BRIEFING

EU Legislation in Progress

European Parliament

Building up resilience to cross-border health threats

Moving towards a European health union

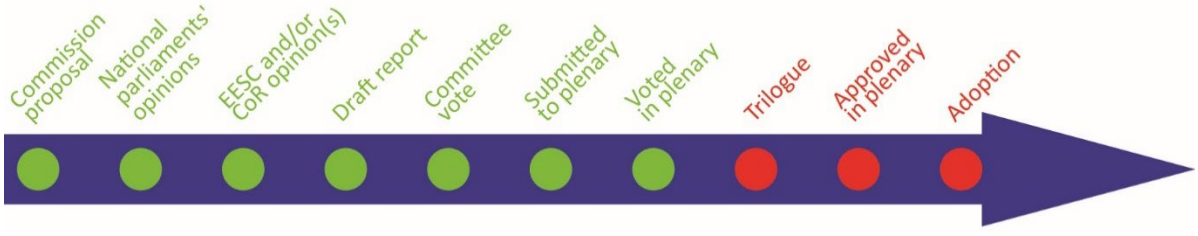
OVERVIEW

On 11 November 2020, the European Commission put forward a proposal for a regulation on serious cross-border threats to health. In the light of lessons learned from the coronavirus crisis, it aims to strengthen the EU's health security by revising Decision 1082/2013/EU (the 'Cross-Border Health Threats Decision'). The proposal was presented in a package that also includes proposals to strengthen the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA), as first steps towards a European health union.

Stakeholders widely welcome the proposal and the package. Some say it could be improved further, suggesting concrete elements, while others think it should go beyond crisis preparedness. Still others consider it a springboard to a bigger role for the European Union (EU) in health. The European Parliament has repeatedly called for stronger cooperation on health, for a new regulation to replace the Cross-Border Health Threats Decision, and for revised mandates of both the ECDC and the EMA.

Parliament's Committee on the Environment, Public Health and Food Safety is responsible for the file. The report was adopted in committee on 13 July 2021. The Council agreed its position on 23 July 2021. Parliament voted the committee report in plenary on 15 September 2021, thereby setting its negotiating mandate and opening the way for interinstitutional negotiations.

Proposal for a regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU		
Committee responsible:	Environment, Public Health and Food Safety (ENVI)	COM(2020) 727 11.11.2020
	Véronique Trillet-Lenoir (Renew, France)	
Rapporteur:	Esther de Lange (EPP, Netherlands)	2020/0322 (COD)
Shadow rapporteurs:	Sara Cerdas (S&D, Portugal) Joëlle Mélin (ID, France) Margrete Auken (Greens/EFA, Denmark) Joanna Kopcińska (ECR, Poland) Kateřina Konečná (The Left, Czechia)	Ordinary legislative procedure (COD) (Parliament and Council on equal footing – formerly 'co-decision')
Next steps expected:	Trilogue negotiations	



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Introduction

On 11 November 2020, the European Commission put forward a proposal for a regulation on serious cross-border threats to health. Building on lessons learned from the coronavirus crisis, it aims to strengthen existing structures and mechanisms for better protection, prevention, preparedness and response against all health hazards at EU level, by revising and repealing Decision No 1082/2013/EU (the 'Cross-Border Health Threats Decision').[1]

The proposal was presented as part of a package of associated measures, namely:

- a communication setting out key lessons learned from the coronavirus pandemic, and proposing a stronger and more comprehensive health security framework for the EU, and outlining the main elements of an EU 'health emergency preparedness and response authority' (HERA);
- a proposal to strengthen the European Centre for Disease Prevention and Control (ECDC); and
- a proposal on a reinforced role for the European Medicines Agency (EMA) in crisis preparedness and management for medicinal products and medical devices.

According to the Commission, the measures are first steps towards building the European health union announced by President Ursula von der Leyen in her 2020 State of the Union address. They would complement other provisions on crisis response and health, such as strategic stockpiling under the rescEU scheme; the emergency support instrument (ESI); the pharmaceutical strategy; and the new EU4Health programme. The three proposals are among the Commission, Council and European Parliament Joint Declaration 2021 legislative priority files, on which the three institutions want to ensure substantial progress. This briefing will focus on the cross-border health threats proposal.

Context

It is up to the EU Member States to define their health policies and to manage public health crises, with the EU playing a supporting role. However, serious cross-border threats have, by their nature, a transnational dimension, and no country can tackle them on its own. So, as the Commission argues in the proposal's exploratory memorandum, individual countries' public health measures need to be consistent with each other and coordinated. The Commission noted in its 2021 work programme, adopted in October 2020, that the coronavirus pandemic 'has exposed the need to strengthen the EU's crisis preparedness and management of cross-border health threats'. Drawing early lessons from the current crisis, this proposal is put forward in answer to that. The set of proposals was presented as the first building blocks of a more secure, better-prepared and more resilient EU in the area of health – a European health union – and are also referred to as the 'European health union proposals' or the 'European health union proposal package'.

At the same time, some commentators have criticised the EU's (initial) response to the pandemic. They say that initiatives came too late or were implemented in fragments, and that, at the onset of the outbreak, the EU's reaction was defined by poorly coordinated national approaches. Some also argue that the coronavirus pandemic has exposed both the unpreparedness of European health systems to absorb a health crisis of this magnitude and the pre-existing structural weaknesses that rendered the systems even more vulnerable to the shock. The EU's lack of preparedness, among other shortcomings, has also been partly blamed for the slow Covid-19 vaccination rollout. A Court of Auditors December 2020 report also highlighted some of the challenges faced by the EU in its initial support to the Member States' public health response to the pandemic (from January to the end of June 2020). These include setting an appropriate framework for cross-border health threats; facilitating provision of appropriate supplies in a crisis; and supporting the development of vaccines. According to the report, 'it was a challenge for the EU to rapidly complement the measures taken

within its formal remit, by additional actions to support the public health response to the crisis. These experiences can provide lessons for any future reform of the EU's competences in this field'.

From a broader perspective, the coronavirus crisis has thus amplified calls to increase the EU's competences in health. More than half of respondents (54 %) to a special Parliament survey conducted in October 2020 said that public health should be a spending priority for the EU budget, with public health the top spending priority for respondents in 18 countries. In the Special Eurobarometer 500 'Future of Europe', carried out in October/November 2020, respondents were asked to choose developments they wanted to see for Europe's future. A quarter of Europeans prioritised the development of a common health policy, and health-related risks were cited by 37 % as among the main global challenges affecting the EU in the future. The Conference on the Future of Europe, officially launched on 24 March 2021, is expected by many to play a central role in shaping the future European health union.

Existing situation

The current European health security arrangements, as established by the 2013 Cross-Border Health Threats Decision, provide a – limited – legal framework for EU action on preparedness and response. The framework is based essentially on the early warning and response system (EWRS), and on information and cooperation exchange in the Health Security Committee, which coordinates preparedness and response planning, as well as the Member States' public health responses and crisis communication. However, as the Commission notes in the proposal's explanatory memorandum, early lessons learned from the pandemic have shown that the current system has failed to ensure an optimal EU-level response. While it laid the groundwork for information exchange and joint procurement for the purchase of medical counter-measures, such as personal protection gear and medical equipment, it did little to trigger a timely common EU level response, coordinate crucial aspects of risk communication, or ensure solidarity among Member States. It is therefore necessary to address the weaknesses exposed by setting out a comprehensive legislative framework for EU-level preparedness, surveillance, risk assessment, early warning and response, and to enhance the guidance offered by the EU for the adoption of common measures to face future health threats. As the proposed legal instrument will be about establishing procedures and structures for cooperation on joint, EU-level work, it was considered most suitable that it take the form of a regulation.

Parliament's starting position

Parliament has consistently promoted the establishment of a coherent EU public health policy. In its April 2020 resolution on EU coordinated action to combat the pandemic and its consequences, Parliament called for the competences, budget and staff of the ECDC and the EMA to be strengthened substantially, to enable them to coordinate medical responses in times of crisis. Parliament also called for the creation of a European health response mechanism, to improve preparation and respond in a common and coordinated way to any type of health or sanitary crisis that emerges at EU level. It argued that such a mechanism should function as both an information hub and an emergency response team 'able to deliver vital supplies, medical equipment and medical staff to regions experiencing a sudden surge in infections'.

In its July 2020 resolution on the EU's public health strategy post-Covid-19, Parliament called for the European institutions and the Member States 'to draw the right lessons from the Covid-19 crisis and engage in far stronger cooperation in the area of health', calling for a number of measures to set up a European health union. More specifically, it called on the Commission to propose a new regulation on cross-border health treats to replace the Cross-Border Health Threats Decision, not least to make EU joint procurement faster and more effective in health crises, to guarantee the efficiency and transparency of the process, and to ensure equal and affordable access to new treatments. Parliament reiterated its call for a revised mandate for the ECDC, which would enable the ECDC, inter alia, to draw up mandatory guidance for Member States, as well as for a stronger role for the EMA as

regards avoiding medicine shortages and coordinating the design and approval of EU clinical trials in times of crisis. The resolution also called for a European health response mechanism to be created, to tackle health crises effectively through better coordination at EU level and the proper functioning of the strategic reserve of medicines and medical equipment.

Council and European Council starting position

In a December 2020 video-conference, health ministers welcomed the European health union proposals overall as a decisive step towards building a strong and autonomous EU that is better prepared to counter serious cross-border health threats. According to the Council, a large majority of ministers emphasised that the ECDC and EMA needed to be provided with more human and financial resources to assist Member States in preventing and countering health crises. As the Council notes, many delegations identified a number of areas that would have to be addressed during the forthcoming discussions, such as avoiding duplication of tasks and additional administrative burden, as well as responsibilities of the different crisis management bodies and mechanisms, and a clear distinction between expert and political decision-making levels. In this context, ministers agreed that national competences needed to be respected. They also stressed the importance of enhanced transparency, closer cooperation and intensive dialogue, including with the WHO.

Preparation of the proposal

Owing to the urgency of the matter, the proposal is not accompanied by an impact assessment. As the Commission points out, the proposal will broaden the scope of the existing legislation based on an assessment of data collected in the early months of the pandemic. Exchanges held with public and private stakeholders also fed into the proposal and are summarised in the communication accompanying the package. As regards medical devices, the proposal takes into account the impact assessment carried out for the adoption of Regulations (EU) 2017/745 on medical devices and 2017/746 on *in vitro* diagnostic medical devices. The proposal also draws on the recommendations contained in the November 2020 opinion on 'Improving pandemic preparedness and management' jointly prepared by the Commission's independent Group of Chief Scientific Advisors (GCSA), the European Group on Ethics in Science and New Technologies (EGE) and Peter Piot, Special Advisor to the President of the European Commission on the response to Covid-19.

The changes the proposal would bring

The proposal puts forward the following main modifications to the existing framework:[2]

Preparedness and response planning (articles 5-12):

- an EU health crisis and pandemic preparedness plan, including interregional elements, and requirements for the national preparedness plans, coupled with a comprehensive framework for reporting and auditing, including regular stress tests and exercises carried out with the Member States;
- a rule on the provision of training for the healthcare and public health workforce;
- reinforced joint procurement beyond the EU.

Epidemiological surveillance, new networks (articles 13-16):

- a new, integrated epidemiological surveillance system at EU level, supported by artificial intelligence (AI), harmonised datasets and digital tools for modelling, risk assessment and response, for the surveillance of novel pathogens based on common EU case definitions;
- strengthened access of the ECDC to health data for research and epidemiological aspects, in the context of the forthcoming European health data space;

- reporting requirements on Member States' health system capacity (such as hospital bed availability, intensive care capacity, number of medically trained staff, etc.) and other data relevant for managing cross-border threats;
- an EU reference laboratory network that would allow alignment on diagnostics, serological tests, testing methods, and the use and validation of certain tests;
- a network including Member State services supporting transfusion, transplantation and medically assisted reproduction.

Early warning and risk assessment (articles 18-20):

- alert notifications, including on urgent need or shortage of medical counter-measures; cross-border emergency assistance requests and offers;
- increased EU and Member States capacity for accurate risk assessment and response, with enhanced capacities for risk assessment by the relevant agencies,[3] and risk assessment coordination where more agencies are concerned in an 'all-hazards' approach, including rapid and appropriate recommendations for public health response measures that Member States should implement.

Coordinated response at EU level (articles 21-25):

- adoption of opinions and guidance, including on specific response measures, within the Health Security Committee and in liaison with the Commission, including Commission recommendations on response measures, based on ECDC recommendations, in particular;
- recognition of a public health emergency situation at EU level and establishment of an independent advisory committee on public health emergencies to advise on response measures;
- following an EU emergency situation declaration, activation of EU emergency mechanisms for the management of health crises (such as measures for medicinal products and medical devices), including deployment of outbreak assistance teams (the 'EU health task force').[4]

Furthermore, as laid out in its communication, the Commission will propose the establishment of a European health emergency preparedness and response authority (HERA).[5] HERA would develop and procure biomedical products and other solutions to ensure a fast response to urgent needs in health emergencies. HERA was officially launched on 16 September 2021 as a department within the Commission.[6]

Most of the actions would be funded through the EU4Health programme. Some work could be financed through other EU programmes, such as InvestEU. Strengthening the EU agencies would involve increasing their budgets, as negotiated with the budgetary authorities.

Advisory committees

On 5 May 2021, the European Committee of the Regions (CoR) adopted two related opinions: on the 'European health union: Reinforcing the EU's resilience' (CDR/5487/2020) and on 'Cross-border health threats and the mandate of the European Centre for Disease Prevention and Control (ECDC)' (CDR 5624/2020). The former opinion notes that, although health policy remains a primary Member State competence, a reflection is needed on how to improve coordination and strengthen the EU's response to cross-border health threats during the debate on the future of Europe. It stresses that the CoR needs to be represented in all discussions at EU level on health competences, including in the ambit of the Conference on the Future of Europe. The latter opinion insists that CoR representatives should be involved in the work of teams, committees and task forces set up at EU level to deal with public health emergencies, and considers it necessary to launch a reflection on EU competences in health during the debate on Europe's future. The Committee's territorial impact

assessment on cross-border health threats, prepared to inform the latter opinion, concluded that the proposals still fail to address the regional and local levels properly.

On 27 April 2021, the European Economic and Social Committee (EESC) adopted an opinion on the package as a whole, 'Building a European Health Union'. Regarding the cross-border health threats proposal, the opinion stresses the need: to stockpile and develop medicines that are useable and affordable for the entire population; for preparedness in protecting high-risk groups to begin immediately, particularly with regard to those in closed settings and institutions; for data collection to be better disaggregated to provide a clear understanding of the people most at risk; and for medical innovations and responses to be accessible to all, regardless of their income, Member State or region of residence.

National parliaments

The deadline for national parliaments to submit comments on the current proposal was 24 February 2021. The French Senate submitted a reasoned opinion, according to which the proposal's articles 6 and 7 (on preparedness and response plans), articles 8 and 9 (on audits and assessments of national plans); and – pending clarifications – articles 21(4) and 22 (on the measure to reinforce coordination) do not respect the subsidiarity principle.

Stakeholder views[7]

While centred on the cross-border health threats proposal, this section also collates wider views expressed on the health union package and the other two proposals it contains.

Public health figures and organisations

The European Federation of Allergy and Airways Diseases Patients' Association (EFA) supports a stronger EU role in health in all possible aspects, and welcomes the proposal to reinforce the EMA. The EFA's main priorities include: a strengthened mandate for the EMA to curb medicine shortage; increasing the EMA's capacity to address critical medical devices; upgrading the EMA's role in promoting effective research; maximising vaccine effectiveness, and in particular, the initiative to build a new vaccine monitoring platform; and improving the communication of the EMA's work. The EFA also hopes that the proposal can be a first step towards greater transparency in pricing and reimbursement for centrally authorised medicines and medical devices, thus ensuring better access.

The European Patients' Forum (EPF) welcomes the health union package, but calls for the vision to go beyond crisis preparedness and cross-border threats and to address 'systemic challenges', such as access to quality care, inequalities and healthcare digitalisation, while tackling non-communicable and communicable diseases alike. Civil society organisations should be welcomed as partners, and 'co-production' should be built into all EU-level health-related initiatives.

The 'manifesto for a European health union', initiated by 16 renowned public health figures, sets out a vision of a European health union that would, among other things, strengthen solidarity within and among Member States; ensure environmental sustainability; provide security for all Europeans, protecting them from major threats to health and from the vulnerability that results from living a precarious existence; and enable everyone's voice to be heard. It calls on political leaders in the European Council and the Conference on the future of Europe to take the next step and commit to creating a European health union. The manifesto has over 1 200 signatories (as of April 2021).

Healthcare providers and social security institutions

The European Social Insurance Platform (ESIP) welcomes the proposal. ESIP believes cooperation and coordination between the Health Security Committee and the integrated political crisis response mechanism (IPCR) should be improved to avoid duplication of efforts. To increase preparedness for cross-border health crises, the joint procurement mechanism should be further developed with the aim of preventing distortions in competition in the single market and

maximising opportunities for Member States to participate. While welcoming the use of new digital tools for risk assessment, ESIP highlights that protecting data privacy and confidentiality remains key, and that particular attention should be paid to the use of AI for data validation.

The European Association of Hospital Pharmacists (EAHP) notes with interest that implementation of national response plans could cover response to antimicrobial resistance and healthcare-associated infection. The EAHP welcomes the suggestion that the national response plans should take into account the training of human resources for emergency situations, and underlines the benefits that involving hospital pharmacy expertise can bring in this context. Moreover, the EAHP believes that hospital pharmacists should be involved in procurement procedures, to ensure procurement quality and continued supply of quality medicines to patients. The EAHP notes that, for successful implementation of measures that support communication and cooperation to better address cross-border health threats, local data collection points need to be equipped with the necessary tools to facilitate digital data collection and exchange of this information with other entities in the same country or in other European countries.

Pharmaceutical and medical device industry associations

EuropaBio, the association representing the biotechnology sector, welcomes the European health union proposals. According to EuropaBio, the ECDC's extended mandate should ensure the agency has full access to all relevant data from Member States and can increase its monitoring, surveillance and risk assessment capacities. As for the proposal to involve the EMA in managing the risks of medicine shortages, EuropaBio thinks that communication channels should be streamlined to avoid duplication with Member States' reporting requirements and an unnecessary burden on marketing authorisation holders. The future HERA should remediate structural gaps in the EU's health preparedness and response capacities with regard to biomedical development, production and surge capacity development. According to EuropaBio, the European health union's implementation will be largely dependent on a clear division of competences between the EU and its Member States, good governance, and clarification of the future role of the Health Security Committee and the European agencies, not least to avoid any unnecessary burden on stakeholders in the new structures. It invites the Commission to make good use of the Conference on the Future of Europe and the May 2021 Global Health Summit to ascertain citizens' expectations and frame the EU's future role in health.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) welcomes the proposed regulation on cross-border health threats, but believes that it can be improved further. According to EFPIA, the new mechanisms and governance structure should aim to ensure free movement of medical counter-measures and essential workers in emergency situations, and should support sustained supply of active pharmaceutical ingredients and finished products. To enhance informed decision-making and improve coordination, the Health Security Committee and the advisory committee on public health emergencies should be allowed to consult stakeholders, including manufacturers, on specific topics. EFPIA welcomes clearer rules on recognising emergency situations, but considers that the proposed regulation should be equally clear in defining the circumstances under which mechanisms such as joint procurement of medical counter-measures, as well as stockpiling, should be allowed. As regards epidemiological surveillance, EFPIA regrets that the proposal does not make provisions to ensure that manufacturers are made aware, in a timely manner, of epidemiological data and response scenarios developed by EU authorities, and suggests that this communication could be ensured, for example, via the digital platform for surveillance.

In separate feedback on the EMA proposal, EFPIA notes, among other things, that the proposed regulation should provide for an EU-harmonised definition of shortages, based on actual patients' needs, and for agreed standardised reporting requirements via a single platform. In setting up new requirements, the regulation should do more to acknowledge the multiple drivers of shortages, and therefore the roles and responsibilities of all stakeholders across the supply chain, including

manufacturers. In separate feedback on the ECDC proposal, EFPIA states, among other things, that the proposed regulation is an opportunity to provide the framework for an institutionalised dialogue between the ECDC and the industry, delimited by stringent standards regulating stakeholder engagement with public institutions, to avoid any conflicts of interest. As regards the ECDC's mandate to provide the public with evidence-based communication messages, EFPIA believes that Member States should be involved in the dissemination of such messages via dedicated campaigns targeting national audiences, to be co-developed with stakeholders.

MedTech Europe supports the EU's plans to strengthen preparedness for another health crisis, but cautions that the proposed plan could duplicate existing regulations and potentially lead to legal uncertainty. Specifically, MedTech Europe asks for clarification of the role, composition and practical operation of a new EMA executive steering group on medical devices, to be established in the EMA proposal, in light of the role of the medical devices coordination group implementing the new regulations on medical devices (MDR) and on *in vitro* diagnostic medical devices (IVDR). Moreover, MedTech Europe is concerned that the EMA should not jeopardise the urgently needed deployment of the MDR, due on 26 May 2021, or the IVDR, scheduled to enter into effect on 26 May 2022.

Academic views

The *European Journal of Risk Regulation*'s November 2020 Special Issue 4 explores various aspects of a European health union. In the editorial 'Towards a European Health Union: Time to Level Up', Alberto Alemanno writes that the European response to Covid-19 has revealed an inconvenient truth. The EU cannot directly act to save people's lives – only Member States can. Yet the unilateral measures they adopted to counter the coronavirus's spread proved not only ineffective but also disruptive to vital supply chains. As the editorial argues, while these fragmented efforts to tackle cross-border health threats almost immediately prompted political calls for the urgent creation of a European health union, such calls raise more questions than answers. The editorial notes that, unless the envisaged health union tackles the root causes of what prevented the Union from responding effectively to Covid-19 – that is divergent health capacity across the Union – it might fall short of its declared objective of strengthening the EU's resilience to cross-border health threats.

In 'Time to strengthen capacity in infectious disease control at the European level' (*International Journal of Infectious Diseases*, Volume 99, October 2020), Michael Anderson and Elias Mossialos note that the coronavirus pandemic has made the European Commission revaluate its role in Member States' health systems. In response, the EU is planning to significantly increase investment to tackle cross-border health threats. According to the article, the ECDC is well positioned to capitalise on this increased investment by designing and implementing a renewed European strategy for infectious disease control. To secure meaningful and sustainable improvements, the ECDC needs to be strengthened with more resources, an expanded geographical scope, and legislative change.

As Simona Guagliardo points out in a European Policy Centre (EPC) brief, the first building blocks of a revamped and strengthened EU health agenda are in place. To 'build back better', Europe now has to lay the foundations for more resilient national health systems, while embarking on a serious reflection on the EU's role in health. According to the brief, a reflection on the feasibility and desirability of transferring some health competences to the EU level can no longer be ignored, and the Conference on the Future of Europe should serve as a platform to start the debate on levelling up the EU's role in health policy.

In their June 2020 policy brief 'Health sovereignty: How to build a resilient European response to pandemics', published on the European Council on Foreign Relations website, Jonathan Hackenbroich et al. argue that Europe must improve its early warning systems, supply chain resilience, medical research and development, and cyber security and technology, to act decisively in future public health emergencies. According to the brief, Europe can build greater health security by building up common strategic stocks, diversifying and reshoring supply chains,

strengthening investment protection in innovative companies, investing in research and development, and by coordinating efforts in multilateral fora.

Legislative process

Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) is responsible for the file. The rapporteur, Véronique Trillet-Lenoir (Renew Europe, France) was appointed on 26 November 2020. The committee for opinion is the Committee on the Internal Market and Consumer Protection (IMCO). The Commission presented its proposal in the ENVI committee meeting of 25 February 2021.

The rapporteur's draft report proposed several amendments to the Commission proposal. Among other things, it highlighted the need to promote 'health solidarity' in the EU and beyond, putting more emphasis on international cooperation. To strengthen coordination at EU level, it suggested broadening the proposal beyond communicable diseases, to include related special health issues, such as mental health conditions. The draft report was considered in ENVI on 22 April 2021. Two further sets of amendments (103-302 and 303-643) to the Commission proposal were tabled on 29 April 2021. The IMCO opinion of 31 May 2021 included among other things, introducing a reference to 'green lanes' in a pandemic situation, and stressed the need to ensure proper functioning of the single market in the event serious cross-border health threats arise. The final ENVI vote took place on 13 July 2021. Among other things, the committee report supports the 'one health' approach that recognises the connection between human and animal health and the environment, and the need for actions against health threats to take into account these three dimensions. It also calls for enhanced cooperation and transparency on joint procurement for medical counter-measures.

After a debate on the report in Parliament's plenary on 13 September 2021, the full house adopted a position on the legisaltive proposal on 15 September with 594 votes in favour, 85 against and 16 abstentions, thereby adopting Parliament's negotiating mandate and opening the way to interinstitutional trilogue negotiations.

In Council, the Commission presented its proposal to the working party on pharmaceuticals and medical devices on 18 November 2020. The Council agreed its position on 23 July 2021. The main changes concern the preparation of national preparedness plans and their assessment by the EU, highlighting the Member States' competences in this area.

In formal comments of March 2021, the European Data Protection Supervisor welcomed the proposal, including the specific references to the General Data Protection Regulation (GDPR) and the regulation on the processing of personal data by the EU institutions and bodies (EUDPR). It recommended, among other things, providing for further implementing or delegated acts that would define the roles of the actors involved in the processing of personal data through the IT tools and systems envisaged in the proposal.

EUROPEAN PARLIAMENT SUPPORTING ANALYSIS

European Parliament Legislative Train Schedule: Cross-border threats to health, ECDC mandate extension, EMA mandate extension, EU4Health, European health data space, HERA, and Pharmaceutical strategy for Europe.

Scholz N. Cross-border threats to health: EU action on preparedness and response, Briefing, EPRS, European Parliament, January 2020.

Scholz N., EU4 Health programme, 'Legislation in Progress' briefing, EPRS, European Parliament, February 2021.

Scholz N., European Centre for Disease Prevention and Control: During the pandemic and beyond, Briefing, EPRS, European Parliament, June 2020.

Scholz N., European Medicines Agency: A look at its activities and the way ahead, Briefing, EPRS, European Parliament, July 2017.

Towards a more resilient Europe post-coronavirus. Options to enhance the EU's resilience to structural risks, Study, EPRS with the Directorates-General for Internal Policies (IPL) and External Policies (EXPO), European Parliament, April 2021.

OTHER SOURCES

Serious cross-border threats to health, Legislative Observatory (OEIL), European Parliament.

European Commission, Building a European Health Union: Stronger crisis preparedness and response for Europe, Press release with accompanying links, 11 November 2020.

ENDNOTES

1 For an overview of the existing framework, see a January 2020 EPRS briefing.

2 A correlation table comparing the new with the existing provisions is annexed to the proposal.

3 The ECDC, the European Food Safety Authority (EFSA), the European Chemicals Agency (ECHA), the European Environment Agency (EEA), the European Centre Monitoring Centre for Drugs and Drug Addictions (EMCDDA), the European Police Office (Europol), and the EMA.

4 The creation of an EU health task force, hosted by the ECDC, to support countries with preparedness strengthening and quickly intervene in a health crisis, is provided for in the ECDC proposal.

5 Modelled on the example of the US Biomedical Advanced Research and Development Authority (BARDA), the authority was initially referred to as a 'European BARDA'.

6 For further information, see the Commission communication (including its annex) on introducing HERA; the Commission decision establishing HERA; and the Q&A and factsheet.

7 This section aims to provide a flavour of the debate and is not intended to be an exhaustive account of all different views on the proposal. Additional information can be found in related publications listed under 'European Parliament supporting analysis'.

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