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)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tbody>
<tr>
<td><em>(1a)</em> 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.</td>
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**Amendment 2**

Proposal for a regulation
Recital 2

<table>
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<td><em>(2)</em> 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</td>
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<td><em>(2)</em> 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, 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,</td>
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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, and cooperation by Member States with the European Centre for Disease Prevention and Control (ECDC). Moreover, in order to ensure a promptly coordinated and 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 or animal origin. The capacity for contact tracing should be strengthened via the creation of an automated system, using modern technologies, without prejudice to the protection of personal data. Taking into account lessons learnt from the COVID-19 pandemic, the legal framework provided for in this Regulation should set the basis for ensuring that there is supply chain resilience as regards critical medicines.

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

(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  

(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 of and the degree to which access to medical countermeasures in the participating countries is equitable.

Proposal for a regulation
Recital 8 d (new)  

Text proposed by the Commission  

(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 medical countermeasures as strategic products.

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 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. The functioning of the Joint Procurement Agreement should abide by


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 9 b (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 9 c (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 9 d (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)

Text proposed by the Commission

(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)
(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

(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

(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

(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 in the field of export restrictions, through the prior authorisation mechanism.

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.

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

(17) Inconsistent communication with the public and stakeholders such as healthcare and public health professionals, **such as veterinarians, and failure to keep citizens informed** can have a negative impact on the effectiveness of the response from a public health perspective, **encourage the dissemination of false information but also negatively affect economic operators.** The coordination of
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

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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 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

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
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 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

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
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.\(^{18}\)


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

**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;
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

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.

Amendment 29
Proposal for a regulation
Article 4 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

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

Amendment 30
Proposal for a regulation
Article 4 – paragraph 2 – point d

Text proposed by the Commission

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. 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

Amendment

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

Amendment 32
Proposal for a regulation
Article 4 – paragraph 7 – subparagraph 1 a (new)

Text proposed by the Commission

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 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

Amendment

(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 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; 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, *adequate stock of personal protective equipment of the highest quality*;

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

*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
Parliament and of the Council\textsuperscript{29} with a view to the advance purchase of medical countermeasures for serious cross-border threats to health.


Amendment 37

Proposal for a regulation

Article 12 – paragraph 2 – point c

\textit{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;

\textit{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; \textit{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

(c) 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 39
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

Amendment

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 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 responding to a serious cross-border threat to health, including, but not limited to joint procurement procedures, development, stockpiling, distribution 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

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 47

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 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

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

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 52

Proposal for a regulation
Article 14 – paragraph 3

(b) allow for the computerised processing and exchange of information, data and documents, taking into account Union law concerning the protection of personal data.
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 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
(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
(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.
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 56

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

Text proposed by the Commission

(c) 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

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

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.

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, 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><strong>Title</strong></th>
<th>Regulation on serious cross-border threats to health repealing Decision No 1082/2013/EU</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>References</strong></td>
<td>COM(2020)0727 – C9-0367/2020 – 2020/0322(COD)</td>
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<tr>
<td><strong>Committee responsible</strong></td>
<td>ENVI 14.12.2020</td>
</tr>
<tr>
<td><strong>Opinion by</strong></td>
<td>IMCO 14.12.2020</td>
</tr>
<tr>
<td><strong>Rapporteur for the opinion</strong></td>
<td>Rasmus Andresen 26.1.2021</td>
</tr>
<tr>
<td><strong>Discussed in committee</strong></td>
<td>17.3.2021</td>
</tr>
<tr>
<td><strong>Date adopted</strong></td>
<td>26.5.2021</td>
</tr>
</tbody>
</table>
| **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 Benífei, Adam Bielan, Hynek Blaško, Vlad-Marius Botoș, Markus Buchheit, Andrea Caroppi, 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 Štefanec, 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

<p>| | |</p>
<table>
<thead>
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<tr>
<td><strong>35</strong></td>
<td><strong>+</strong></td>
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<tr>
<td>PPE</td>
<td>Pablo Arias Echeverría, Andrea Caroppo, Maria da Graça Carvalho, Deirdre Clune, Christian Doleschal, Andrey Kovatchev, Antonius Manders, Andreas Schwab, Tomislav Sokol, Ivan Štefanec, Róża Thun und Hohenstein, Tom Vandenkendelaere</td>
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<tr>
<td>Renew</td>
<td>Andrus Ansip, Vlad-Marius Botoş, Jordi Cañas, Dita Charanzová, Sandro Gozi, Svenja Hahn, Morten Løkkegaard</td>
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<tr>
<td>S&amp;D</td>
<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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<tr>
<td>The Left</td>
<td>Kateřina Konečná, Anne-Sophie Pelletier</td>
</tr>
<tr>
<td>Verts/ALE</td>
<td>Rasmus Andresen, Anna Cavazzini, David Cormand, Claude Gruffat, Marcel Kolaja</td>
</tr>
</tbody>
</table>

| **2** | **-** |
| ECR | Eugen Jurzyca |
| ID | Hynek Blaško |

| **8** | **0** |
| ECR | Adam Bielan, Carlo Fidanza, Beata Mazurek |
| ID | Alessandra Basso, Markus Buchheit, Virginie Joron, Jean-Lin Lacapelle |
| NI | Miroslav Radačovský |

**Key to symbols:**
- + : in favour
- - : against
- 0 : abstention