission

Amendment

3e. Where the joint procurement procedure for medical countermeasures to cross-border threats to health is not applied, the Commission shall encourage Member States to exchange information on pricing and delivery dates for medical countermeasures.

Amendment 146

Proposal for a regulation
Article 13 – paragraph 1

Text proposed by the Commission

Amendment

1. The network for the epidemiological surveillance of the communicable diseases and of the related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1) shall ensure a permanent communication between the Commission, the ECDC, and the competent authorities responsible at national level for epidemiological surveillance.

Amendment 147

Proposal for a regulation
Article 13 – paragraph 2 – point b a (new)

Text proposed by the Commission

Amendment

(ba) monitor the impact of communicable diseases on the continuity of screening, diagnosis, monitoring, treatment and care for other diseases and conditions;

Amendment 148
Proposal for a regulation
Article 13 – paragraph 2 – point b b (new)

Text proposed by the Commission  

Amendment

(bb) monitor the impact of communicable diseases on mental health;

Amendment 149

Proposal for a regulation
Article 13 – paragraph 2 – point d

Text proposed by the Commission  

Amendment

(d) identify and monitor risk factors for disease transmission, population groups at risk and in need of targeted prevention measures;

Amendment 150

Proposal for a regulation
Article 13 – paragraph 2 – point e

Text proposed by the Commission  

Amendment

(e) contribute to the assessment of the burden of communicable diseases on health systems and care delivery and on the population using such data as disease prevalence, complications, hospitalisation and mortality, the mental health impact, deferred screening, diagnosis, monitoring, treatment and care for other diseases and conditions and their social and economic impact;

Amendment 151
Proposal for a regulation
Article 13 – paragraph 2 – point h a (new)

Text proposed by the Commission

(ha) identify any weakness in the global supply chain involved in the production and manufacturing of medical countermeasures needed for the prevention, diagnosis, treatment and follow up of communicable diseases and make plans to mitigate such weaknesses. Other mechanisms, such as a Union export control mechanism, regulatory flexibility, cooperation agreements, compulsory or voluntary licensing agreements between companies, may enable the Union to facilitate access to counter-measures for its citizens and residents as well as for people from the Eastern Partnership countries and low and middle-income countries.

Amendment 152

Proposal for a regulation
Article 13 – paragraph 3 – point f a (new)

Text proposed by the Commission

(fa) information on the availability of medical countermeasures needed for the prevention, diagnosis, treatment and follow up of the disease.

Amendment 153

Proposal for a regulation
Article 13 – paragraph 3 a (new)

Text proposed by the Commission

3a. The information communicated by Member States referred to in point (a) shall be reported at least at NUTS II level to the European Surveillance System (TESSy) or another platform, on a timely
basis determined in accordance with Article 9.

Amendment 154

Proposal for a regulation
Article 13 – paragraph 6 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

The ECDC shall support the Member States to ensure the collection and sharing of data in times of health crisis and the integrated operation of the network for the epidemiological surveillance of communicable diseases and of the related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1). The ECDC shall, where appropriate, also make available its expertise in that domain to third countries.

Amendment 155

Proposal for a regulation
Article 13 – paragraph 9 – subparagraph 1 – introductory part

Text proposed by the Commission

Amendment

9. The Commission shall, by means of implementing acts, establish and update:

9. The Commission shall adopt delegated acts in accordance with Article 28 concerning the establishment and update of:

Amendment 156

Proposal for a regulation
Article 13 – paragraph 9 – subparagraph 1 – point c

Text proposed by the Commission

Amendment

(c) procedures for the operation of the epidemiological surveillance network as developed pursuant to Article 5 of

deleted
Regulation (EU) …/… [OJ: Please insert the number of Regulation ECDC [ISC/2020/ 12527]].

Amendment 157

Proposal for a regulation
Article 13 – paragraph 9 a (new)

Text proposed by the Commission

Amendment

9a. Where duly justified imperative grounds of urgency related to the severity or novelty of a serious cross-border threat to health or to the rapidity of its spread between Member States so require, the procedure provided for in Article 28a shall apply to delegated acts adopted pursuant to this Article.

Amendment 158

Proposal for a regulation
Article 13 – paragraph 9 b (new)

Text proposed by the Commission

Amendment

9b. The Commission shall, by means of implementing acts, establish and update procedures for the operation of the epidemiological surveillance network developed pursuant to Article 5 of Regulation (EU) …/… [OJ: Please insert the number of Regulation ECDC [ISC/2020/ 12527]].

Amendment 159

Proposal for a regulation
Article 13 – paragraph 10

Text proposed by the Commission

Amendment

10. On duly justified imperative grounds of urgency related to the severity or novelty of a serious cross-border threat

10. On duly justified imperative grounds of urgency related to the severity or novelty of a serious cross-border threat
to health or to the rapidity of its spread among the Member States, the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 27(3) for the adoption of case definitions, procedures and indicators for surveillance in Member States in the case of a threat referred to in points (i) and (ii) of point (a) of Article 2(1). *The indicators mentioned above shall also support the assessment of capacity for diagnosis, prevention and treatment.*

Amendment 160

Proposal for a regulation

Article 14 – paragraph 1

*Text proposed by the Commission*

1. The ECDC shall ensure the **further** development of the digital platform through which data are managed and automatically exchanged, to establish integrated and interoperable surveillance systems enabling real-time surveillance where appropriate, for the purpose of supporting communicable disease prevention and control.

*Amendment*

1. The ECDC shall ensure the **continued** development of the digital platform *after having conducted a data protection impact assessment and having mitigated any risks to the rights and freedoms of the data subjects*, through which data are managed and automatically exchanged, to establish integrated and interoperable surveillance systems enabling real-time surveillance where appropriate, for the purpose of supporting communicable disease prevention and control. *It shall ensure there is human oversight of the digital platform and include specific measures for minimising risks that may emerge from the transfer of biases or incomplete data from multiple sources, as well as establish procedures for data quality review. Digital platforms and applications supporting epidemiological surveillance at Union and Member State level shall be implemented in compliance with the principle of data protection by design pursuant to Art. 27(1) of Regulation (EU) 2018/1725.*
Amendment 161
Proposal for a regulation
Article 14 – paragraph 2 – point a

Text proposed by the Commission

(a) enable the automated collection of surveillance and laboratory data, make use of information from electronic health records, media monitoring, and apply artificial intelligence for data validation, analysis and automated reporting;

Amendment

(a) enable the automated collection of surveillance and laboratory data, make use of relevant health data from a previously defined and authorised list from electronic health records and health databases, media monitoring, and apply artificial intelligence for data validation, analysis and statistical reporting in accordance with Article 22 GDPR;

Amendment 162
Proposal for a regulation
Article 14 – paragraph 2 – point b

Text proposed by the Commission

(b) allow for the computerised handling and exchange of information, data and documents.

Amendment

(b) allow for the computerised processing and exchange of information, data and documents, taking into account Union law concerning the protection of personal data.

Amendment 163
Proposal for a regulation
Article 14 – paragraph 2 – point b a (new)

Text proposed by the Commission

(ba) allow for automated notification on EWRS when communicable diseases rise above warning thresholds, as referred to in point (a) of Article 13(2). The notification shall be validated by the competent health authority.

Amendment
Proposal for a regulation
Article 14 – paragraph 3

Text proposed by the Commission

3. Member States are responsible for ensuring that the integrated surveillance system is fed on a regular basis with timely and complete information, data and documents transmitted and exchanged through the digital platform.

Amendment

3. Member States are responsible for ensuring that the integrated surveillance system is fed on a regular basis with timely, complete and accurate information, data and documents transmitted and exchanged through the digital platform. The Member States shall promote the automation of this process between the national and the Union surveillance system.

Amendment 165

Proposal for a regulation
Article 14 – paragraph 5

Text proposed by the Commission

5. For epidemiological purposes, ECDC shall also have access to relevant health data accessed or made available through digital infrastructures enabling the use of health data for research, policy making and regulatory purposes.

Amendment

5. For epidemiological surveillance purposes, ECDC shall also have access to relevant health data accessed or made available through digital infrastructures enabling the use of health data for research, policy making and regulatory purposes. The access to the health data shall be proportionate to specific and concrete purposes that shall have been defined previously by ECDC.

Amendment 166

Proposal for a regulation
Article 14 – paragraph 6 – introductory part

Text proposed by the Commission

6. The Commission shall adopt implementing acts for the functioning of the surveillance platform which lay down:

Amendment

6. The Commission, following the carrying out of a consultation procedure as set out in Article 42(2) of Regulation (EU) 2018/1725, shall adopt delegated acts in accordance with Article 28 concerning the functioning of the surveillance platform.
laying down:

**Amendment 167**

*Proposal for a regulation*

*Article 14 – paragraph 6 – point a*

*Text proposed by the Commission*

(a) the technical specifications of the platform, including the electronic data exchange mechanism for exchanges with existing national systems, identification of applicable standards, definition of message structures, data dictionaries, exchange of protocols and procedures;

*Amendment*

(a) the technical specifications of the platform, including the electronic data exchange mechanism for exchanges with existing international and national systems, identification of applicable standards, definition of message structures, data dictionaries, exchange of protocols and procedures;

**Amendment 168**

*Proposal for a regulation*

*Article 14 – paragraph 6 – point c*

*Text proposed by the Commission*

(c) contingency arrangements to be applied in the event of unavailability of any of the functionalities of the platform;

*Amendment*

(c) contingency arrangements and secure data backups to be applied in the event of unavailability of any of the functionalities of the platform;

**Amendment 169**

*Proposal for a regulation*

*Article 14 – paragraph 6 – point d*

*Text proposed by the Commission*

(d) the cases where, and the conditions under which the third countries and international organisations concerned may be granted partial access to the functionalities of the platform and the practical arrangements of such access;

*Amendment*

(d) the cases where, and the conditions under which the international organisations concerned may be granted partial access to the functionalities of the platform and the practical arrangements of such access, in full compliance with Regulations (EU) 2018/1725 and (EU) 2016/679 and Directive (EU) 2016/680;
Amendment 170
Proposal for a regulation
Article 14 – paragraph 6 – point f a (new)

Text proposed by the Commission

Amendment

(fa) Ensure standardization of the infrastructure on storage, processing and analysis of data.

Amendment 171
Proposal for a regulation
Article 14 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6a. Digital platforms and applications supporting epidemiological surveillance at Union and Member State level shall be implemented in compliance with the principle of data protection by design pursuant to Art. 27(1) of Regulation (EU) 2018/1725.

Amendment 172
Proposal for a regulation
Article 15 – paragraph 1

Text proposed by the Commission

Amendment

1. In the area of public health or for specific areas of public health relevant for the implementation of this Regulation or of the national plans referred to in Article 6, the Commission may, by means of implementing acts, designate EU reference laboratories to provide support to national reference laboratories to promote good practice and alignment by Member States on a voluntary basis on diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases by
reporting of diseases by Member States.

Amendment 173

Proposal for a regulation
Article 15 – paragraph 2 – point f

Text proposed by the Commission
(f) monitoring, alert and support in outbreak response and

Amendment
(f) monitoring, alert and support in outbreak response, in particular for emerging pathogens; and

Amendment 174

Proposal for a regulation
Article 15 – paragraph 3

Text proposed by the Commission
3. The network of EU reference laboratories shall be operated and coordinated by the ECDC.

Amendment
3. The network of EU reference laboratories shall be operated and coordinated by the ECDC, in cooperation with WHO network laboratories to avoid duplication of activities. The governance structure of the network shall cover cooperation and coordination with existing national and regional reference laboratories and networks.

Amendment 175

Proposal for a regulation
Article 15 – paragraph 3 a (new)

Text proposed by the Commission

Amendment
3a. The laboratories referred to in paragraph 1 shall contribute to sharing good practices and to improving the epidemiological surveillance referred to in Article 13.
Amendment 176
Proposal for a regulation
Article 15 – paragraph 4

Text proposed by the Commission

4. The designations provided for in paragraph 1 shall follow a public selection process, be limited in time, with a minimum period of 5 years, and be reviewed regularly. Designations shall establish the responsibilities and tasks of the designated laboratories.

Amendment

4. The designations provided for in paragraph 1 shall follow a public selection process, be limited in time, with a minimum period of 5 years, and be reviewed regularly. The Commission shall consult the Member States and the ECDC to elaborate the terms of reference and the criteria of the designation process. Designations shall establish the responsibilities and tasks of the designated laboratories. Laboratory consortia shall be eligible for designation.

Amendment 177
Proposal for a regulation
Article 15 – paragraph 5 – point a

Text proposed by the Commission

(a) be impartial, free from any conflict of interest, and in particular not be in a situation which may, directly or indirectly, affect the impartiality of their professional conduct as regards the exercise of their tasks as EU reference laboratories;

Amendment

(a) be impartial, free from any conflict of interest, and in particular not be in a situation which may, directly or indirectly, affect the impartiality of their professional conduct as regards the exercise of their tasks as EU reference laboratories. Particular attention shall be paid to proprietary tests and methods that may be the property of laboratories;

Amendment 178
Proposal for a regulation
Article 17 – paragraph 1 a (new)

Text proposed by the Commission

1a. The European Surveillance System (TESSy) shall be used for ad hoc monitoring of a serious cross-border
threat to health referred to in point (iii) of point (a) of Article 2(1) and in points (b), (c) and (d) of Article 2(1).

Amendment 179

Proposal for a regulation
Article 17 – paragraph 3 – subparagraph 1

Text proposed by the Commission
The Commission shall, by means of implementing acts, adopt, where necessary, the case definitions to be used for ad hoc monitoring, in order to ensure the comparability and compatibility at Union level of the collected data.

Amendment
The Commission shall adopt, where necessary, delegated acts in accordance with Article 28 concerning the case definitions to be used for ad hoc monitoring, in order to ensure the comparability and compatibility at Union level of the collected data.

Amendment 180

Proposal for a regulation
Article 17 – paragraph 3 – subparagraph 2

Text proposed by the Commission
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

Amendment
deleted

Amendment 181

Proposal for a regulation
Article 17 – paragraph 3 – subparagraph 3

Text proposed by the Commission
On duly justified imperative grounds of urgency related to the severity of a serious cross-border threat to health or to the rapidity of its spread between the Member States, the Commission may adopt or update the case definitions referred to in the first subparagraph through immediately applicable implementing acts in accordance with the procedure referred

Amendment
Where duly justified imperative grounds of urgency related to the severity or novelty of a serious cross-border threat to health or to the rapidity of its spread between the Member States so require, the procedure provided for in Article 28a shall apply to delegated acts adopted pursuant to this Article.
to in Article 27(3).

Amendment 182
Proposal for a regulation
Article 18 – paragraph 1

Text proposed by the Commission

1. The EWRS shall enable the Commission and the competent authorities responsible at national level to be in permanent communication for the purposes of preparedness, early warning and response, alerting, assessing public health risks and determining the measures that may be required to protect public health.

Amendment

1. The EWRS shall enable the Commission, the ECDC, and the competent authorities responsible at national level to be in permanent communication for the purposes of preparedness, early warning and response, alerting, assessing public health risks and determining the measures that may be required to protect public health.

Amendment 183
Proposal for a regulation
Article 18 – paragraph 2 – subparagraph 1 – introductory part

Text proposed by the Commission

The management and use of the EWRS involve the exchange of personal data in specific cases where the relevant legal instruments so provide. This includes:

Amendment

The management and operational use of the EWRS involve the exchange of personal data in specific cases where the relevant legal instruments so provide. This includes:

Amendment 184
Proposal for a regulation
Article 18 – paragraph 2 – subparagraph 2

Text proposed by the Commission

The ECDC shall continuously update the EWRS allowing for the use of modern technologies, such as digital mobile applications, artificial intelligence models, space enabled applications, or other technologies for automated contact tracing, building upon the contact tracing

Amendment

The ECDC shall continuously update the EWRS allowing for the use of modern technologies, such as digital mobile applications, artificial intelligence models, space enabled applications, or other technologies for automated contact tracing, building upon the contact tracing
technologies developed by the Member States.

Amendment 185
Proposal for a regulation
Article 18 – paragraph 2 – subparagraph 2 a (new)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>To ensure data quality and consistency, the EWRS shall implement robust, accurate and interoperable data processes with Member States. The ECDC shall coordinate with Member States throughout such data exchange processes, from assessing the data requirements, transmission and collection, up to date actualisation and interpretation, ensuring strong collaboration between the Commission, the ECDC and national and regional competent bodies.</td>
<td></td>
</tr>
</tbody>
</table>

Amendment 186
Proposal for a regulation
Article 18 – paragraph 2 a (new)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2a. The ECDC shall develop and improve the EWRS, to augment the automation of information collection and analysis, upgrade the categorisation of notification and reduce open text communication, reduce the administrative burden and improve the standardisation of the notifications.</td>
<td></td>
</tr>
</tbody>
</table>

Amendment 187
Proposal for a regulation
Article 18 – paragraph 2 b (new)

Text proposed by the Commission

2b. The EWRS shall be improved to reduce the burden of bureaucracy and duplications of notification. The EWRS shall allow the national competent authorities to notify the WHO of events that may constitute public health emergencies of international concern in accordance with Article 6 of the IHR and shall integrate this information in the EWRS system, in order to automatically notify an alert in the EWRS.

Amendment 188

Proposal for a regulation
Article 18 – paragraph 4

Text proposed by the Commission

4. The Commission shall, by means of implementing acts, adopt procedures concerning the information exchange with other rapid alert systems at Union level, including exchange of personal data, in order to ensure the proper functioning of the EWRS and to avoid overlap of activities or conflicting actions with existing structures and mechanisms for preparedness, monitoring, early warning and combating serious cross-border threats to health.

Amendment 189

Proposal for a regulation
Article 18 – paragraph 4 a (new)

Text proposed by the Commission

4a. The EWRS shall be able to automatically collect information from other important databases, such as those...
comprising environmental data, climate data, water irrigation data and other data relevant to serious cross-border threats to health, that could facilitate understanding and mitigate the risk of potential health threats.

Amendment 190
Proposal for a regulation
Article 19 – paragraph 2

_text proposed by the Commission_

2. Where the national competent authorities notify the WHO of events that may constitute public health emergencies of international concern in accordance with Article 6 of the IHR, they shall at the latest simultaneously notify an alert in the EWRS, provided that the threat concerned falls within those referred to in Article 2(1) of this Regulation.

Amendment

2. Where the national competent authorities notify the WHO of events that may constitute public health emergencies of international concern in accordance with Article 6 of the IHR, as referred to in point 2b, Article 18, shall be simultaneously notify an alert in the EWRS, provided that the threat concerned falls within those referred to in Article 2(1) of this Regulation.

Amendment 191
Proposal for a regulation
Article 19 – paragraph 3 – point f

_text proposed by the Commission_

(f) public health risks;

-Amendment-

(f) public health risks, especially for vulnerable groups, including, as far as possible, their impact on major non-communicable diseases;

Amendment 192
Proposal for a regulation
Article 19 – paragraph 3 – point h

_text proposed by the Commission_

(h) measures other than public health

-Amendment-

(h) multisectoral measures other than
measures; public health measures;

Amendment 193
Proposal for a regulation Article 19 – paragraph 3 – point i a (new)

Text proposed by the Commission Amendment

(ia) the existing and potential production sites, with the sole aim of allowing the Union to map the strategic production capacities for the Union as a whole;

Amendment 194
Proposal for a regulation Article 19 – paragraph 3 – point j

Text proposed by the Commission Amendment

(j) requests and offers for cross-border emergency assistance;

Amendment 195
Proposal for a regulation Article 19 – paragraph 4 a (new)

Text proposed by the Commission Amendment

4a. The Member State shall update the information referred to in paragraph 3 as new data become available.

Amendment 196
Proposal for a regulation Article 20 – paragraph 1 – introductory part
1. Where an alert is notified pursuant to Article 19, the Commission shall, where necessary for the coordination of the response at Union level or upon request of the HSC referred to in Article 21 or on its own initiative, make promptly available to the national competent authorities and to the HSC, through the EWRS, a risk assessment of the potential severity of the threat to public health, including possible public health measures. That risk assessment shall be carried out by:

**Amendment**

1. Where an alert is notified pursuant to Article 19, the Commission shall, where necessary for the coordination of the response at Union level or upon request of the HSC referred to in Article 21 or on its own initiative, make promptly available to the national competent authorities and to the HSC, through the EWRS, a risk assessment of the potential severity of the threat to public health, including possible public health measures, **including a risk assessment of the mental health of the affected population**. That risk assessment shall be carried out by:

**Amendment 197**

**Proposal for a regulation**

**Article 20 – paragraph 1 – point a**

*Text proposed by the Commission*

(a) the ECDC in accordance with Article 8a of Regulation (EU) …/… [OJ: Please insert the number of Regulation ECDC [ISC/2020/12527]] in the case of a threat referred to in points (i) and (ii) of point (a) of Article 2(1) including substances of human origin: blood, organs, tissues and cells potentially impacted by communicable diseases; or point (d) of Article 2(1); and/or

*Amendment*

(a) the ECDC in accordance with Article 8a of Regulation (EU) …/… [OJ: Please insert the number of Regulation ECDC [ISC/2020/12527]] in the case of a threat referred to in point (a) of Article 2(1) including substances of human origin: **such as** blood, organs, tissues and cells potentially impacted by communicable diseases; or point (d) of Article 2(1); and/or

**Justification**

*The Centre's expertise could be used in other cases not related to communicable diseases, such as, for example, biosecurity, therefore the entire point (a) should be included here.*
Amendment 198

Proposal for a regulation
Article 20 – paragraph 1 – point a (new)

Text proposed by the Commission
(aa) the European Medicines Agency (EMA), in accordance with Article 1 of Regulation (EU) 2021/... [insert the number of revised EMA regulation 2020/0321(COD)], in the case of a threat linked to a defective medical product or in the event a threat is becoming more severe as a result of a shortage of medical products for human use or medical devices; and/or

Amendment 199

Proposal for a regulation
Article 20 – paragraph 1 – point f a (new)

Text proposed by the Commission
(fa) Union or national entities engaged in stockpiling of medical products.

Justification

As of 2023, HERA should be engaged in stockpiling of medical countermeasures.

Amendment 200

Proposal for a regulation
Article 20 – paragraph 2

Text proposed by the Commission
2. At the request of the agency or body carrying out the risk assessment within its mandate, the agencies and bodies referred to in paragraph 1 shall, without undue delay, provide any relevant information data at their disposal.

Amendment
2. At the request of the agency or body carrying out the risk assessment within its mandate, the agencies and bodies referred to in paragraph 1 shall, without undue delay, provide any relevant information data and expertise at their disposal. When delivering its risk
assessment, the agency or body shall be designated as the 'lead' agency in accordance with paragraph 3 below. The agency or body shall ensure that it takes note of any information or expertise obtained from other agencies or bodies referred to in paragraph 1.

Amendment 201
Proposal for a regulation
Article 20 – paragraph 3 – subparagraph 1

Text proposed by the Commission
Where the risk assessment needed is totally or partially outside the mandates of the agencies referred to in paragraph 1, and it is considered necessary for the coordination of the response at Union level, the Commission shall, upon request of the HSC or its own initiative, provide an ad hoc risk assessment.

Amendment
Where the risk assessment needed is totally or partially outside the mandates of the agencies referred to in paragraph 1, and it is considered necessary for the coordination of the response at Union level, the Commission shall, upon request of the HSC or its own initiative, provide an ad hoc risk assessment. Where the risk assessment needed falls under the mandate of several of the agencies referred to in paragraph 1, the Commission shall designate a lead agency to be in charge of carrying out the risk assessment, in collaboration with the other agencies concerned, and set a deadline for the submission of the assessment by that agency.

Amendment 202
Proposal for a regulation
Article 20 – paragraph 3 – subparagraph 2

Text proposed by the Commission
The Commission shall make the risk assessment available to the national competent authorities promptly through the EWRS, and, if appropriate, through linked alerts systems. Where the risk assessment is to be made public, the national competent authorities shall receive it prior

Amendment
The Commission shall make the risk assessment available to the national competent authorities promptly through the EWRS, and, if appropriate, through linked alerts systems. Where the risk assessment is to be made public, the national competent authorities shall receive it prior
to its publication.

Amendment 203

Proposal for a regulation
Article 20 – paragraph 3 – subparagraph 3

Text proposed by the Commission

The risk assessment shall take into account, if available, relevant information provided by other entities, in particular by the WHO in the case of a public health emergency of international concern.

Amendment

The risk assessment shall take into account, if available, relevant information provided by public health experts and other entities, in particular by the WHO in the case of a public health emergency of international concern.

Amendment 204

Proposal for a regulation
Article 21 – paragraph 1 – point b

Text proposed by the Commission

(b) risk and crisis communication, to be adapted to Member State needs and circumstances, aimed at providing consistent and coordinated information in the Union to the public and to healthcare professionals;

Amendment

(b) risk and crisis communication, to be adapted to Member State needs and circumstances, aimed at providing consistent and coordinated information in the Union to the public, to healthcare professionals and public health professionals;

Amendment 205

Proposal for a regulation
Article 21 – paragraph 1 – point c

Text proposed by the Commission

(c) adoption of opinions and guidance, including on specific response measures for the Member States for the prevention and control of a serious cross-border threat to health.

Amendment

(c) adoption of opinions and guidance, including on specific response measures for the Member States for the prevention and control of a serious cross-border threat to health, including coordination of response measures.
Amendment 206
Proposal for a regulation
Article 21 – paragraph 1 – point c a (new)

Text proposed by the Commission

(ca) national travel restrictions and other cross-border restrictions on movement and the gathering of people, as well as quarantine requirements and supervision of quarantines following cross-border travel.

Amendment 207
Proposal for a regulation
Article 21 – paragraph 2

Text proposed by the Commission

2. Where a Member State intends to adopt public health measures to combat a serious cross-border threat to health, it shall, before adopting those measures, inform and consult the other Member States and the Commission on the nature, purpose and scope of the measures, unless the need to protect public health is so urgent that the immediate adoption of the measures is necessary.

Amendment

2. Where a Member State intends to adopt or cease public health measures to combat a serious cross-border threat to health, it shall, before adopting or ceasing those measures, inform, consult and coordinate with the other Member States in particular neighbouring Member States, the Commission and Health Security Committee on the nature, purpose and scope of the measures, unless the need to protect public health is so urgent that the immediate adoption of the measures is necessary.

Amendment 208
Proposal for a regulation
Article 21 – paragraph 3

Text proposed by the Commission

3. Where a Member State has to adopt, as a matter of urgency, public health measures in response to the appearance or resurgence of a serious cross-border threat to health, it shall, immediately upon

Amendment

3. Where a Member State has to adopt, as a matter of urgency, public health measures in response to the appearance or resurgence of a serious cross-border threat to health, it shall, immediately upon
adoption, inform the other Member States and the Commission on the nature, purpose and scope of those measures.

adoption, inform the other Member States, relevant regional authorities, the Commission and the Health Security Committee on the nature, purpose and scope of those measures especially in cross-border regions.

Amendment 209

Proposal for a regulation
Article 21 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. In the event of a serious cross-border threat to health overwhelming national response capacities in a Member State, that Member State may also request assistance from other Member States through the ERCC provided for in Decision No 1313/2013/EU of the European Parliament and of the Council¹a.

¹a Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism.

Amendment 210

Proposal for a regulation
Article 22 – paragraph 2 – point c

Text proposed by the Commission

Amendment

(c) be proportionate to the public health risks related to the threat in question, avoiding in particular any unnecessary restriction to the free movement of persons, of goods and of services.

(c) be necessary, suitable and proportionate to the public health risks related to the threat in question, avoiding in particular any unnecessary restriction to the free movement of persons, of goods and of services, and to the rights, freedoms and principles enshrined in the Charter of Fundamental Rights of the European Union, and promote coordination of
measures between Member States.

Amendment 211
Proposal for a regulation
Article 22 – paragraph 2 – point c a (new)

Text proposed by the Commission

Amendment

(ca) be time limited, and cease as soon as one of the applicable conditions set out in points (a), (b) and (c) is no longer met.

Amendment 212
Proposal for a regulation
Article 22 – paragraph 2 – point c b (new)

Text proposed by the Commission

Amendment

(cb) take into account the need for an internal market that functions normally, in particular the existence of green lanes for free circulation of food and medical countermeasures.

Amendment 213
Proposal for a regulation
Article 23 – paragraph 3

Text proposed by the Commission

Amendment

3. Before recognising a situation of public health emergency at Union level, the Commission should liaise with the WHO in order to share the Commission’s analysis of the situation of the outbreak and to inform the WHO of its intention to adopt such a decision.

3. Before recognising a situation of public health emergency at Union level, the Commission shall liaise with the WHO in order to share the Commission’s analysis of the situation of the outbreak and to inform the WHO of its intention to adopt such a decision.
Article 23 – paragraph 4 – subparagraph 1

Text proposed by the Commission

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

Amendment

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).

Justification

The decisions referred to in paragraphs 1 and 2 only make sense if they are urgent. So in these cases the urgent procedure should become a normal procedure.

Amendment 215

Proposal for a regulation

Article 24 – paragraph 1 – introductory part

Text proposed by the Commission

1. For the purpose of the formal recognition of a public health emergency at Union level, the Commission shall establish an Advisory Committee on public health emergencies (‘Advisory Committee’) which, at the request of the Commission, shall advise the Commission by providing its views on:

Amendment

1. For the purpose of the formal recognition of a public health emergency at Union level, the Commission, with the consultation of the Health Security Committee shall establish an Advisory Committee on public health emergencies (‘Advisory Committee’) which, at the request of the Commission or the Health Security Committee, shall advise the Commission and the Health Security Committee by providing its views on:

Amendment 216

Proposal for a regulation

Article 24 – paragraph 1 – point c – point ii

Text proposed by the Commission

(ii) identification and mitigation of significant gaps, inconsistencies or inadequacies in measures taken or to be taken to contain and manage the specific threat and overcome its impact, including in clinical management and treatment, non-pharmaceutical countermeasures and

Amendment

(ii) identification and mitigation of significant gaps, inconsistencies or inadequacies in measures taken or to be taken to contain and manage the specific threat and overcome its impact, including in clinical management and treatment, and public health research needs;
public health research needs;

Amendment 217

Proposal for a regulation
Article 24 – paragraph 1 – point c – point ii a (new)

Text proposed by the Commission

(iia) in consultation with EMA pursuant to Regulation (EU) …/… [OJ: Please insert the number of EMA Regulation] on the stability of supply chains and production capacity of medical supply chains involved in the production and manufacturing of medical countermeasures needed for the diagnosis, treatment and follow-up of the disease concerned;

Amendment 218

Proposal for a regulation
Article 24 – paragraph 2

Text proposed by the Commission

2. The Advisory Committee shall be composed of independent experts, selected by the Commission according to the fields of expertise and experience most relevant to the specific threat that is occurring. The Committee should have multidisciplinary membership so it can advise on biomedical, behavioural, social, economic, cultural and international aspects. The representatives of the ECDC and of the EMA participate as observers in the Advisory Committee. The representatives of other Union bodies or agencies relevant to the specific threat shall participate as observers in this Committee as necessary. The Commission may invite experts with specific expertise with respect to a subject matter on the agenda to take part in the work of the Advisory Committee on an ad-

Amendment

2. The Advisory Committee shall be composed of independent experts, representatives of health and care workers and civil society representatives, selected by the Commission according to the fields of expertise and experience most relevant to the specific threat that is occurring. The Committee should have multidisciplinary membership so it can advise on sanitary, biomedical, behavioural, social, economic, research, development, manufacturing, cultural, transport and international aspects. The representatives of the ECDC and of the EMA shall take an active part in the Advisory Committee. The representatives of other Union bodies or agencies relevant to the specific threat shall participate as observers in this Committee as necessary. The Commission or the
Hoc basis.

Health Security Committee may invite experts and stakeholders with specific expertise with respect to a subject matter on the agenda to take part in the work of the Advisory Committee on an ad-hoc basis. The Commission shall publish the names of the experts selected to form part of the Advisory Committee and details of the professional and/or scientific backgrounds that justify their appointment.

Amendment 219

Proposal for a regulation
Article 24 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. The Commission shall publish on its website the list of members of the Advisory Committee and the qualifications supporting their appointment. A geographical balance of the membership shall be ensured whenever possible. The members shall act in the public interest and in an independent manner. They shall make declarations of interest and of commitments. Such declarations shall include any activity, position, circumstances or other facts potentially involving a direct or indirect interest, in order to make it possible to identify interests which might be considered prejudicial to those experts’ independence.

Amendment 220

Proposal for a regulation
Article 24 – paragraph 3

Text proposed by the Commission

Amendment

3. The Advisory Committee shall meet whenever the situation requires, on a
request from the Commission or a Member State.

request from the Commission, the Health Security Committee or a Member State.

Amendment 221

Proposal for a regulation
Article 24 – paragraph 6

Text proposed by the Commission

6. The Advisory Committee shall establish its rules of procedure including on the rules for the declaration and termination of an emergency situation, and adoption of recommendations and voting. The rules of procedures shall enter into force after receiving a favourable opinion from the Commission.

Amendment

6. The Advisory Committee shall establish its rules of procedure including on the rules for the declaration and termination of an emergency situation, and adoption of recommendations and voting. The rules of procedures shall enter into force after receiving a favourable opinion from the Commission and the Health Security Committee.

Amendment 222

Proposal for a regulation
Article 24 – paragraph 6 a (new)

Text proposed by the Commission

6a. The minutes of the Advisory Committee shall be public.

Amendment

6a. The advisory committee shall work in close cooperation with national advisory bodies.

Amendment 223

Proposal for a regulation
Article 24 – paragraph 6 b (new)

Text proposed by the Commission

6b. The advisory committee shall work in close cooperation with national advisory bodies.

Amendment 224
Proposal for a regulation
Article 25 – paragraph 1 – point b

Text proposed by the Commission
(b) mechanisms to monitor shortages of, develop, procure, manage and deploy medical countermeasures;

Amendment
(b) mechanisms to monitor shortages of, the development, the manufacture, the procurement, actions taken to ensure security of supply, the management, the storage, the distribution and the deployment of medical countermeasures;

Amendment 225

Proposal for a regulation
Article 25 – paragraph 1 – point c

Text proposed by the Commission
(c) activation of support from the ECDC as referred to in Regulation (EU) …/… [OJ: Please insert the number of Regulation ECDC [ISC/2020/12527]] to mobilise and deploy the EU Health Task Force.

Amendment
(c) activation of support from the ECDC as referred to in Regulation (EU) …/… [OJ: Please insert the number of Regulation ECDC [ISC/2020/12527]] to mobilise and deploy the EU Health Task Force and in particular the establishment of a list of accommodation facilities in intensive care units in the Member States for the purpose of potential cross-border relocation of patients;

Amendment 226

Proposal for a regulation
Article 25 – paragraph 1 – point c a (new)

Text proposed by the Commission
(ca) A Union export control mechanism with the aim of enabling the Union to guarantee timely and effective access to counter-measures.

Amendment

Proposal for a regulation
Article 25 – paragraph 1 – point c b (new)

Text proposed by the Commission

Amendment

(cb) green lanes referred to in Article 25a of this Regulation, in exceptional cases.

Amendment 228

Proposal for a regulation
Article 25 a (new)

Text proposed by the Commission

Amendment

Article 25a
Green lanes

1. After recognising a public health emergency for a pandemic situation under Article 23(1), the Commission shall, in the case of border restrictions, establish green lanes to ensure that essential goods, medical countermeasures and cross border workers can move freely within the internal market.

2. The Commission is empowered to adopt delegated acts to supplement this Regulation with provisions on the establishment of the green lanes referred to in paragraph 1.

3. A Member State may only prohibit or restrict exports of medical countermeasures in cases defined in Article 36 TFEU during a public health emergency at Union level, on condition that it obtains prior authorisation from the Commission.

4. The Commission shall decide on the request for prior authorisation within five days of the request. If the Commission takes no decision within this period, the authorisation shall be deemed granted.
Amendment 229
Proposal for a regulation
Article 26 – paragraph 1

**Text proposed by the Commission**

1. The EWRS shall include a selective messaging functionality allowing personal data, including contact and health data, to be communicated only to national competent authorities involved in the contact tracing measures concerned. That selective messaging functionality shall be designed *and* operated so as to ensure safe and lawful processing of personal data and to link with contact tracing systems at Union level.

**Amendment**

1. The EWRS shall include a selective messaging functionality allowing personal data, including contact and health data, to be communicated only to national competent authorities involved in the contact tracing measures concerned. That selective messaging functionality shall be designed *with respect for the principle of data minimisation and data protection by design and by default,* and shall be operated so as to ensure safe and lawful processing of personal data and to link with contact tracing systems at Union level.

Amendment 230
Proposal for a regulation
Article 26 – paragraph 5

**Text proposed by the Commission**

5. Personal data may also be exchanged in the context of automated contact tracing, using contact tracing applications.

**Amendment**

5. Personal data may also be exchanged in the context of automated contact tracing, using contact tracing applications, *in full compliance with Regulation (EU) 2016/679 of the European Parliament and of the Council (‘GDPR’)*

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Amendment 231

Proposal for a regulation
Article 26 – paragraph 6 – subparagraph 1 – introductory part

Text proposed by the Commission

6. The Commission shall, by means of implementing acts, adopt:

Amendment

6. Following a prior consultation procedure as set out in Article 42(2) of Regulation (EU) 2018/1725, the Commission shall adopt delegated acts in accordance with Article 28 concerning:

Amendment 232

Proposal for a regulation
Article 26 – paragraph 6 – subparagraph 1 – point b

Text proposed by the Commission

(b) procedures for the interlinking of the EWRS with contact tracing systems at Union level;

Amendment

(b) procedures for the interlinking of the EWRS with contact tracing systems at Union level and international level;

Amendment 233

Proposal for a regulation
Article 26 – paragraph 6 – subparagraph 1 – point d

Text proposed by the Commission

(d) the modalities for processing automated contract tracing applications and interoperability of these applications, as well as the cases where, and the conditions under which, the third countries may be granted access to contract tracing interoperability and the practical arrangements for such access.

Amendment

(d) the modalities for processing automated contract tracing applications and interoperability of these applications, as well as the cases where, and the conditions under which, the third countries may be granted access to contract tracing interoperability and the practical arrangements for such access, in full compliance with the EUDPR and applicable case law of the Court of Justice.
Amendment 234
Proposal for a regulation
Article 26 – paragraph 6 – subparagraph 1 – point d a (new)

Text proposed by the Commission
(da) a detailed description of the roles of the actors involved in the processing of personal data through the proposed IT tools and systems.

Amendment 235
Proposal for a regulation
Article 26 – paragraph 6 – subparagraph 2

Text proposed by the Commission
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

Amendment 236
Proposal for a regulation
Article 28 – paragraph 2

Text proposed by the Commission
2. The power to adopt delegated acts referred to in Article 8(3) shall be conferred on the Commission for an indeterminate period of time from … [date of entry into force of the basic legislative act or any other date set by the co-legislators].

Amendment
2. The power to adopt delegated acts referred to in Articles 8(3), 13(9), 14(6), 17(3), 25a(2), and 26(6) shall be conferred on the Commission for a period of five years from … [date of entry into force of the basic legislative act or any other date set by the co-legislators]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each
Amendment 237

Proposal for a regulation
Article 28 – paragraph 3

Text proposed by the Commission

3. The delegation of power referred to in Article 8(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Amendment

3. The delegation of power referred to in Articles 8(3), 13(9), 14(6), 17(3), 25a(2) and 26(6) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Amendment 238

Proposal for a regulation
Article 28 – paragraph 6

Text proposed by the Commission

6. A delegated act adopted pursuant to Article 8(3) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Amendment

6. A delegated act adopted pursuant to Articles 8(3), 13(9), 14(6), 17(3), 25a(2) and 26(6) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.
Amendment 239

Proposal for a regulation
Article 28 a (new)

Text proposed by the Commission

Amendment

Article 28a

Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 28(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

Amendment 240

Proposal for a regulation
Article 29 – paragraph 1

Text proposed by the Commission

Amendment

By 2025 and every 5 years thereafter the Commission shall carry out an evaluation of this Regulation and present a report on the main findings to the European Parliament and the Council. The evaluation shall be conducted in accordance with the Commission’s better regulation guidelines. The evaluation shall include, in particular, an assessment of the operation of the EWRS and the epidemiological surveillance network, as well as the coordination of the response with the HSC.

By 2025 and every 3 years thereafter the Commission shall carry out an evaluation of this Regulation and present a report on the main findings to the European Parliament and the Council. The evaluation shall be conducted in accordance with the Commission’s better regulation guidelines. The evaluation shall include, in particular, an assessment of the operation of the EWRS and the epidemiological surveillance network, as well as the coordination of the response with the HSC and the impact of the Regulation on the
proper functioning of the single market when serious cross-border threats to health arise.

Amendment 241
Proposal for a regulation
Article 29 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Based on the evaluation referred to in the previous paragraph, the Commission shall, where appropriate, submit a legislative proposal to amend this Regulation.
EXPLANATORY STATEMENT

The COVID-19 pandemic has once again revealed the European Union's fragility in terms of public health.

Facing this full-scale test, our national health systems have found themselves overwhelmed. This weakness initially led our governments to adopt reflexes of national protection.

However, the temptation to turn inwards soon gave way to European solidarity and coordination.

We are undeniably stronger together, but we still need to be able to activate the tools available to counter a health crisis of this magnitude.

These instruments, which have been adopted in the course of health crises over the last few decades, exist alongside each other and are juxtaposed, but lack reactive and effective coordination.

By publishing the legislative package "Building a European Health Union" on 11 November 2020, the European Commission is seeking to bring coherence to our policy on anticipating, preparing for and managing health crises.

The Rapporteur welcomes the regulation on serious cross-border health threats, which will in the future become a real European health emergency plan.

This legislation will be a true conductor of crisis management and will make it possible to coordinate existing and future European health instruments, legislation and agencies.

From the ECDC to the EMA, from the EU Civil Protection Mechanism to the European Medical Corps, from the joint procurement procedure to the management of medical product shortages, from the Pharmaceutical Strategy to the future Health Emergency Response and Preparedness Authority (HERA), these tools will have to be structured around this legislation.

The Rapporteur fully supports the new measures proposed by the Commission in this regulation.

Several of them were strongly supported by Parliament's resolutions: the updating of the Early Warning and Response System (EWRS), the organisation of audits and stress tests of national plans, the generalisation of joint procurement procedures, the training and mobility of health professionals, the network of substances of human origin and the strengthening of European health agencies.

In addition to these essential measures, the Rapporteur welcomes the fact that the threats posed by climate change have been taken into account, the establishment of a European network of reference laboratories and the possible introduction of an exclusive "European Union" clause in joint procurement contracts.
The Rapporteur considers, however, that major aspects of the legislative proposal should be strengthened.

1. **Promote solidarity in the European Union and beyond**

The COVID-19 crisis demonstrates that no country can fight a global pandemic alone. Cooperation and coordination between national health systems and a close and structured dialogue with all stakeholders are essential to ensure solidarity within the European Union.

Our priority should be to ensure 'health solidarity' by reducing health inequalities between and within Member States. All Europeans must have the same protection against all health threats and have access to the same care and treatment regardless of the country in which they live.

Our values of solidarity for equitable and universal coverage of quality health services must also be promoted beyond Europe.

There is a need to strengthen cooperation with third countries in the exchange of knowledge and best practice in the field of preparedness and response to threats. To this end, we should establish a strong and effective partnership with international organisations and third countries, particularly in Africa.

International cooperation is a major lever for all European actions in the field of prevention, preparedness and response to health crises. For this reason, the Rapporteur puts more emphasis on international cooperation in her report and supports in particular the development of an International Treaty on Pandemics to facilitate the implementation of the International Health Regulations (IHR 2005).

2. **Strengthen operational coordination at European level**

The European Union must learn from the crisis and seize the opportunity to put in place, through this legislative proposal, an effective system for coordinating the European response to any kind of future threat to public health (infectious diseases or other threats, whether of environmental, food, biological, chemical or unknown origin).

The Rapporteur particularly encourages the promotion of the "One health" approach at the heart of all European policies. The COVID-19 crisis demonstrates how a public health problem can impact on the proper functioning of all European sectors.

This cross-cutting vision of health must guide our entire system of anticipation and crisis management, whatever its nature. The European Union must be prepared to deal with a new pandemic but also, for example, an environmental or chemical threat. For this reason, the Rapporteur strives to broaden the scope and instruments of the legislative proposal beyond communicable diseases. The involvement of all health agencies in the risk assessment of a threat reflects this approach.

At the heart of the fight against COVID-19, the Rapporteur was able to identify the strengths and weaknesses of the European Centre for Disease Prevention and Control (ECDC). In particular, difficulties have been encountered in accessing comparable data. It would therefore seem appropriate to provide support to Member States to ensure the collection and sharing of
data in times of health crisis. The receipt of comparable data will enable the ECDC to carry out surveillance of epidemiological data at European level which would ensure better preparedness. This surveillance could also be extended to the impact of communicable diseases on non-communicable diseases or on people at risk.

In line with its recommendations to Member States and health professionals, the ECDC should broaden its communication to European citizens by establishing a portal to share verified information. This tool would further enhance the fight against disinformation.

The Early Warning and Response Systerm (EWRS), an instrument managed by the ECDC, should be updated with modern technology to ensure its interoperability with international, European, national and regional alert systems regardless of the nature of the threat.

3. Ensure European supply of health products

The COVID-19 crisis has exacerbated the long-standing fact that the European Union has become dependent on medical products.

In European and national crisis preparedness and response plans, it would be essential for all medical products (personal protective equipment, medicines, vaccines, medical devices and in vitro medical devices and their accessories) to be taken into account in the resources and capacities of the Member States. The stockpiles of medical products, the risks of shortages and the assessment of production capacity for these products should be assessed as part of the plans and their audits.

The Rapporteur fully supports the generalisation of the procedure for joint procurement of countermeasures. The European Union is stronger when it negotiates with industry with one voice on behalf of all Member States. This collective negotiation guarantees equal access at the same time for all European citizens. This procedure should also be considered outside of health threats. It may be necessary to distinguish between an accelerated procedure in times of crisis and another procedure that is more permanent and predictable over time.

The European Medicines Agency (EMA), which is the key player in anticipating and managing health crises, should play a much more important role in the legislative proposal. According to the Rapporteur, EMA should be placed on the same level as the other European agencies in the context of health risk assessment. Its responsibilities in the area of marketing authorisation of countermeasures, continuous risk assessment of medicinal products and management of shortages would make it a fully-fledged agency.

4. Establish inclusive health governance

This strengthened system of preparedness and crisis management should be based on inclusive health governance.

The Rapporteur fully supports the strengthening of the Health Security Committee and its working groups, the increased involvement of all European agencies and the creation of the Advisory Committee for Public Health Emergencies.
The COVID-19 crisis has demonstrated the extent to which European citizens want more transparency and participation in the decision-making process. For this reason, the Rapporteur believes that it would be appropriate to give the Parliament an observer role in the Health Security Committee and to give a significant role to representatives of society in the Advisory Committee, provided, of course, that they are free of any conflict of interest.

Beyond the decision-making aspect, the EU should involve all authorities in the implementation of European and national crisis preparedness and response plans. The latter would promote enhanced cross-border health cooperation through interregional crisis anticipation planning. The inclusion of regional and local authorities in this process would allow Member States to mobilise funding in a proportionate way according to needs, including facilitating partnerships in border regions to share the costs of infrastructure and workforce.

This legislative proposal, and those on the revision of the EMA and ECDC mandates, are the first steps towards a true European Health Union. The expectations of European citizens are high. The EU4Health 2021-2027 programme finally gives us the means to prioritise coherence and efficiency in our health policy. The co-legislators have, more than ever, an obligation to succeed in these major negotiations. The response must be equal to the challenge.
31.5.2021

OPINION OF THE COMMITTEE ON THE INTERNAL MARKET AND CONSUMER PROTECTION

for the Committee on the Environment, Public Health and Food Safety


Rapporteur for opinion: Rasmus Andresen

AMENDMENTS

The Committee on the Internal Market and Consumer Protection calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to take into account the following amendments:

Amendment 1

Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission Amendment

(1a) Health provisions of the Treaties are still largely under-used in terms of the purposes they were designed to achieve.
This Regulation should therefore be aimed at making the best possible use of such health provisions, in order to demonstrate the strength of the Union’s health policy, while preserving the normal functioning of the single market in the event serious cross-border threats to health arise.
Amendment 2

Proposal for a regulation
Recital 2

(2) In light of the lessons learnt during the ongoing COVID-19 pandemic and in order to facilitate adequate Union-wide preparedness and response to all cross-border threats to health, the legal framework for epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, as set out in Decision No 1082/2013/EU, needs to be broadened with regard to additional reporting requirements and analysis on health systems indicators, and cooperation by Member States with the European Centre for Disease Prevention and Control (ECDC). Moreover, in order to ensure effective Union response to novel cross-border threats to health, the legal framework to combat serious cross-border threats to health should enable to immediately adopt case definitions for the surveillance of novel threats and should provide for the establishment of a network of EU reference laboratories and a network to support monitoring of disease outbreaks that are relevant to substances of human origin. The capacity for contact tracing should be strengthened via the creation of an automated system, using modern technologies.
Amendment 3
Proposal for a regulation
Recital 5

Text proposed by the Commission

(5) This Regulation should apply without prejudice to other binding measures concerning specific activities or quality and safety standards for certain goods, which provide for special obligations and tools for monitoring, early warning and combating specific threats of a cross-border nature. Those measures include, in particular, relevant Union legislation in the area of common safety concerns in public health matters, covering goods such as pharmaceutical products, medical devices and foodstuffs, substances of human origin (blood, tissues and cells, organs), and exposure to ionising radiation.

Amendment

(5) This Regulation should apply without prejudice to other binding measures concerning specific activities or quality and safety standards for certain goods, which provide for special obligations and tools for monitoring, early warning and combating specific threats of a cross-border nature. Those measures include, in particular, relevant Union legislation in the area of common safety concerns in public health matters, covering goods such as pharmaceutical products, medical devices, personal protective equipment (PPE) and foodstuffs, substances of human origin (blood, tissues and cells, organs), and exposure to ionising radiation.

Amendment 4
Proposal for a regulation
Recital 6

Text proposed by the Commission

(6) The protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant

Amendment

(6) The protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, as well as in close dialogue with industry and supply chain actors, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy
to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health. In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States through the Early Warning and Response System (‘EWRS’) set up by Decision No 2119/98/EC.

Amendment 5
Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission

(8a) Building on lessons learnt from the COVID-19 pandemic, this Regulation should create a more robust mandate for coordination at Union level. The shift from national to European level as regards procurement of PPE, medical equipment and vaccines, under rescEU, the Joint Procurement Agreement (JPA) and the EU Emergency Support Initiative (ESI), has been effective and beneficial to citizens. That shift avoids unfair competition between Member States and ensures that there is secure, fair, equitable and affordable access to medical countermeasures. The declaration of a public health emergency at Union level would bring about increased coordination and allow for joint procurement procedures for the development, stockpiling, distribution and donation of medical countermeasures. Therefore, the Commission should encourage Member States to conduct joint procurement for medical countermeasures to cross border threats to health.
Amendment 6
Proposal for a regulation
Recital 8 b (new)

Text proposed by the Commission

Amendment

(8b) This Regulation also ensures coordinated action at Union level, in order to ensure that the internal market functions properly, and to ensure that basic supplies, including medicines, medical products and personal protective equipment (PPE) circulate freely.

Amendment 7
Proposal for a regulation
Recital 8 c (new)

Text proposed by the Commission

Amendment

(8c) The primary purpose of joint procurement should be to improve preparedness, predictability and response as regards serious cross-border threats to health, and particularly to improve the security and capacity of supply and the degree to which access to medical countermeasures in the participating countries is equitable.

Amendment 8
Proposal for a regulation
Recital 8 d (new)

Text proposed by the Commission

Amendment

(8d) To ensure that the internal market remains resilient during future health emergency situations, and in order to reduce Union’s dependence on third countries, this Regulation should foster the creation of minimum Union stocks of
Amendment 9

Proposal for a regulation
Recital 9

Text proposed by the Commission

(9) As serious cross-border threats to health are not limited to Union borders, joint procurement of medical countermeasures should be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union legislation. The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU, should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the Union. The Commission should ensure coordination and information exchange between the entities organizing any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council.\(^\text{16}\)

Amendment

(9) As serious cross-border threats to health are not limited to Union borders, joint procurement of medical countermeasures should be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union legislation. The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU, should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the Union and for enhanced security and greater capacity of supply of the medical countermeasure in question. The exclusivity clause should be such that countries participating in the joint procurement procedure are not allowed to negotiate and sign parallel contracts for the same product. If such countries negotiate and sign parallel contracts for the same product, they should be excluded from the group of participating countries. The Commission should ensure coordination and information exchange between the entities organizing and participating in any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement, stockpiling and distribution of medical countermeasures, such as the strategic rescEU reserve under Decision No
Amendment 10

Proposal for a regulation
Recital 9 a (new)

Text proposed by the Commission

(9a) The functioning of the Joint Procurement Agreement should abide by high standards of transparency, including in relation to the disclosure of the exact amount of medical countermeasures provided to each participating country, details regarding supply chains, production and delivery of procured products, and details of the liability of participating countries. Transparency measures should, as soon as possible, ensure that access to medical countermeasures is rapid, equal, fair and affordable whilst avoiding price speculation between Member States. It should prevent market disruption and ensure fulfilment of contractual responsibilities. In this respect, it is crucial to define transparent steps to apply from the beginning of the procedure in terms of process, scope, tender specifications, timelines and formalities and to ensure that communication throughout the whole procedure is clear.

Amendment 11


Proposal for a regulation
Recital 9b (new)

Text proposed by the Commission

(9b) Where a joint procurement procedure has not been used to purchase medical countermeasures, the Commission should encourage Member States to exchange information on pricing and delivery dates of medical countermeasures, to provide an increased level of transparency and thus allow Member States to access and negotiate medical countermeasures in more equitable conditions.

Amendment 12
Proposal for a regulation
Recital 9c (new)

Text proposed by the Commission

(9c) In order to achieve transparency, the European Parliament should scrutinise contracts concluded under the Joint Procurement Procedure. The Commission should provide to the Parliament complete, timely and accurate information on the ongoing negotiations and give access to the tender documents as well as to the contracts concluded.

Amendment 13
Proposal for a regulation
Recital 9d (new)

Text proposed by the Commission

(9d) The joint procurement procedure should foster cooperation and solidarity between the Member States in response to a serious cross border threat to health, strengthen their negotiating position by
ensuring preferential purchasing conditions, concerning the quantity, price and availability of a procured medical countermeasure.

Amendment 14
Proposal for a regulation
Recital 9 e (new)

Text proposed by the Commission

(9e) The COVID-19 pandemic has exposed the limited diversity of suppliers and over-reliance on particular supply chains. Such vulnerabilities need to be addressed by encouraging broader participation of small and medium-sized enterprises (SMEs) in joint procurement procedures. Particular emphasis should be placed on providing technical assistance and reducing unnecessary administrative requirements in order to boost the involvement of SMEs in the process.

Amendment 15
Proposal for a regulation
Recital 9 f (new)

(9f) In order for this Regulation to fulfil its main objectives, mainly to ensure a rapid response in the event of serious cross-border threats to health, special attention should be given to the joint procurement contractual provisions regulating delivery and scheduled commitments in order to ensure that timely delivery of medical countermeasures to the participating countries is respected under all circumstances.
Amendment 16
Proposal for a regulation
Recital 9 g (new)

Text proposed by the Commission

(9g) Joint procurement implies shared responsibilities and obligations for all parties involved. Commitments from the manufacturers to deliver on the production, and from the authorities to purchase their agreed reserved volumes, should be defined and respected.

Amendment 17
Proposal for a regulation
Recital 9 h (new)

Text proposed by the Commission

(9h) In order for joint procurement to be sustainable, the Commission and Member States should ensure that technical specifications and selection and award criteria are accessible, transparent, proportionate and non-discriminatory, by placing a significant and priority value on and giving consideration to the highest safety and quality standards for medical countermeasures, in accordance with the applicable legislation, and beyond the price and costs of such medical countermeasures. Such criteria should also cover the ability of the bidder to ensure that there is security and capacity of supply in a serious cross-border health threat situation, as well as provide for adequate flexibility to allow for a wider selection of successful suppliers and the effective participation of SMEs in the procurement process.

Amendment 18
Proposal for a regulation
Recital 9 i (new)

Text proposed by the Commission

Amendment

(9i) The Commission should pay special attention to ensuring that joint procurement of medical countermeasures within the meaning of Article 12, also includes procurement of orphan drugs.

Amendment 19

Proposal for a regulation
Recital 14 a (new)

Text proposed by the Commission

Amendment

(14a) Green lanes should only be considered as an appropriate tool for pandemic situations of a declared public health emergency with the aim of ensuring that essential goods, medical countermeasures and cross border workers circulate freely and safely within the internal market. The creation of green lanes in such situations should not affect the relevant Treaty provisions or legislation regulating border controls.

Amendment 20

Proposal for a regulation
Recital 14 b (new)

Text proposed by the Commission

Amendment

(14b) Quantitative restrictions on exports of medical countermeasures, and all measures having equivalent effect, are prohibited between Member States under Article 35 TFEU in general. However, given that Article 36 TFEU provides for such restrictions on justified grounds, this Regulation should be aimed at ensuring that Union law is correctly implemented.
Amendment 21

Proposal for a regulation
Recital 15

Text proposed by the Commission

(15) The Member States have a responsibility to manage public health crises at national level. However, measures taken by individual Member States could affect the interests of other Member States if they are inconsistent with one another or based on diverging risk assessments. The aim to coordinate the response at Union level should, therefore, seek to ensure, inter alia, that measures taken at national level are proportionate and limited to public health risks related to serious cross-border threats to health, and do not conflict with obligations and rights laid down in the Treaty on the Functioning of the European Union such as those related to free movement of persons, goods and services.

Amendment

(15) The Member States have a responsibility to manage public health crises at national level. However, measures taken by individual Member States could affect the interests of other Member States if they are inconsistent with one another or based on diverging risk assessments. The aim to coordinate the response at Union level should, therefore, avoid competition between Member States seek to ensure, inter alia, that access to medical countermeasures is fair, equitable and affordable across the Union. The measures taken at national level should be proportionate and limited to public health risks related to serious cross-border threats to health, and do not conflict with obligations and rights laid down in the Treaty on the Functioning of the European Union such as those related to free movement of persons, goods and services.

Amendment 22

Proposal for a regulation
Recital 15 a (new)

Text proposed by the Commission

(15a) The Commission should ensure that, at the time of the declaration of a state of emergency, the number of accommodation facilities in hospitals in the Member States, as well as the number of available accommodation units in intensive care units in the Member States, are known, for the purpose of cross-
border movement of patients.

**Amendment 23**

**Proposal for a regulation**

**Recital 17**

*Text proposed by the Commission*

(17) Inconsistent communication with the public and stakeholders such as healthcare professionals can have a negative impact on the effectiveness of the response from a public health perspective as well as on economic operators. The coordination of the response within the HSC, assisted by relevant subgroups, should, therefore, encompass rapid information exchange concerning communication messages and strategies and addressing communication challenges with a view to coordinating risk and crisis communication, based on robust and independent evaluation of public health risks, to be adapted to national needs and circumstances. Such exchanges of information are intended to facilitate the monitoring of the clarity and coherence of messages to the public and to healthcare professionals. Given the cross-sectoral nature of this type of crises, coordination should also be ensured with other relevant constituencies, such as the Union Civil Protection Mechanism established by Decision (EU) 2019/420 of the European Parliament and of the Council\(^ {17}\).

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Amendment 24

Proposal for a regulation
Recital 18

Text proposed by the Commission

(18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at Union level, and advise on public health response measures and on the termination of this emergency recognition. The advisory committee should consist of independent experts, selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the ECDC, of the EMA, and of other Union bodies or agencies as observers. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as ‘EU Health Task Force’.

Amendment

(18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level through the creation of a new mechanism that increases the coordination of and facilitates joint procurement procedures for the development, stockpiling and donation of medical countermeasures. In order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at Union level, and advise on public health response measures and on the termination of this emergency recognition. The advisory committee should consist of independent experts, selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the European Parliament, the ECDC, of the EMA, and of other Union bodies or agencies as observers. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as ‘EU Health Task Force’.
Amendment 25
Proposal for a regulation
Recital 20

Text proposed by the Commission

(20) The occurrence of an event that corresponds to serious cross-border threats to health and is likely to have Union-wide consequences should require the Member States concerned to take particular control or contact-tracing measures in a coordinated manner in order to identify people already contaminated and those persons exposed to risk. Such cooperation could require the exchange of personal data through the system, including sensitive information related to health and information about confirmed or suspected human cases of the disease, between those Member States directly involved in the contact-tracing measures. The exchange of personal data concerning health by the Member States has to comply with Article 9(2)(i) of Regulation (EU) 2016/679 of the European Parliament and of the Council.

Amendment

(20) The occurrence of an event that corresponds to serious cross-border threats to health and is likely to have Union-wide consequences should require the Member States concerned to take particular control or contact-tracing measures in a coordinated manner in order to identify people already contaminated and those persons exposed to risk. The Commission should ensure that such data are processed securely and should ensure that they are treated in accordance with Union law on data protection. Such cooperation could require the exchange of personal data through the system, including sensitive information related to health and information about confirmed or suspected human cases of the disease, between those Member States directly involved in the contact-tracing measures. The exchange of personal data concerning health by the Member States has to comply with Article 9(2)(i) of Regulation (EU) 2016/679 of the European Parliament and of the Council.


Amendment 26
Proposal for a regulation
Article 1 – paragraph 1 – point c

Text proposed by the Commission

(c) joint procurement of medical countermeasures;

Amendment

(c) joint procurement, management and deployment of medical countermeasures;

Amendment 27
Proposal for a regulation
Article 3 – paragraph 1 – point 7

Text proposed by the Commission

(7) ‘serious cross-border threat to health’ means a life-threatening or otherwise serious hazard to health of biological, chemical, environmental, climate or unknown origin which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection;

Amendment

(7) ‘serious cross-border threat to health’ means a life-threatening or otherwise serious hazard to health of biological, chemical, environmental, climate or unknown origin, and which may necessitate coordination at Union level in order to ensure a high level of human health protection;

Amendment 28
Proposal for a regulation
Article 3 – paragraph 1 – point 8 a (new)

Text proposed by the Commission

(8a) ‘green lanes’ means passable and safe transit corridors that preserve supply chains in the event of a declared public health emergency at Union level in a pandemic situation by ensuring that essential goods, medical countermeasures and cross border workers can circulate freely and safely within the internal market, while fully respecting Article 77 (2) (e) TFEU.

Amendment

(8a) ‘green lanes’ means passable and safe transit corridors that preserve supply chains in the event of a declared public health emergency at Union level in a pandemic situation by ensuring that essential goods, medical countermeasures and cross border workers can circulate freely and safely within the internal market, while fully respecting Article 77 (2) (e) TFEU.
Proposal for a regulation
Article 4 – paragraph 1 – introductory part

Text proposed by the Commission

1. The Health Security Committee (‘HSC’) is hereby established. It shall be composed of representatives of the Member States, in two working formations:

Amendment

1. The Health Security Committee (‘HSC’) is hereby established. It shall be composed of representatives of all the Member States, in two working formations:

Amendment 30

Proposal for a regulation
Article 4 – paragraph 2 – point d

Text proposed by the Commission

(d) adoption of opinions and guidance, including on specific response measures for the Member States for the prevention and control of serious cross-border threats to health.

Amendment

(d) adoption of opinions and guidance, including on specific response measures for the Member States for the prevention and control of serious cross-border threats to health while taking into account the proper functioning of the single market.

Amendment 31

Proposal for a regulation
Article 4 – paragraph 6 – point c a (new)

Text proposed by the Commission

(ca) remote digital working in situations when the HSC cannot physically meet for justified reasons.

Amendment

Recognised Union social partners in the relevant health and social services dialogue committees shall have observer
status in the HCS.

Justification

The pandemic underlined the important role of social partners in risk assessments and ensuring preparedness. Preparedness is also a health and safety issue that involved workers, employers, and the public authorities when dealing with cross-border health threats. One of the examples of the relevant EU sectoral social dialogue committee is the Social Dialogue Committee for the Hospital and Healthcare sector.

Amendment 33

Proposal for a regulation
Article 5 – paragraph 3 – point g b (new)

Text proposed by the Commission

(gb) adequate stock of personal protective equipment of the highest quality;

Amendment 34

Proposal for a regulation
Article 5 – paragraph 4 a (new)

Text proposed by the Commission

4a. The Union preparedness and response plan shall also provide for measures to ensure that the single market functions normally in the event serious cross-border threats to health arise.

Amendment 35

Proposal for a regulation
Article 7 – paragraph 1 – subparagraph 1 – point b – point ii

Text proposed by the Commission

(ii) capacities: including assessments of risks and capacities to determine priorities for emergency preparedness; surveillance and early warning, information

Amendment

(ii) capacities: including assessments of risks and capacities to determine priorities for emergency preparedness; surveillance and early warning, information
management; access to diagnostic services during emergencies; basic and safe gender-sensitive health and emergency services; risk communications; research development and evaluations to inform and accelerate emergency preparedness;

Amendment 36

Proposal for a regulation
Article 12 – paragraph 1

Text proposed by the Commission

1. The Commission and any Member States which so desire may engage in a joint procurement procedure conducted pursuant to Article 165(2) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council\(^{29}\) with a view to the advance purchase of medical countermeasures for serious cross-border threats to health.

Amendment

1. The Commission shall propose, and any Member States which so desire may, as contracting parties, engage in, a joint procurement procedure conducted pursuant to Article 165(2) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council\(^{29}\) with a view to the advance purchase of medical countermeasures for the purpose of preparedness for and response to serious cross-border threats to health.


Amendment 37

Proposal for a regulation
Article 12 – paragraph 2 – point c

*Text proposed by the Commission*

(c) Member States, EFTA States and Union candidate countries participating in a joint procurement shall procure the medical countermeasure in question through that procedure and not through other channels, and shall not run parallel negotiation processes for that product;

*Amendment*

(c) Member States, EFTA States and Union candidate countries participating in a joint procurement shall procure the medical countermeasure in question through that procedure and not through other channels, and shall not run parallel negotiation processes for that product; running parallel negotiation processes for that product shall lead to being excluded from the group of participating countries;

Amendment 38

Proposal for a regulation

Article 12 – paragraph 2 – point c a (new)

*Text proposed by the Commission*

(ca) joint procurement shall be conducted in such a way as to strengthen the purchasing power of participating countries, improve the capacity and security of supply of, and ensure fair, equitable and affordable access to, medical countermeasures against serious cross-border threats to health;

*Amendment*

Amendment

Proposal for a regulation

Article 12 – paragraph 2 – point d

*Text proposed by the Commission*

(d) the joint procurement shall not affect the internal market, shall not constitute discrimination or a restriction of trade and shall not cause distortion of competition;

*Amendment*

(d) the joint procurement shall not affect the internal market, shall not constitute discrimination or a restriction of trade and shall not cause distortion of competition or concentration of demand; the joint procurement shall ensure that supply flows are continuous, and shall not contribute to shortages in the Union;
Amendment 40

Proposal for a regulation
Article 12 – paragraph 2 – point d a (new)

Text proposed by the Commission

(da) dialogue and coordination between the Commission, participating producers, countries and public health experts, including representatives of ECDC, EMA and the Emergency Task Force, shall be guaranteed, when necessary, at all stages of the public procurement procedure in order to ensure that there is clarity and transparency as regards the procurement procedure, timelines and the commitments made by all sides;

Amendment 41

Proposal for a regulation
Article 12 – paragraph 2 a (new)

Text proposed by the Commission

2a. The Commission and the other contracting parties involved in the joint procurement shall carry out the joint procurement in a transparent, timely and effective way, including when agreeing upon the process, scope, timelines, details regarding supply chains, production and delivery of procured medical countermeasures, tender specifications, disclosure of the exact amount provided to each participating country, the detailed practical arrangements for the evaluation of the requests for participation or of the tenders, the award of the contract, details of the liability of participating countries, the law applicable to the contract, and the competent court for hearing disputes, while defining clear steps from the beginning of the procedure.
Amendment 42
Proposal for a regulation
Article 12 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2b. Joint public procurement procedures shall include accessible, transparent, qualitative and non-discriminatory technical specifications and selection criteria, which shall be considered in the awards process for the joint procurement bids and comply with the following conditions:

Amendment 43
Proposal for a regulation
Article 12 – paragraph 2 b (new) – point a (new)

Text proposed by the Commission

Amendment

(a) highest safety and quality standards, as required by the relevant legislation;

Amendment 44
Proposal for a regulation
Article 12 – paragraph 2 b (new) – point b (new)

Text proposed by the Commission

Amendment

(b) the ability to ensure the security and capacity of supply of the medical countermeasure in question.

Amendment 45
Proposal for a regulation
Article 12 – paragraph 3

Text proposed by the Commission

Amendment

3. The Commission shall, in liaison

The Commission shall, in liaison
with the Member States, ensure coordination and information exchange between the entities organizing any action, including, but not limited to joint procurement procedures, stockpiling and donation of medical countermeasures under different mechanisms established at Union level, in particular under:

Amendment 46
Proposal for a regulation
Article 12 – paragraph 3 a (new)

*Text proposed by the Commission*

3a. Participating countries shall ensure that there is adequate stockpiling and distribution of procured medical countermeasures. The main details and characteristics of that stockpiling and distribution shall be set out in national plans.

Amendment 47
Proposal for a regulation
Article 12 – paragraph 3 b (new)

*Text proposed by the Commission*

3b. In accordance with the principle of transparency, the Commission shall regularly inform the European Parliament about negotiations concerning the joint procurement of medical countermeasures.

Amendment 48
Proposal for a regulation
Article 12 – paragraph 3 c (new)

Text proposed by the Commission

Amendment

3c. The European Parliament reserves at all times the right to scrutinize, under existing confidentiality rules, the uncensored content of all contracts concluded in proceedings under this Article.

Amendment 49

Proposal for a regulation

Article 12 – paragraph 3 d (new)

Text proposed by the Commission

Amendment

3d. The Commission and Member States shall provide up-to-date, accessible and clear information to consumers on their rights and duties regarding jointly procured medical countermeasures, including details on liability for damages, and access to legal protection and to consumer representation.

Amendment 50

Proposal for a regulation

Article 12 – paragraph 3 e (new)

Text proposed by the Commission

Amendment

3e. Where the joint procurement procedure for medical countermeasures to cross-border threats to health is not applied, the Commission shall encourage Member States to exchange information on pricing and delivery dates for medical countermeasures.

Amendment 51

Proposal for a regulation
Article 14 – paragraph 2 – point b

Text proposed by the Commission

(b) allow for the computerised handling and exchange of information, data and documents.

Amendment

(b) allow for the computerised processing and exchange of information, data and documents, taking into account Union law concerning the protection of personal data.

Amendment 52

Proposal for a regulation
Article 14 – paragraph 3

Text proposed by the Commission

3. Member States are responsible for ensuring that the integrated surveillance system is fed on a regular basis with timely and complete information, data and documents transmitted and exchanged through the digital platform.

Amendment

3. Member States are responsible for ensuring that the integrated surveillance system is fed on a regular basis with timely, complete and accurate information, data and documents transmitted and exchanged through the digital platform.

Amendment 53

Proposal for a regulation
Article 21 – paragraph 1 – point b

Text proposed by the Commission

(b) risk and crisis communication, to be adapted to Member State needs and circumstances, aimed at providing consistent and coordinated information in the Union to the public and to healthcare professionals;

Amendment

(b) risk and crisis communication, to be adapted to Member State needs and circumstances, aimed at providing consistent and coordinated information in the Union to the public and to healthcare and when appropriate to other public health professionals such as veterinarians;

Amendment 54

Proposal for a regulation
Article 22 – paragraph 2 – point c a (new)

Text proposed by the Commission

Amendment

(ca) take into account the need for an internal market that functions normally, in particular the existence of green lanes for free circulation of food and medical countermeasures.

Amendment 55

Proposal for a regulation

Article 25 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) activation of support from the ECDC as referred to in Regulation (EU) …/… [OJ: Please insert the number of Regulation ECDC [ISC/2020/12527]] to mobilise and deploy the EU Health Task Force and in particular the establishment of a list of accommodation facilities in intensive care units in the Member States for the purpose of potential cross-border relocation of patients;

Amendment 56

Proposal for a regulation

Article 25 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) green lanes referred to in Article 25a of this Regulation, in exceptional cases.

Amendment 57
Proposal for a regulation
Article 25 a (new)

Text proposed by the Commission

Amendment

Article 25a

Green lanes

1. After recognising a public health emergency for a pandemic situation under Article 23(1), the Commission shall, in the case of border restrictions, establish green lanes, to ensure that essential goods, medical countermeasures and cross border workers can move freely within the internal market.

2. The Commission is empowered to adopt delegated acts to supplement this Regulation with provisions on the establishment of the green lanes referred to in paragraph 1.

3. A Member State may only prohibit or restrict exports of medical countermeasures in cases defined in Article 36 TFEU during a public health emergency at Union level, on condition that it obtains prior authorisation from the Commission.

The Commission shall decide on the request for prior authorisation within five days of the request. If the Commission takes no decision within this period, the authorisation shall be deemed granted.

Amendment 58

Proposal for a regulation
Article 29 - paragraph 1

Text proposed by the Commission

Amendment

By 2025 and every 5 years thereafter the Commission shall carry out an evaluation of this Regulation and present a report on the main findings to the European
Parliament and the Council. The evaluation shall be conducted in accordance with the Commission’s better regulation guidelines. The evaluation shall include, in particular, an assessment of the operation of the EWRS and the epidemiological surveillance network, as well as the coordination of the response with the HSC. The evaluation shall include, in particular, an assessment of the operation of the EWRS and the epidemiological surveillance network, as well as the added-value of the joint public procurement procedure, as well as the coordination of the response with the HSC and the impact of the Regulation on the proper functioning of the single market when serious cross-border threats to health arise.
**PROCEDURE – COMMITTEE ASKED FOR OPINION**

<table>
<thead>
<tr>
<th>Title</th>
<th>Regulation on serious cross-border threats to health repealing Decision No 1082/2013/EU</th>
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<tbody>
<tr>
<td>Committee responsible</td>
<td>ENVI 14.12.2020</td>
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<td>Opinion by</td>
<td>IMCO 14.12.2020</td>
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<td>Rapporteur for the opinion</td>
<td>Rasmus Andresen 26.1.2021</td>
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<tr>
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<td>17.3.2021</td>
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<td>26.5.2021</td>
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| Result of final vote | +: 35  
                       : 2  
                       0: 8 |
| Members present for the final vote | Alex Agius Saliba, Andrus Ansip, Pablo Arias Echeverría, Alessandra Basso, Brando Benifei, Adam Bielan, Hynek Blaško, Vlad-Marius Botoş, Markus Buchheit, Andrea Caroppo, Anna Cavazzini, Dita Charanzová, Deirdre Clune, David Cormand, Carlo Fidanza, Evelyne Gebhardt, Sandro Gozi, Maria Grapini, Svenja Hahn, Virginie Joron, Eugen Jurzyca, Marcel Kolaja, Kateřina Konečná, Andrey Kovatchev, Jean-Lin Lacapelle, Maria-Manuel Leitão-Marques, Morten Lokkegaard, Adriana Maldonado López, Antonius Manders, Beata Mazurek, Leszek Miller, Anne-Sophie Pelletier, Miroslav Radačovský, Christel Schaldemose, Andreas Schwab, Tomislav Sokol, Ivan Štefaneč, Róża Thun und Hohenstein, Tom Vandenkendelaere |
| Substitutes present for the final vote | Rasmus Andresen, Marc Angel, Jordi Cañas, Maria da Graça Carvalho, Christian Doleschal, Claude Gruffat |
### FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

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<td>Alex Agius Saliba, Marc Angel, Brando Benifei, Evelyne Gebhardt, Maria Grapini, Maria-Manuel Leitão-Marques, Adriana Maldonado López, Leszek Miller, Christel Schaldemose</td>
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<td>Kateřina Konečná, Anne-Sophie Pelletier</td>
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<td>Verts/ALE</td>
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<td>Eugen Jurzyca</td>
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<td>Miroslav Radačovský</td>
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**Key to symbols:**
- + : in favour
- - : against
- 0 : abstention
## PROCEDURE – COMMITTEE RESPONSIBLE

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<th><strong>Title</strong></th>
<th>Regulation on serious cross-border threats to health repealing Decision No 1082/2013/EU</th>
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<td><strong>References</strong></td>
<td>COM(2020)0727 – C9-0367/2020 – 2020/0322(COD)</td>
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<td><strong>Date submitted to Parliament</strong></td>
<td>12.11.2020</td>
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<td>ENVI 14.12.2020</td>
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<td><strong>Rapporteurs</strong></td>
<td>Véronique Trillet-Lenoir 26.11.2020</td>
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<td>25.2.2021, 22.4.2021, 12.7.2021</td>
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<td>13.7.2021</td>
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<td>Manuel Bompard, Antoni Comín i Oliveres, Martin Häusling, Kateřina Konečná, Ulrike Müller</td>
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<td>22.7.2021</td>
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## FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

| 67  |   |  
|-----|---|---
| S&D | Marek Pawel Balt, Monika Beňová, Simona Bonaří, Delara Burkhardt, Sara Cerdas, Mohammed Chahim, Tudor Ciuhodaru, Cyrus Engerer, Jytte Guteland, Javi López, César Luena, Alessandra Moretti, Sándor Rónai, Günther Sidl, Petar Vitanov, Tiemo Wölken |   |
| Renew | Pascal Canfin, Martin Hojsík, Jan Huitema, Ulrike Müller, Frédérique Ries, María Soraya Rodríguez Ramos, Nicolae Ștefanuță, Linea Søgaard-Lidell, Nils Torvalds, Véronique Trillet-Lenoir, Emma Wiesner |   |
| Greens/ALE | Margreet Auken, Bas Eickhout, Eleonora Evi, Martin Häusling, Pär Holmgren, Yannick Jadot, Tilly Metz, Ville Niinistö, Grace O'Sullivan |   |
| ECR | Sergio Berlato, Pietro Fiocchi, Joanna Kopcińska, Giuseppe Milazzo, Alexandr Vondra, Anna Zalewska |   |
| The Left | Manuel Bompard, Anja Hazekamp, Petros Kokklalis, Kateřina Konečná |   |
| NI | Antoni Comín i Oliveres |   |

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