21.4.2021

AMENDMENTS
7 - 171

Draft opinion
Rasmus Andresen
(PE689.513v01-00)

Regulation on serious cross-border threats to health repealing Decision No 1082/2013/EU

Proposal for a regulation
(COM(2020)0727 – C9-0367/2020 – 2020/0322(COD))
Amendment 7
Tomislav Sokol, Romana Toms, Ivan Štefanec, Christian Doleschal
Proposal for a regulation
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 could be used to achieve. The aim is therefore to ensure that this Regulation makes the best possible use of the legal bases on health set out in the Treaty, in order to manifest the European Union’s strong health policy while preserving the normal functioning of the single market during serious cross-border threats to health.

Or. en

Amendment 8
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron, Alessandra Basso, Marco Campomenosi
Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission

(1a) Public health falls, as a matter of principle under the responsibility of the Member States, which are free to organise and deliver their health-care services in whatever manner they wish, as well as to procure medical devices, medicines, vaccines and health products, and to devise policies for cooperation and sharing of best practice, information and medical equipment, however they see fit.

Or. fr
(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.

Or. fr
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 origin. The capacity for contact tracing should be strengthened via the creation of an automated system, using modern technologies.

Amendment

(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 health and zoonotic 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 or animal origin. The capacity for contact tracing should be strengthened via the creation of an automated system, using modern technologies.

Or. en

Amendment 11
Maria Grapini

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.

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Further learning on the lessons from the COVID-19 pandemic, the legal framework should set the basis to ensure supply chain resilience of critical medicines.

Or. en

Amendment 13
Tomislav Sokol, Romana Tomc, Ivan Štefanec, Christian Doleschal, Dan-Ștefan Motreanu, Arba Kokalari

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 origin. The capacity for contact tracing should be strengthened via the creation of an automated system, using modern technologies. Further learning on the lessons from the COVID-19 pandemic, the legal framework should set the basis to ensure supply chain resilience of critical medicines.

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Amendment 14
Tomislav Sokol, Romana Tomc, Ivan Štefanec, Christian Doleschal, Dan-Ştefan Motreanu, Arba Kokalari
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

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(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 15
Kateřina Konečná

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.

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Amendment 16
Carlo Fidanza, Adam Bielan

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.

Or. en

Amendment 17
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron, Alessandra Basso, Marco Campomenosi

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

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Amendment 18
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

Proposal 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

Amendment

(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 knowledge and necessary skills 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 and reviews of the plans, corrective actions should be implemented and the Commission should be kept informed of all updates.

Or. fr

Amendment 19
Kateřina Konečná

Proposal 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

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Amendment 20
Kateřina Konečná

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)\(^1\)\(^5\). 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 national preparedness and response plans are adequate. In order to support the

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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.

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

Amendment 21
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

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)\(^\text{15}\). In turn, the

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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 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.

International Health Regulation (IHR, 2005),
https://www.who.int/ihr/publications/9789241596664/en/

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 there is consistency between national preparedness and response plans. 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.

International Health Regulation (IHR, 2005),
https://www.who.int/ihr/publications/9789241596664/en/

Or. fr

Amendment 22
Tomislav Sokol, Romana Tomec, Ivan Štefanec, Christian Doleschal

Proposal for a regulation
Recital 8

Text proposed by the Commission

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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)15. 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 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.

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

Amendment 23
Adriana Maldonado López, Maria-Manuel Leitão-Marques, Biljana Borzan, Marc Angel, Evelyne Gebhardt, Andreas Schieder, Maria Grapini, Leszek Miller, Brando Benifei, Clara Aguilera
Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission

(8a) In light of the lessons learnt during the ongoing COVID-19 pandemic, this Regulation should create a more robust framework for coordination at Union level. The shift for procurement of PPE, medical equipment and vaccines (under rescEU, the Joint Procurement Agreement (JPA) and the EU Emergency Support Initiative (ESI)) from national to European level has been effective and beneficial to citizens. It avoids competition between Member States and guarantees a secure, fair, equitable and affordable access to medical countermeasures. Therefore, joint procurement procedures should be applied by default for medical countermeasures to cross border threats to health.

Amendment 24
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron, Alessandra Basso, Marco Campomenosi

Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission

(8a) This regulation should draw on lessons learned from the COVID-19 pandemic to assess whether an EU coordination mandate is needed, particularly in view of the difficulties encountered in the European Commission’s negotiation of contracts for centralised procurement of vaccines as when as during their delivery. Such lessons should lead to the incorporation into negotiating mandates of provisions
on negotiators’ qualifications, terms and conditions and deadlines for delivery, as well as the benefits or sanctions applicable in the event of diligence or default.

Amendment 25
Jordi Cañas, Liesje Schreinemacher, Sandro Gozi, Stéphanie Yon-Courtin, Vlad-Marius Botoş
Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission

Amendment

(8a) Building on lessons learnt from the COVID-19 pandemic, this Regulation should create a more robust mandate for coordination at Union level. The declaration by the WHO of a public health emergency, formally recognised at Union level, would bring about increased coordination and exceptionally allow for joint procurement procedures for the development, stockpiling, distribution and donation of medical countermeasures, to the most recommendable needs and where their purchase and supply cannot be ensured as efficiently by other means.

Amendment 26
Jordi Cañas, Liesje Schreinemacher, Sandro Gozi, Stéphanie Yon-Courtin, Vlad-Marius Botoş
Proposal for a regulation
Recital 8 b (new)

Text proposed by the Commission

Amendment

(8b) The primary purpose of joint procurement should be to improve the
preparedness and response to serious cross-border threats to health, and particularly to improve the security and capacity of supply of medical countermeasures in the participating countries throughout their existence, ensure equitable access to patients and provide increased visibility and predictability for actors involved.

Or. en

Amendment 27
Adriana Maldonado López, Maria-Manuel Leitão-Marques, Christel Schaldemose, Biljana Borzan, Marc Angel, Evelyne Gebhardt, Andreas Schieder, Maria Grapini, Leszek Miller, Brando Benifei, Clara Aguilera

Proposal for a regulation
Recital 8 b (new)

Text proposed by the Commission

(8b) To ensure resilience of the single market during future health emergency situations and in order to reduce the dependence on third countries, this Regulation should foster the creation of minimum European stocks of medical countermeasures as strategic products.

Or. en

Amendment 28
Adriana Maldonado López, Maria-Manuel Leitão-Marques, Biljana Borzan, Marc Angel, Evelyne Gebhardt, Andreas Schieder, Maria Grapini, Leszek Miller, Brando Benifei, Clara Aguilera

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. Transparency measures must be improved in order to guarantee rapid, equal, fair and affordable access to critical medical countermeasures as fast as possible whilst avoiding price speculation between Member States. In case that joint procurement procedures are not applied, a high level of transparency regarding pricing, reimbursement of different treatments, medical products marketing and health technology assessment needs to be guaranteed, to allow Member States equal conditions when negotiating with pharmaceutical companies.

16 Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil


Amendment 29
Adam Bielan, Carlo Fidanza

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\(^16\).

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Amendment 30
Jordi Cañas, Liesje Schreinemacher, Sandro Gozi, Stéphanie Yon-Courtin, Vlad-Marius Botoş

Proposal for a regulation
Recital 9

Text proposed by the Commission

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European Parliament and of the Council\textsuperscript{16}.


Or. en

Amendment 31
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

Proposal for a regulation
Recital 9

\textit{Text proposed by the Commission}

(9) \textit{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 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. This exclusivity clause should nevertheless ensure that Member States who wish to be able to negotiate other contracts with different suppliers are free to do, so to be insulated from the eventuality of lateness or other failure affecting the joint procedure. 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

\textit{Amendment}

(9) \textit{The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU, should 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. This exclusivity clause should nevertheless ensure that Member States who wish to be able to negotiate other contracts with different suppliers are free to do, so to be insulated from the eventuality of lateness or other failure affecting the joint procedure. 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}
Decision No 1313/2013/EU of the European Parliament and of the Council\textsuperscript{16}.


Amendment 32
Carlo Fidanza, Nicola Procaccini, Raffaele Stancanelli, Pietro Fiocchi, Sergio Berlato, Vincenzo Sofo

Proposal for a regulation
Recital 9

\textit{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\textsuperscript{16}.

\textit{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 EU. The Commission should ensure coordination and information exchange between the entities organizing \textit{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
European Parliament and of the Council\textsuperscript{16}.


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Amendment 33
Tomislav Sokol, Romana Tomc, Ivan Štefanec, Christian Doleschal, Dan-Ştefan Motreau, Arba Kokalari

Proposal for a regulation
Recital 9

\textit{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

\textit{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 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
The European Commission shall pay special attention to ensure that joint procurement of medical countermeasures within the meaning of Article 12, also includes procurement of orphan drugs.

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Amendment 34
Jordi Cañas, Liesje Schreinemacher, Sandro Gozi, Stéphanie Yon-Courtin, Vlad-Marius Botoș
Proposal for a regulation
Recital 9 a (new)

Text proposed by the Commission

(9a) The Joint procurement should be carried in a transparent, timely and effective way to prevent market disruption and to ensure actors involved fulfil their contractual responsibilities. In this respect, it is crucial to define clear and transparent steps since the beginning of the procedure in terms of process, scope, tender specifications, timelines and formalities. A preliminary consultation phase involving participating actors should be guaranteed, as well as a clear and mutual communication throughout the whole procedure.

Amendment

Or. en

Amendment 35
Jean-Lin Lacapelle, Virginie Joron
Proposal for a regulation
Recital 9 a (new)

Text proposed by the Commission

(9a) As the purpose of joint procurement was to ensure the swift provision of medical countermeasures to EU Member States in a highly competitive market, participation in this mechanism should be restricted to EU Member States only, as otherwise demand would outstrip supply and place too great a strain on suppliers’ capacity to cover orders.

Or. fr

Amendment 36
Adam Bielan, Carlo Fidanza

Proposal for a regulation
Recital 9 a (new)

Text proposed by the Commission

(9a) The joint procurement procedure should first and foremost foster cooperation and solidarity between the Member States during a serious health crisis, strengthen their negotiating position and allow for a preferable purchasing conditions, concerning the quantity, price or availability of a procured medical countermeasure.

Or. en

Amendment 37
Tomislav Sokol, Romana Tomec, Ivan Štefanec, Christian Doleschal, Dan-Ștefan Motreanu, Arba Kokalari

Proposal for a regulation
Recital 9 a (new)
(9a) In order to achieve transparency, the Commission shall provide to the European Parliament complete, timely and accurate information on the ongoing negotiations and give an access to the tender documents for the purposes of carrying out the procedure referred to in Article 12 of this Regulation.

Amendment 38
Carlo Fidanza, Nicola Procaccini, Raffaele Stancanelli, Sergio Berlato, Pietro Fiocchi, Vincenzo Sofo, Adam Bielan
Proposal for a regulation
Recital 9 a (new)

(9a) The primary purpose of joint procurement should be to guarantee stability in an unpredictable environment in the context of a cross-border health crisis only, ensuring equitable access for patients and increased visibility and predictability for actors involved.

Amendment 39
Adriana Maldonado López, Maria-Manuel Leitão-Marques, Biljana Borzan, Marc Angel, Evelyne Gebhardt, Andreas Schieder, Maria Grapini, Leszek Miller, Brando Benifei, Clara Aguilera
Proposal for a regulation
Recital 9 a (new)

(9a) In order to ensure a fair and equal procedure and access for all European
citizens, the European Parliament shall scrutinize contracts concluded under the Joint Procurement Procedure.

Or. en

Amendment 40
Adam Bielan

Proposal for a regulation
Recital 9 b (new)

Text proposed by the Commission

(9b) Since one of the primary responsibility of the Member States is to ensure the protection of their citizens, additional flexibility is needed when it comes to being able to adjust contractual provisions after the initial contract has been established, in order to increase, decrease or cancel the order for the medical countermeasures. In order to protect the contractors, directly engaged in activities that serve Union policies, such contractual adjustments should be duly justified by the national authorities participating in the joint procurement procedure, by explaining the seriousness or urgency of the circumstances in question and such adjustments should be enforced in close cooperation with contracted partners and taking due account of the commitments made up to date of contractual adjustment.

Or. en

Amendment 41
Jordi Cañas, Sandro Gozi, Stéphanie Yon-Courtin, Vlad-Marius Botoş

Proposal for a regulation
Recital 9 b (new)
Text proposed by the Commission

(9b) The functioning of the Joint Procurement Agreement and rescEU should abide by high standards of transparency, provided it does not jeopardize the negotiation and compliance of purchase agreements, including in relation to the disclosure of the exact amount provided to each participating country, details regarding supply chains, production and delivery of procured products, and details of the liability of participating countries, as well as information on the existence of no-fault compensation systems in those participating countries.

Or. en

Amendment 42
Carlo Fidanza, Nicola Procaccini, Raffaele Stancanelli, Sergio Berlato, Pietro Fiocchi, Vincenzo Sofo, Adam Bielan

Proposal for a regulation
Recital 9 b (new)

Text proposed by the Commission

(9b) The Joint procurement shall be carried in a transparent, timely and effective way to prevent market disruption and to ensure actors involved can fulfil their contractual responsibilities. In this respect, it is crucial to define clear and transparent steps since the beginning of the procedure in terms of process, scope, tender specifications, timelines and formalities. A preliminary consultation phase involving participating actors shall be guaranteed, as well as a two-way communication throughout the whole procedure.

Or. en
Amendment 43  
Jean-Lin Lacapelle, Virginie Joron 

Proposal for a regulation  
Recital 9 b (new) 

*Text proposed by the Commission*

**Amendment**

(9b) For the same reason, the joint ordering of medical countermeasures by the European Union should be reserved for the priority use of the Member States participating in this mechanism, in preference over those not taking part, and should rule out any redistribution outside the European Union.

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Amendment 44  
Adam Bielan, Carlo Fidanza 

Proposal for a regulation  
Recital 9 c (new) 

*Text proposed by the Commission*

**Amendment**

(9c) The COVID-19 pandemic has exposed the limited diversity of suppliers and an 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 the administrative burdens in order to boost the involvement of SMEs in the process.

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Amendment 45
Jordi Cañas, Liesje Schreinemacher, Sandro Gozi, Stéphanie Yon-Courtin, Vlad-Marius Botoş

Proposal for a regulation
Recital 9 c (new)

Text proposed by the Commission

(9c) During the existence of a cross-border health threat situation, manufacturing is often needed rapidly and with short notice. It is therefore crucial that the joint procurement lead times are aligned and coherent with manufacturers’ lead times to ensure clarity and expectations from both organizing and participating entities.

Amendment

Or. en

Amendment 46
Carlo Fidanza, Nicola Procaccini, Raffaele Stancanelli, Pietro Fiocchi, Vincenzo Sofo

Proposal for a regulation
Recital 9 c (new)

Text proposed by the Commission

(9c) During a health crisis situation, manufacturing is often needed rapidly and with short notice. It is therefore crucial that the joint procurement lead times are aligned and coherent with manufacturers’ lead times to ensure clarity and expectations from both organizing and participating entities.

Amendment

Or. en

Amendment 47
Jordi Cañas, Liesje Schreinemacher, Sandro Gozi, Stéphanie Yon-Courtin, Vlad-Marius Botoş
Proposal for a regulation
Recital 9 d (new)

Text proposed by the Commission

Amendment

(9d) In order for this regulation to fulfil its main objectives, mainly to ensure a rapid response in the case of serious cross-border health threats, a priority conditionality binding the undertaking of the joint procurement procedures should be provided for, in order to ensure that the delivery and scheduled commitments to the participating countries are respected under all circumstances.

Or. en

Amendment 48
Carlo Fidanza, Nicola Procaccini, Raffaele Stancanelli, Pietro Fiocchi, Vincenzo Sofo

Proposal for a regulation
Recital 9 d (new)

Text proposed by the Commission

Amendment

(9d) Regulatory flexibility should be considered and allowed to ensure faster supply to the markets, for example by accepting each other Marketing Authorizations in case of emergencies.

Or. en

Amendment 49
Carlo Fidanza, Nicola Procaccini, Raffaele Stancanelli, Sergio Berlato, Pietro Fiocchi, Vincenzo Sofo

Proposal for a regulation
Recital 9 e (new)

Text proposed by the Commission

Amendment

(9e) Joint procurement implies shared responsibilities and a fair approach with
rights and obligations for all parties involved, relevant authorities and manufacturers. In this respect, commitments should be defined since the beginning and respected, from the manufacturers to deliver on the production, and from the authorities to purchase their agreed reserved volumes. This is also important to avoid waste of medicinal products.

Amendment 50
Jordi Cañas, Liesje Schreinemacher, Vlad-Marius Botoş

Proposal for a regulation
Recital 9e (new)

Text proposed by the Commission
(9e) In addition, suitable regulatory flexibilities should be considered and allowed by Member States’ authorities in the framework of joint procurement procedures and including, where relevant, for marketing authorisations, to ensure faster and timely supply in the European Single Market.

Amendment

Amendment 51
Jordi Cañas, Sandro Gozi, Stéphanie Yon-Courtin, Vlad-Marius Botoş

Proposal for a regulation
Recital 9f (new)

Text proposed by the Commission
(9f) Joint procurement implies shared responsibilities and a fair approach with rights and obligations for all parties involved, relevant authorities and manufacturers. In this respect,
commitments should be defined since the beginning and respected, from the manufacturers to deliver on the production, and from the authorities to purchase their agreed reserved volumes.

Amendment 52
Carlo Fidanza, Nicola Procaccini, Raffaele Stancanelli, Sergio Berlato, Pietro Fiocchi, Vincenzo Sofo

Proposal for a regulation
Recital 9 f (new)

Text proposed by the Commission

Amendment

(9f) If used, in order for joint procurement to be sustainable, it is crucial to define criteria beyond the price/cost only to be considered in the awarding process. Such criteria should take into consideration for instance the ability of the bidder to ensure security of supply in a health crisis situation.

Or. en

Amendment 53
Jordi Cañas, Liesje Schreinemacher, Vlad-Marius Botoş

Proposal for a regulation
Recital 9 g (new)

Text proposed by the Commission

Amendment

(9g) If used, in order for joint procurement to be sustainable, the Commission should ensure accessible, transparent, proportionate and non-discriminatory technical specifications, selection and award criteria by placing a significant and priority value and consideration on the highest safety and quality standards of the medical
countermeasures, in accordance with the applicable legislation, and beyond the price and costs of those. Such criteria should also include the ability of the bidder to ensure security and capacity of supply in a 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 small and medium-sized enterprises in the awarding process.

Amendment 54
Jordi Cañas, Sandro Gozi, Stéphanie Yon-Courtin, Vlad-Marius Botoş

Proposal for a regulation
Recital 9 h (new)

Text proposed by the Commission

(9h) To facilitate the negotiation of joint procurement procedures, Member States should establish no-fault compensation systems which should be used in the event of a cross-border health threat declared by the EU, allowing citizens who may suffer an adverse reaction to a particular medical countermeasure, subject to a joint procurement procedure, to receive fair compensation by proving solely the causal link between the medical countermeasure in question and the damages caused. These possible damages should not be borne individually by each injured person, but should be considered as a social burden shared by society as a whole. Therefore, equal access to fair compensation through no-fault compensation schemes should be provided.

Amendment
Amendment 55  
Kateřina Konečná

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 **Tripartite (WHO, OIE, FAO)** to improve the prevention of communicable diseases, such as vaccine preventable diseases, as well as other health issues, such as antimicrobial resistance.

Or. en

Amendment 56  
Carlo Fidanza, Adam Bielan

Proposal for a regulation
Recital 13 a (new)

*Text proposed by the Commission*

(13a) Regular two-way communication and exchange of information between authorities, industry and relevant entities of the pharmaceutical supply chain should be encouraged to facilitate preliminary dialogue concerning foreseeable serious cross-border threats to health in the market by way of sharing information on the expected supply constraints, allowing better coordination, synergies and robust reaction if needed.

*Amendment*

(13a) Regular two-way communication and exchange of information between authorities, industry and relevant entities of the pharmaceutical supply chain should be encouraged to facilitate preliminary dialogue concerning foreseeable serious cross-border threats to health in the market by way of sharing information on the expected supply constraints, allowing better coordination, synergies and robust reaction if needed.

Or. en

Amendment 57  
Tomislav Sokol, Romana Tomec, Ivan Štefanec, Christian Doleschal, Dan-Ștefan
Motreanu, Arba Kokalari

Proposal for a regulation
Recital 14 a (new)

Text proposed by the Commission

(14a) This Regulation ensures coordinated action at European Union’s level, in order to avoid the closure of internal borders and the paralysis of the internal market, which could threaten the circulation of basic supplies, including medicines, medical products and personal protective equipment (PPE). It is therefore necessary to ensure the correct implementation of European law in the field of export restrictions through a permanent notification mechanism.

Amendment

Or. en

Amendment 58
Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel, Evelyne Gebhardt, Andreas Schieder, Maria Grapini, Leszek Miller, Brando Benifei, Clara Aguilera

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

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, fair, equitable and affordable access to medical countermeasures across Europe. The measures taken at national level shall be proportionate and limited to public health risks related to serious cross-
Union such as those related to free movement of persons, goods and services.

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 59
Tomislav Sokol, Romana Tomec, Ivan Štefanec, Christian Doleschal, Dan-Ștefan Motreanu, Arba Kokalari

Proposal for a regulation
Recital 15 a (new)

Text proposed by the Commission

Amendment

(15a) The European Commission shall 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 60
Kateřina Konečná

Proposal for a regulation
Recital 17

Text proposed by the Commission

Amendment

(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\textsuperscript{17}.


\textit{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 \textit{as well as on} economic operators. The coordination of the response within the HSC, assisted by relevant subgroups,

\textit{Amendment}

(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, \textit{encourage the dissemination of false information but also negatively affect} economic operators. The coordination of

\textit{Amendment 61}

\textbf{Tomislav Sokol, Romana Tomc, Ivan Štefanec, Christian Doleschal, Dan-Ştefan Motreanu, Arba Kokalari}

\textbf{Proposal for a regulation}

\textbf{Recital 17}

\textit{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 \textit{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 62**

**Maria Grapini**

**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

*Amendment*

(17) Inconsistent communication with the public and stakeholders such as healthcare professionals and failure to keep citizens informed 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,
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\textsuperscript{17}.


Amendment 63
Adriana Maldonado López, Maria-Manuel Leitão-Marques, Christel Schaldemose, Biljana Borzan, Marc Angel, Evelyne Gebhardt, Andreas Schieder, Maria Grapini, Leszek Miller, Brando Benifei, Clara Aguilera

Proposal for a regulation
Recital 18

\textit{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

\textit{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 \textit{through the creation of a new mechanism that increases the coordination and}
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’.

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 ECDC, of the EMA, and of other Union bodies or agencies as observers, and of the European Parliament. 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 64
Carlo Fidanza, Adam Bielan

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

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.
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’. 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 65
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron, Alessandra Basso

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

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, 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’.

In accordance with the limits set by the Treaties, none of these mechanisms should be binding on Member States, but they should make it easier for the Union and the Member States to coordinate and adopt measures at the European level.

Amendment 66
Tomislav Sokol, Romana Tomc, Ivan Štefanec, Christian Doleschal, Dan-Ştefan Motreanu, Arba Kokalari

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

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. 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. 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.


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 68
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

Proposal for a regulation
Recital 23

Text proposed by the Commission

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

Amendment

(23) Since the objectives of this text apply only to voluntary cooperation by the Member States and to organisation at the level of the Union institutions, bodies and offices and agencies alone, issuing a regulation is not the right way to achieve them in a meaningful manner. In accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union, it is preferable, since the repealed text is a decision, to replace it with another decision or a directive.
Amendment 69
Kateřina Konečná

Proposal for a regulation
Recital 24 a (new)

Text proposed by the Commission

Amendment

(24a) National authorities should where appropriate consult and involve in the implementation of this regulation representative national social partners in the healthcare and social services sector.

Or. en

Justification

Trade unions and employers play an important role in implementation of the preparedness plans.

Amendment 70
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

Proposal for a regulation
Recital 25

Text proposed by the Commission

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 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. These definitions apply only within the above-mentioned European-level framework and shall not replace the national-level definitions used by the Member States.

Amendment 71
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

Proposal for a regulation
Recital 26

Text proposed by the Commission

(26) Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council. As the implementing acts provided for by this Regulation concern the protection of human health, the Commission may not adopt a draft implementing act where the Committee on serious cross-border threats to health delivers no opinion, in accordance with point (a) of the second subparagraph of Article 5(4) of Regulation (EU) No

Amendment 72
Kateřina Konečná
Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission

(26a) The recommendations of the World Health Organisation’s High Level Expert Group on Health Employment and Economic Growth (2016)\(^1\) to address workforce shortages shall be integrated in the preparedness plans to ensure adequate and needs-oriented staffing level.

\(^{1}\) https://www.who.int/hrh/comeheeg/reports/report-expert-group/en/

Justification

One of the most important part of preparation should be to ensure adequate and needs-oriented level of health and social service personnel.

Amendment 73
Kateřina Konečná
Proposal for a regulation
Recital 26 b (new)

Text proposed by the Commission

(26b) The COVID 19 health crisis has shown that neither the joint procurement of medical countermeasures or Union’s funding for research of them have proved to be a sufficient solution to tackle the public health emergency. In the event that a public health emergency is declared at Union level and instruments under this regulation, such as joint procurement of medical countermeasures, will prove that are not sufficient to address the health crisis, the Commission should in the future have the power to grant so-called compulsory licenses on patents on these medicines, vaccines and medical devices to European manufactures to enhance Union production capacity. The Commission and the Member States should consider possible delegation of power to grant compulsory licenses to Commission in the next revision of this Regulation.

Or. en

Amendment 74
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

Proposal for a regulation
Recital 27

Text proposed by the Commission

(27) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the severity or novelty of a serious cross-border threat to health or to the rapidity of its spread between the Member States imperative grounds of urgency so require.

deleted

Or. fr
Amendment 75  
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron  
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 Commission should also be able to propose decisions or recommendations 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 201621. In particular, to ensure equal participation in the preparation of these 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 these acts.

Amendment 76  
Adriana Maldonado López, Maria-Manuel Leitão-Marques, Biljana Borzan, Evelyne Gebhardt, Andreas Schieder, Maria Grapini, Leszek Miller, Brando Benifei, Clara Aguilera

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;

Or. en

Amendment 77
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

Proposal for a regulation
Article 2 – paragraph 1 – point c

Text proposed by the Commission
(c) threats of environmental or climate origin;

Amendment
deleted

Or. fr

Amendment 78
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

Proposal for a regulation
Article 2 – paragraph 1 – point d

Text proposed by the Commission
(d) threats of unknown origin;

Amendment
deleted

Or. fr

Amendment 79
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

Proposal for a regulation
Article 2 – paragraph 6
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.

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. They shall also have the right not to comply with the Commission's decisions, recommendations and guidelines.

Or. fr

Amendment 80
Adriana Maldonado López, Biljana Borzan, Evelyne Gebhardt, Andreas Schieder, Maria Grapini, Leszek Miller, Brando Benifei, Clara Aguilera

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;

Or. en

Justification

Individual national healthcare systems are as well often not able to afford expensive new breakthrough medicines to treat for example antibiotic-resistances, rare and chronic diseases. EU joint procurement avoids Member States competing against each other and secures equitable access to important medical countermeasures for citizens.
Amendment 81  
Tomislav Sokol, Romana Tomc, Ivan Štefanec, Christian Doleschal, Dan-Ştefan Motreanu  

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

Text proposed by the Commission  

Amendment  

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Amendment 82  
Tomislav Sokol, Romana Tomc, Ivan Štefanec, Christian Doleschal, Dan-Ştefan Motreanu, Arba Kokalari, Tom Vandenkenendelaere  

Proposal for a regulation  
Article 3 – paragraph 1 – point 8 a (new)
Text proposed by the Commission

(8a) ‘green lines’ means passable and safe passage transit corridors that in case of declared public health emergency at Union level allows Member States to preserve the free circulation of essential goods and medical countermeasures.

Or. en

Amendment 83
Tomislav Sokol, Romana Tomc, Ivan Štefanec, Christian Doleschal, Dan-Ștefan Motreanu, Arba Kokalari

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:

Or. en

Amendment 84
Tomislav Sokol, Romana Tomc, Ivan Štefanec, Christian Doleschal, Dan-Ștefan Motreanu, Arba Kokalari, Tom Vandenkendelaere

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 85
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

Proposal for a regulation
Article 4 – paragraph 3 – introductory part

Text proposed by the Commission

Amendment

3. As far as possible, the group shall adopt its guidance or opinions by consensus.

3. As far as possible, the group shall adopt its guidance or opinions by consensus. These decisions shall not be binding.

Amendment 86
Tomislav Sokol, Romana Tomec, Ivan Štefanec, Christian Doleschal, Dan-Ștefan Motreanu, Arba Kokalari

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

Text proposed by the Commission

Amendment

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

Amendment 87
Kateřina Konečná

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

Text proposed by the Commission

Amendment

Recognised European social partners in the relevant EU sectoral social dialogue committees in the health and social
services shall have an 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 88
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

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

Text proposed by the Commission  Amendment
(e) the risk and crisis communication; deleted

Or. fr

Amendment 89
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

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

Text proposed by the Commission  Amendment
(f) the health preparedness and deleted response and intersectoral collaboration;

Or. fr

Amendment 90
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

Proposal for a regulation
Article 5 – paragraph 3 – point g
(g) the management of the plan. deleted

Amendment 91
Kateřina Konečná
Proposal for a regulation
Article 5 – paragraph 3 – point g a (new)

Text proposed by the Commission
Amendment
(ga) adequate and needs-oriented staffing level;

Or. en

Amendment 92
Kateřina Konečná
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;

Or. en

Amendment 93
Kateřina Konečná
Proposal for a regulation
Article 5 – paragraph 3 – point g c (new)

Text proposed by the Commission
Amendment
(gc) monitoring if adequate risk
assessments, preparedness plans and trainings are foreseen for the health and social care at the work place level;

Amendment 94
Kateřina Konečná

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

Text proposed by the Commission  
Amendment

(gd) inclusiveness of the national health systems to ensure equal access to health and social services and to allow for quality treatments without a delay

Justification

Response plans should include information about the adequate, needs-oriented staffing level, safety protection for healthcare personnel and as well as the resources to ensure more equal access to health services. It is crucial that there is a monitoring if risk assessments are carried out at workplaces and each relevant workplace has its preparedness plan. It has been in social care that the necessary risk assessments were not carried out, preparedness plans were not ready, PPEs were not available, and training was not provided sufficiently in time.

Amendment 95
Tomislav Sokol, Romana Tomec, Ivan Štefanec, Christian Doleschal, Dan-Ștefan Motreanu, Arba Kokalari, Tom Vandenkendelaere

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

Text proposed by the Commission  
Amendment

4a. The Union preparedness and response plan also provides for measures to ensure the normal functioning of the single market during serious cross-border threat to health.
Amendment 96
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

Proposal for a regulation
Article 6 – paragraph 1

Text proposed by the Commission

1. When preparing national preparedness and response plans each Member State shall coordinate with the Commission in order to reach consistency with the Union preparedness and response plan, also inform without delay the Commission and the HSC of any substantial revision of the national plan.

Amendment

1. When preparing national preparedness and response plans each Member State shall inform the Commission and the HSC in order to ensure that the Union preparedness and response plan is kept suitably up to date.

Or. fr

Amendment 97
Kateřina Konečná

Proposal for a regulation
Article 6 – paragraph 1

Text proposed by the Commission

1. When preparing national preparedness and response plans each Member State shall coordinate with the Commission in order to reach consistency with the Union preparedness and response plan, also inform without delay the Commission and the HSC of any substantial revision of the national plan.

Amendment

1. When preparing national preparedness and response plans each Member State shall consult national social partners and coordinate with the Commission in order to reach consistency with the Union preparedness and response plan, also inform without delay the Commission and the HSC of any substantial revision of the national plan.

Or. en

Amendment 98
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron
Proposal for a regulation
Article 7

Text proposed by the Commission

Amendment

[...] deleted

Or. fr

Amendment 99
Kateřina Konečná

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

Text proposed by the Commission

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;

(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;

Or. en

Amendment 100
Tomislav Sokol, Romana Tomc, Ivan Štefanec, Christian Doleschal

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

Text proposed by the Commission

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;

(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;
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;

management; access to diagnostic services during emergencies; basic and safe health and emergency services; risk communications; research development and evaluations to inform and accelerate emergency preparedness;

Or. en

Amendment 101
Kateřina Konečná

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

Amendment

(iii) resources: including financial resources for emergency preparedness and contingency funding for response; logistics mechanisms and essential supplies for health; and adequate needs-oriented number of dedicated, trained and equipped human resources for emergencies in the health and social services; and

Or. en

Amendment 102
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

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

Amendment

(iii) resources: including financial resources for emergency preparedness and contingency funding for response; logistics mechanisms, means of national production and essential supplies for health; and dedicated, trained and equipped human resources for emergencies; and

Or. fr
Amendment 103
Kateřina Konečná

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

Text proposed by the Commission  
(c) the consultation with social partners that has taken place to ensure risk assessments, preparedness plans and implementation are broadly shared and supported and in line with prevailing labour legislation and collective agreements;

Or. en

Amendment 104
Maria Grapini

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

Text proposed by the Commission  
Based on the report, the Commission shall, in a timely manner, initiate discussion in the HSC to discuss progress and gaps in preparedness.

Amendment
Based on the report, the Commission shall, in a timely manner, initiate discussion in the HSC to discuss progress and gaps in preparedness and propose specific measures and actions to close existing gaps and prepare more effectively for future developments.

Or. ro

Amendment 105
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron, Alessandra Basso, Marco Campomenosi

Proposal for a regulation
Article 8 – paragraph 2
2. Member States shall present an action plan addressing the proposed recommendations of the audit and the corresponding corrective actions and milestones.

These actions may, in particular, include:

(a) review/adjustment of the legislation, if necessary;
(b) training initiatives;
(c) overview reports of audits series, which present cases of good practice.

Or. fr

Amendment 106
Kateřina Konečná

Proposal for a regulation
Article 8 – paragraph 2 – subparagraph 1 – point b

Text proposed by the Commission

(b) training initiatives;

(b) initiatives in relation to recruitment and retention of healthcare personnel and training initiatives;

Or. en

Amendment 107
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

Proposal for a regulation
Article 10 – paragraph 1 – introductory part

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

Amendment

1. The Commission and the Member States that wish to do so may, in complement to HSC’s monitoring role, work together within it to coordinate their
the monitoring, early warning and assessment of, and response to serious cross-border threats to health.

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 108**

Kateřina Konečná

**Proposal for a regulation**

**Article 11 – paragraph 1 – introductory part**

*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 for healthcare and social service staff and public health staff in the Member States, including preparedness capacities under the International Health Regulations.

**Or. en**

**Amendment 109**

Kateřina Konečná

**Proposal for a regulation**

**Article 11 – paragraph 1 – subparagraph 1**

*Text proposed by the Commission*

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

*Amendment*

The Commission shall organise those activities in cooperation with the Member States concerned. *The Commission will consult the relevant European social partners for the health and social care sector on the training activities.*

**Or. en**

**Amendment 110**

Jordi Cañas, Liesje Schreinemacher, Vlad-Marius Botoș
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 Council29 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 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 Council29 with a view to the advance purchase of medical countermeasures for the purpose of preparedness and response to serious cross-border threats to health only.


Amendment 111
Adriana Maldonado López, Maria-Manuel Leitão-Marques, Biljana Borzan, Marc Angel, Evelyne Gebhard, Andreas Schieder, Maria Grapini, Leszek Miller, Brando Benifei, Clara Aguilera

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

Amendment

1. With a view to the advance purchase of medical countermeasures for serious cross-border threats to health, joint procurement procedures conducted
pursuant to Article 165(2) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council 29 should be conducted by default.


Amendment 112
Jean-Lin Lacapelle, Virginie Joron

Proposal for a regulation
Article 12 – paragraph 1

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.

In this context, the Commission shall make use of the services of negotiators who can demonstrate practical expertise in contract logistics and public procurement, both public and private, in similar volumes and conditions. These negotiators shall be approved by the representatives of the participating...

Amendment 113
Jordi Cañas, Liesje Schreinemacher, Vlad-Marius Botoș

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

Text proposed by the Commission

Amendment

(-a) the joint procurement shall be time-limited to the existence of a serious cross-border threat to health and be used for the purchase and supply of each medical countermeasure to the most recommendable needs, as long as it cannot be ensured as efficiently by other means;

Or. en

Amendment 114
Jordi Cañas, Liesje Schreinemacher, Sandro Gozi, Stéphanie Yon-Courtin, Vlad-Marius Botoș

Proposal for a regulation
Article 12 – paragraph 2 – point -a a (new)
Text proposed by the Commission

Amendment

(-aa) the commitments and contractual obligations defined by the corresponding purchase agreement shall be respected by all parties involved;

Or. en

Amendment 115
Jordi Cañas, Liesje Schreinemacher, Sandro Gozi, Stéphanie Yon-Courtin, Vlad-Marius Botoș

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

Text proposed by the Commission

Amendment

(-ab) a priority conditionality binding the undertaking of the joint procurement procedures should be provided for, in order to ensure that the delivery and scheduled commitments to the participating countries are respected;

Or. en

Amendment 116
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

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

Text proposed by the Commission

Amendment

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

(a) participation in the joint procurement procedure is open to all Member States;

Or. fr
Amendment 117
Carlo Fidanza, Nicola Procaccini, Raffaele Stancanelli, Sergio Berlato, Pietro Fiocchi, Vincenzo Sofo

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

Text proposed by the Commission

Amendment

(aa) the purpose of joint procurement should be to guarantee stability in an unpredictable environment during a serious cross-border threat to health only. In other circumstances, other measures shall be privileged, such as procurement at national level;

Or. en

Amendment 118
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

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

Text proposed by the Commission

Amendment

(b) the rights and obligations of Member States, EFTA States and Union candidate countries not participating in the joint procurement shall be respected, in particular those relating to the protection and improvement of human health;

(b) the rights and obligations of Member States not participating in the joint procedure are respected, in particular those relating to the protection and improvement of human health;

Or. fr

Amendment 119
Carlo Fidanza, Nicola Procaccini, Raffaele Stancanelli, Sergio Berlato, Pietro Fiocchi, Vincenzo Sofo

Proposal for a regulation
Article 12 – paragraph 2 – point b a (new)
Text proposed by the Commission

Amendment

(ba) the joint procurement shall be carried in a transparent, timely and effective way defining clear steps since the beginning of the procedure in terms of process, scope, tender specifications, timeline and formalities. A preliminary consultation phase involving participating actors shall be guaranteed, as well as a two-way communication throughout the whole procedure;

Or. en

Amendment 120
Adriana Maldonado López, Maria-Manuel Leitão-Marques, Biljana Borzan, Marc Angel, Evelyne Gebhardt, Andreas Schieder, Maria Grapini, Leszek Miller, Brando Benifei, Clara Aguilera

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 only through that procedure and not through other channels, and shall not run parallel negotiation processes for that product; running parallel negotiation processes shall lead to an exclusion from the group of participating countries.

Or. en

Amendment 121
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

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 participating in a specific 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 122
Jordi Cañas, Sandro Gozi, Stéphanie Yon-Courtin, Vlad-Marius Botoş

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 shall lead to being excluded from the group of participating countries, without prejudice to participating countries from honouring existing contractual agreements, nor existing procurement procedures implemented by participating countries;

Or. en

Amendment 123
Carlo Fidanza, Nicola Procaccini, Raffaele Stancanelli, Sergio Berlato, Pietro Fiocchi, Vincenzo Sofo, Adam Bielan

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;

(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. In addition, joint procurement shall not exempt participating countries from honouring existing contractual agreements nor shall replace countries regular procurement processes;

Or. en

Amendment 124
Jordi Cañas, Liesje Schreinemacher, Sandro Gozi, Stéphanie Yon-Courtin, Vlad-Marius Botoş

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

Text proposed by the Commission

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

Amendment 125
Adriana Maldonado López, Maria-Manuel Leitão-Marques, Christel Schaldemose, Biljana Borzan, Marc Angel, Evelyne Gebhardt, Andreas Schieder, Maria Grapini, Leszek Miller, Brando Benifei, Clara Aguilera
Proposal for a regulation
Article 12 – paragraph 2 – point c a (new)

Text proposed by the Commission

Amendment

(ca) 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 fair, equitable and affordable, access to medical countermeasures against serious cross-border threats to health;

Or. en

Amendment 126
Carlo Fidanza, Nicola Procaccini, Raffaele Stancanelli, Pietro Fiocchi, Vincenzo Sofo

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

Text proposed by the Commission

Amendment

(ca) the joint procurement lead times shall be aligned with manufacturers lead times;

Or. en

Amendment 127
Carlo Fidanza, Nicola Procaccini, Raffaele Stancanelli, Sergio Berlato, Pietro Fiocchi, Vincenzo Sofo

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

Text proposed by the Commission

Amendment

(cb) commitments should be defined and respected by all parties involved from manufacturers, supply chain stakeholders and authorities;

Or. en
### Amendment 128
**Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron**

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(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;</td>
<td>(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. It shall enable, among other things, the negotiation and procurement by Member States of medical countermeasures from suppliers other than the specific supplier chosen for the joint procedure in which they are participants;</td>
</tr>
</tbody>
</table>

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### Amendment 129
**Jordi Cañas, Liesje Schreinemacher, Vlad-Marius Botoş**

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
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<tbody>
<tr>
<td>(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;</td>
<td>(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. The joint procurement shall not risk impacting supply flows negatively by increasing the risk of shortages in the EU;</td>
</tr>
</tbody>
</table>

---
Amendment 130
Carlo Fidanza, Nicola Procaccini, Raffaele Stancanelli, Pietro Fiocchi, Sergio Berlato, Vincenzo Sofo

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, nor replace existing procurement procedures implemented by participating countries;

Amendment 131
Jordi Cañas, Liesje Schreinemacher, Sandro Gozi, Stéphanie Yon-Courtin, Vlad-Marius Botoş

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

Text proposed by the Commission
(da) the joint procurement shall be carried in a transparent, timely and effective way defining clear steps since the start of the procedure in terms of process, scope, tender specifications, timelines and formalities;

Amendment

Or. en

Amendment 132
Carlo Fidanza, Nicola Procaccini, Raffaele Stancanelli, Pietro Fiocchi, Sergio Berlato, Vincenzo Sofo, Adam Bielan

Proposal for a regulation
Article 12 – paragraph 2 – point d a (new)
Text proposed by the Commission

Amendment

(da) qualitative criteria beyond the lowest price shall be defined and be considered in the awarding process of the joint procurement bids;

Or. en

Amendment 133
Jordi Cañas, Liesje Schreinemacher, Sandro Gozi, Stéphanie Yon-Courtin, Vlad-Marius Botoș

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

Text proposed by the Commission

Amendment

(db) the joint procurement lead times shall be aligned with manufacturers lead times;

Or. en

Amendment 134
Jordi Cañas, Liesje Schreinemacher, Sandro Gozi, Stéphanie Yon-Courtin, Vlad-Marius Botoș

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

Text proposed by the Commission

Amendment

(dc) a preliminary consultation phase involving participating actors shall be guaranteed, as well as a clear mutual communication throughout the whole procedure;

Or. en
### Amendment 135
Jordi Cañas, Liesje Schreinemacher, Vlad-Marius Botoș

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(dd) Member States’ authorities shall apply regulatory flexibilities, where relevant and with due regard to EMA’s guidance, to ensure the timely supply of medical countermeasures through joint procurement procedures during the existence of a cross-border health threat;</td>
<td>Or. en</td>
</tr>
</tbody>
</table>

### Amendment 136
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(e) the joint procurement shall not have any direct financial impact on the budget of Member States, <strong>EFTA States and Union candidate countries</strong> not participating in the joint procurement.</td>
<td>(e) the joint procurement shall not have any direct financial impact on the budget of Member States not participating in the joint procurement.</td>
</tr>
<tr>
<td></td>
<td>Or. fr</td>
</tr>
</tbody>
</table>

### Amendment 137
Jordi Cañas, Sandro Gozi, Stéphanie Yon-Courtin, Vlad-Marius Botoș

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tbody>
<tr>
<td>(ea) the joint procurement shall be subject to high transparency standards, provided it does not jeopardize the</td>
<td></td>
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</table>
negotiation and compliance of purchase agreements, including in relation to the disclosure of the exact amount provided to each participating country, details regarding supply chains, production and delivery of procured medical countermeasures, and details of the liability of participating countries, as well as information on the existence of no-fault compensation systems in those participating countries.

Or. en

Amendment 138
Adam Bielan

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

Text proposed by the Commission

Amendment

(ea) a Member State engaging in a joint procurement may make a change to the request set out earlier, including resignation from participation in the procurement, if there has been a significant change in the circumstances arising from a well-founded public interest.

Or. pl

Amendment 139
Jordi Cañas, Liesje Schreinemacher, Sandro Gozi, Stéphanie Yon-Courtin, Vlad-Marius Botoş

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

Text proposed by the Commission

Amendment

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

1. **They shall rely on the verification and compliance of the medical countermeasure forming the subject of the joint procurement procedure in question, with the highest safety and quality standards, as required by the relevant legislation;**

2. **They shall evaluate the ability of the bidder to ensure the security and capacity of supply of the medical countermeasure in question in a cross-border health threat situation;**

3. **They shall provide for sufficient and adequate flexibility of technical and economic solvency requirements, and lots shall accordingly be adjusted to those in the corresponding tender documents, thereby allowing the involvement and participation of small and medium-sized enterprises in joint procurement procedures and a wider selection of successful suppliers in the awarding process.**

4. **They shall evaluate lastly the price and costs of the medical countermeasure in question.**

Or. en

**Amendment 140**

Jordi Cañas, Liesje Schreinemacher, Vlad-Marius Botoș

**Proposal for a regulation**

**Article 12 – paragraph 3 – introductory part**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tbody>
<tr>
<td>3. The Commission shall, in liaison with the Member States, ensure</td>
<td>3. The Commission shall, in liaison with the Member States, ensure</td>
</tr>
</tbody>
</table>
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 141
Carlo Fidanza, Nicola Procaccini, Raffaele Stancanelli, Pietro Fiocchi, Sergio Berlato, Vincenzo Sofo

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

Text proposed by the Commission

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:

Amendment

3. The Commission shall, in liaison with the Member States, ensure coordination and information exchange between the entities organizing and participating in any action during the preparedness, response and duration of a serious cross-border threat to health, including, but not limited to joint procurement procedures, stockpiling in accessible facilities complying with specific European regulations, distribution and donation of medical countermeasures under different mechanisms established at Union level, in particular under:

Or. en

Amendment 142
Jordi Cañas, Sandro Gozi, Stéphanie Yon-Courtin, Vlad-Marius Botoş

Proposal for a regulation
Article 12 – paragraph 3 a (new)
3a. Participating Member states shall ensure an adequate stockpiling and distribution of procured medical countermeasures, whose main details and characteristics shall be set out in national plans. In addition, national plans shall address potential bottlenecks and capacity obstacles that may jeopardise the delivery of medical countermeasures acquired through joint procurement mechanisms to their final destination.

Or. en

Amendment 143
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

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

3a. Member States’ ability to hold strategic reserves shall be guaranteed, as well as their capacity to direct the use of these reserves solely for the benefit of their nationals and nationals of other Member States residing on their territory. Member States shall remain free to decide whether or not to share the use of these reserves.

Or. fr

Amendment 144
Adriana Maldonado López, Maria-Manuel Leitão-Marques, Biljana Borzan, Evelyne Gebhardt, Andreas Schieder, Maria Grapini, Leszek Miller, Brando Benifei, Clara Aguilera

Proposal for a regulation
Article 12 – paragraph 3 a (new)
Text proposed by the Commission

Amendment

3a. In case the joint procurement procedure for medical countermeasures is not applied, the European Commission as well as the Member States shall guarantee transparency of net pricing, delivery dates and reimbursement, to allow Member States equal conditions when negotiating with pharmaceutical companies.

Or. en

Amendment 145
Tomislav Sokol, Romana Tomc, Ivan Štefanec, Christian Doleschal, Dan-Ștefan Motreanu, Arba Kokalari

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

Text proposed by the Commission

Amendment

3a. In accordance with the principle of transparency, the Commission shall regularly inform the European Parliament on the negotiations and other details of the joint procurement of medical countermeasures.

Or. en

Amendment 146
Jordi Cañas, Sandro Gozi, Stéphanie Yon-Courtin, Vlad-Marius Botoș

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

Text proposed by the Commission

Amendment

3b. Member States shall establish no-fault compensation systems which shall be used in the event of a cross-border health threat declared by the EU, allowing citizens who may suffer an adverse
reaction to a particular medical countermeasure subject to a joint procurement procedure, to receive fair compensation by proving solely the causal link between the medical countermeasure in question and the damages caused.

Amendment 147
Tomislav Sokol, Romana Tomc, Ivan Štefanec, Christian Doleschal, Dan-Ștefan Motreanu, Arba Kokalari

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

Text proposed by the Commission

3b. The European Parliament reserves at all times the right to inspect the uncensored content of all contracts concluded in proceedings under this Article.

Amendment

Amendment 148
Jordi Cañas, Liesje Schreinemacher, Sandro Gozi, Stéphanie Yon-Courtin, Vlad-Marius Botoș

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

Text proposed by the Commission

3c. 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, access to legal protection and access to consumer representation.

Amendment
Amendment 149
Clara Ponsati Obiols

Proposal for a regulation
Article 13 – paragraph 1

Text proposed by the Commission

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

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, and where applicable regional, level for epidemiological surveillance.

Or. en

Amendment 150
Clara Ponsati Obiols

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

Text proposed by the Commission

(c) contribute to the evaluation and monitoring of communicable disease prevention and control programmes in order to provide the evidence for recommendations to strengthen and improve those programmes at the national and Union level;

Amendment

(c) contribute to the evaluation and monitoring of communicable disease prevention and control programmes in order to provide the evidence for recommendations to strengthen and improve those programmes at the regional, national and Union level;

Or. en

Amendment 151
Clara Ponsati Obiols
Proposal for a regulation
Article 13 – paragraph 2 – point i a (new)

Text proposed by the Commission

Amendment

(ia) make mitigation plans containing preventative measures that help ensure the continued supply of critical medicines, such as diversification of supply chains, as well as including production and supply capacity;

Or. en

Amendment 152
Clara Ponsati Obiols

Proposal for a regulation
Article 13 – paragraph 3 – introductory part

Text proposed by the Commission

Amendment

3. The national competent authorities referred to in paragraph 1 shall communicate the following information to the participating authorities of the epidemiological surveillance network:

3. The national and regional competent authorities referred to in paragraph 1 shall communicate the following information to the participating authorities of the epidemiological surveillance network:

Or. en

Amendment 153
Clara Ponsati Obiols

Proposal for a regulation
Article 13 – paragraph 3 – point f

Text proposed by the Commission

Amendment

(f) information about contract tracing monitoring systems developed at national level.

(f) information about contract tracing monitoring systems developed at national and regional level.

Or. en
Amendment 154
Clara Ponsati Obiols

Proposal for a regulation
Article 13 – paragraph 4

Text proposed by the Commission

4. When reporting information on epidemiological surveillance, the national competent authorities shall, where available, use the case definitions adopted in accordance with paragraph 9 for each communicable disease and related special health issue referred to in paragraph 1.

Amendment

4. When reporting information on epidemiological surveillance, the national and regional competent authorities shall, where available, use the case definitions adopted in accordance with paragraph 9 for each communicable disease and related special health issue referred to in paragraph 1.

Or. en

Amendment 155
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

Proposal for a regulation
Article 13 – paragraph 10

Text proposed by the Commission

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

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 propose decisions or recommendations 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.

Or. fr
Amendment 156
Kateřina Konečná

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 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. The platform should be used with the human in control principle on the artificial intelligence.

Or. en

Justification

Full human control on the artificial intelligence which gathers data on such sensitive information should be ensured.

Amendment 157
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron, Alessandra Basso, Marco Campomenosi

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 information from electronic health records, with the consent of the patients concerned and in strict compliance with personal data protection rules, as well as media monitoring, media monitoring, and apply artificial intelligence for data validation, analysis and automated...
Amendment 158
Maria Grapini

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 the obligation to protect personal data.

Or. fr

Amendment 159
Tomislav Sokol, Romana Tomc, Ivan Štefanec, Christian Doleschal, Dan-Ştefan Motreanu, Arba Kokalari

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.

Or. en

Amendment 160
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron, Alessandra Basso, Marco Campomenosi
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

deleted

Or. fr

Amendment 161
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

Proposal for a regulation
Article 16 – paragraph 1

Text proposed by the Commission

1. A network of Member States’ services supporting transfusion, transplantation and medically assisted reproduction is established to allow for the continuous and rapid access to sero-epidemiological data, including assessment of donor population exposure and immunity, and to monitor, assess and help address disease outbreaks that are relevant to substances of human origin.

Amendment

1. A network of Member States’ services enabling transfusion, transplantation and medically assisted reproduction, when authorised in national law, is established to allow for the continuous and rapid access to sero-epidemiological data, including assessment of donor population exposure and immunity, and to monitor, assess and help address disease outbreaks that are relevant to substances of human origin.

Or. fr

Amendment 162
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

Proposal for a regulation
Article 18 – paragraph 1
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.

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 suggesting the measures that may be required to protect public health.

Amendment 163
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron

Proposal for a regulation
Article 21 – paragraph 1 – introductory part

Text proposed by the Commission

1. Following an alert notification pursuant to Article 19, on a request from the Commission or a Member State and on the basis of the available information, including the information referred to in Article 19 and the risk assessments referred to in Article 20, Member States shall coordinate within the HSC and in liaison with the Commission:

Amendment

1. Following an alert notification pursuant to Article 19, on a request from a Member State and on the basis of the available information, including the information referred to in Article 19 and the risk assessments referred to in Article 20, Member States shall coordinate within the HSC and in liaison with the Commission:

Amendment 164
Kateřina Konečná

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

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 professionals;

consistent and coordinated information in the Union to the public and to healthcare professionals, \textit{e.g.}, veterinarians;

\textbf{Amendment 165}

\textbf{Tomislav Sokol, Romana Tomc, Ivan Štefanec, Christian Doleschal, Dan-Ștefan Motreanu, Arba Kokalari, Tom Vandenkendelaere}

\textbf{Proposal for a regulation}

\textbf{Article 22 – paragraph 2 – point c a (new)}

\begin{tabular}{l}
\textit{Text proposed by the Commission} \\
\textit{Amendment} \\
\end{tabular}

\begin{tabular}{l}
(ca) take into account the need for the normal functioning of the single market, in particular the existence of green lines for free circulation of food and other medical countermeasures. \\
\end{tabular}

\textbf{Amendment 166}

\textbf{Tomislav Sokol, Romana Tomc, Ivan Štefanec, Christian Doleschal, Dan-Ștefan Motreanu, Arba Kokalari}

\textbf{Proposal for a regulation}

\textbf{Article 25 – paragraph 1 – point c}

\begin{tabular}{l}
\textit{Text proposed by the Commission} \\
\textit{Amendment} \\
\end{tabular}

\begin{tabular}{l}
(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. \\
\end{tabular}

\begin{tabular}{l}
(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 \textit{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;}
\end{tabular}
Amendment 167
Tomislav Sokol, Romana Tomc, Ivan Štefanec, Christian Doleschal, Dan-Ștefan Motreanu, Arba Kokalari, Tom Vandenkendelaere

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

Text proposed by the Commission

Amendment

(ca) green lines under Article 25a of this Regulation.

Or. en

Amendment 168
Jean-Lin Lacapelle, Markus Buchheit, Virginie Joron, Alessandra Basso

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

Text proposed by the Commission

Amendment

1a. It shall have no effect on the activation and functioning of health emergency arrangements under Member States’ legislation, where they exist.

Or. fr

Amendment 169
Tomislav Sokol, Romana Tomec, Ivan Štefanec, Christian Doleschal, Dan-Ștefan Motreanu, Arba Kokalari, Tom Vandenkendelaere

Proposal for a regulation
Article 25 a (new)

Text proposed by the Commission

Amendment

Article 25a

Free movement of goods and services

1. After recognising a public health emergency under Article 23 of this
Regulation, green lines shall be set up to allow the free movement of food and medical countermeasures within the internal market.

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

2. Only on condition that the Commission grants prior authorisation Member States may, in accordance with Article 36 of TFEU, impose export restrictions on medical countermeasures concerning another Member State or Member States during a public health emergency at Union level.

Upon receiving a request for prior authorisation referred to in the first subparagraph of paragraph 2 from a Member State, the Commission shall decide whether to grant it without delay.

If within five days the Commission has not granted the prior authorisation in question, it shall be deemed granted.

Or. en

Amendment 170
Adam Bielan, Carlo Fidanza

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,

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.

Amendment 171
Tomislav Sokol, Romana Tomc, Ivan Štefanec, Christian Doleschal, Dan-Ștefan Motreanu, Arba Kokalari, Tom Vandenkendelaere

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, 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 during serious cross-border threats to health.