FEAM
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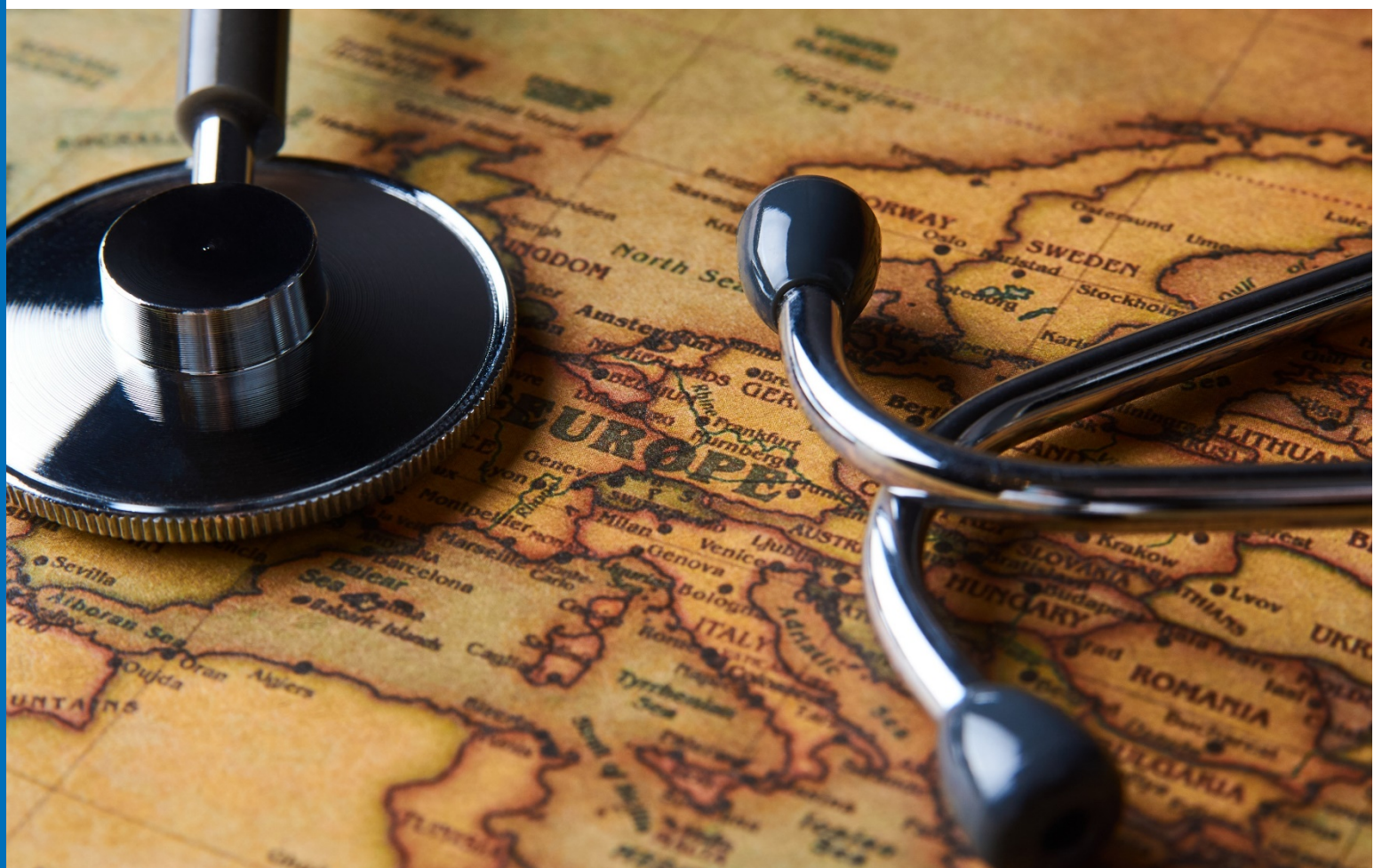
FEAM STATEMENT

The reinforcement of the mandate of the European Centre for Prevention and Disease Control (ECDC) and a new EU Regulation on serious cross-border health threats



FEAM Statement on the reinforcement of the mandate of the European Centre for Prevention and Disease Control (ECDC) and a new EU Regulation on serious cross-border health threats

Table of Contents

Executive Summary

With this statement, FEAM welcomes the European Commission's plans for building a stronger European Health Union. The statement focuses on the proposal to extend the role that the European Centre for Prevention and Disease Control (ECDC) will play in the future, and to a certain extent on the new Regulation on serious cross-border health threats.

FEAM Academies and experts have reflected on these proposals in light of the lessons learned so far from the COVID-19 pandemic. The ongoing COVID-19 crisis has shown the limitations as well as the potential for further EU cooperation in public health and health research. The crisis has also highlighted the need for integrated approaches to address complex issues at the intersection of human and animal health, society and the environment. Beyond their names (e.g. One Health, Planetary Health, Health in All Policies, etc.), these approaches stress the need for coherent policy action that involves all interested sectors and stakeholders in key planning and decision-making. This should be the case for pandemic preparedness and response.

As Europe and the world continue to face the impacts of the ongoing pandemic, FEAM presents some initial recommendations with regard to this important set of proposals. In addition, FEAM calls for a broader dialogue to explore the potential extension of the EU's competences and powers in public health, possibly within the forthcoming Conference on the Future of Europe.

Against this background, FEAM Academies provide the following recommendations to the European Commission, Parliament and Council:

1. make sure **expectations and mandates** allocated to the ECDC as well as to other EU institutions and agencies **are matched by sufficient resources and competences**;
2. keep the focus of the ECDC on communicable diseases and cross-border health threats while following an **integrated health vision** that addresses health inequalities and pays due attention to the health needs of vulnerable populations;
3. provide further details on how the **interoperability and cooperation** between human health and veterinary sectors will be ensured and enable closer alignment with other EU agencies, such as the European Food Safety Authority (EFSA), the European Environment Agency (EEA), and the European Medicines Agency (EMA), in line with the One Health Approach and to respond to the need of increasing information exchange;
4. provide **continuous monitoring and support** for the ECDC and other agencies to ensure fast learning and adaptation to changing circumstances, including emerging health threats and technologies, also via an external

committee composed of independent experts;

5. **strengthen the role of the ECDC** in facilitating the **exchange of knowledge and providing training** to support the development of surveillance, preparedness and laboratory capacities;
6. reinforce **the role of the ECDC in the monitoring and surveillance of health threats**, including by facilitating data sharing within the EU Health Data Space while addressing issues with sharing of health data for research with researchers of public institutions outside of the EEA/EU;
7. **facilitate synergies** between the ECDC and other EU institutions and agencies, including the new EU agency EU Health Emergency Preparedness and Response Authority (HERA) as well as with other building pieces of the European Health Union such as the EU Health Data Space and the new Pharmaceutical Strategy for Europe;
8. **clarify the involvement of external experts** and of the ECDC in the proposed Advisory Committee on public health emergencies and facilitate the involvement of independent advisors on a continuous rather than on an ad-hoc basis;
9. **foster the wider positioning of ECDC** in the global network of agencies by continuing to build connections and sharing data with other lookalike agencies, including in low- and middle- income countries;
10. **improve the design of the proposed EU Advisory Committee** for health emergencies and ensure clear coordination with the WHO for the declaration of a health emergency at Union level to avoid clashes with the WHO and the global framework of the International Health Regulation.

The need for an EU Health Union

"No country can tackle a cross-border public health crisis alone"[1]

The COVID-19 pandemic has left profound wounds across the EU and the world. Initial global and EU responses have been described as slow and uncoordinated, and while these were complicated by the limited scientific evidence about the new virus and dissimilar capacities across health systems, the lack of powers and resources at EU level added additional obstacles[2].

In June 2020, the FEAM Board recommended that limits on EU powers and competences on public health should be better evaluated after the crisis unfolds[3]. There are many lessons to be learned from the ongoing crisis to prepare for future challenges, including pandemics or increasing antimicrobial resistance. Such challenges may be further accelerated or aggravated by the interactions between animals, humans and their environment (leading for instance to more frequent zoonoses due to climate change) as well as by complex demographic and socio-economic factors leading to health inequalities.

Against this background, EU solidarity and coordination have been key to tackle the ongoing crisis. In spite of limited resources and powers, the EU has actively supported Member States, for example by organising a public procurement system to stockpile medical supplies (rescEU) and an Emergency Support Instrument to procure medical equipment, producing recommendations on a coordinated approach to policy measures (e.g. lifting lockdown measures, travel rules), and coordinating actions to ensure that European citizens have access to medical technologies, including vaccines[4]. At global level, the EU has also contributed to initiatives such as the COVID-19 Vaccine Global Access Facility COVAX[5]. Although insufficient, this range of actions proved the EU's added value and highlighted that it has the potential to address complex health challenges, both now and in the future.

Existing EU regulations and the work of agencies such as the European Centre for Disease Prevention and Control (ECDC) have greatly facilitated the exchange of information and supported measures undertaken across Europe, including through surveillance, early warning, and risk assessment activities. However, there is increasing evidence that the existing legislative framework and resources assigned to EU agencies and institutions do not currently enable a coherent and rapid EU

[1] Explanatory Memorandum, https://ec.europa.eu/info/sites/info/files/proposal-regulation-cross-border-threats-health_en.pdf
[2] Explanatory Memorandum, https://ec.europa.eu/info/sites/info/files/proposal-regulation-cross-border-threats-health_en.pdf
[3] https://www.feam.eu/wp-content/uploads/FEAM-Board-Statement-EU-cooperation.pdf
[4] https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans_en
[5] https://ec.europa.eu/commission/presscorner/detail/en/IP_20_1694

response for major challenges such as COVID-19 and potential future health threats[6].

Over the past year, the EU's ambitious plans to coordinate a public health response have been confronted with its limited public health powers. In contrast to this, European citizens seem to increasingly expect that the EU will play a more active role in public health matters[7].

In November 2020, as countries across Europe were entering the second wave of the outbreak, the European Commission unveiled a package of proposals to improve the EU's capacity to prepare for and respond to cross-border health threats. This package included[8]:

- a communication on *Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats*[9];
- a new proposed regulation on serious cross-border health threats[10];
- a regulation strengthening the mandate of the European Centre for Disease Prevention and Control[11];
- a regulation strengthening the mandate of the European Medicines Agency in crisis preparedness for medicinal products and medical devices[12].

With this statement, FEAM and its Member Academies welcome the European Commission's proposal for a stronger European Health Union[13]. FEAM also wishes to contribute with its expertise and diverse national experiences to the foundation of a well-designed plan to strengthen the mandate of the ECDC and the coordinating role of the European Commission to address future health threats. The FEAM Academies support the vision behind this proposal, as expressed in its accompanying Memorandum:

"*Serious cross-border threats to health have, by their nature, transnational implications. In a globalised society, people and goods move across borders in high numbers, facilitating illnesses and contaminated products to circulate rapidly across the globe. Public health measures at national level therefore need to be consistent*

[6] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats, COM/2020/724 final, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0724&qid=1605690513438

[7] See https://www.europarl.europa.eu/at-your-service/files/be-heard/eurobarometer/2020/public_opinion_in_the_eu_in_time_of_coronavirus_crisis/report/en-covid19-survey-report.pdf reporting that "around two-thirds of respondents (69%) agree that "the EU should have more competences to deal with crises such as the Coronavirus pandemic", while less than a quarter of respondents (22%) disagree with this statement.

[8] See https://www.europarl.europa.eu/legislative-train/theme-promoting-our-european-way-of-life/file-european-biomedical-research-and-development-agency. This package was initially discussed in a Webinar with stakeholders organized by DG Sante on 29 October 2020. A video recording is available: https://vimeo.com/474117689

[9] See https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0724&qid=1605690513438.

[10] See https://ec.europa.eu/info/sites/info/files/proposal-regulation-cross-border-threats-health_en.pdf.

[11] See https://ec.europa.eu/info/sites/info/files/proposal-mandate-european-centre-disease-prevention-control_en.pdf.

[12] See https://ec.europa.eu/info/sites/info/files/proposal-mandate-european-medicines-agency_en.pdf

[13] See for instance https://europeanhealthunion.eu/

with each other and be coordinated to contain further spread and minimise the consequences of such threats" [14].

FEAM Academies wish to stress the need for a coherent framework to enable cooperation between EU institutions and agencies, Member States, institutions similar to the ECDC (e.g. the US CDC, China CDC, Africa CDC) and the World Health Organization, in particular through its WHO European Region. As health threats do not stop at national or EU borders, cooperation is key in preparing for and responding to future threats. Therefore, broad cooperation with neighbouring countries (including within the new relationships between the EU and the UK), as well as globally, should be enhanced. This statement focuses on the reinforced mandate of the European Centre for Disease Prevention and Control (ECDC). The ECDC has played a crucial role in dealing with the current crisis in spite of limited resources and powers. It is expected that the current proposals to extend its mandate and resources will lead to an even greater role and impact. Insofar as the new proposed Regulation on serious cross-border health threats directly affects the work of the ECDC, we also elaborate on some of the issues covered by this Regulation.

FEAM's vision on the proposed extension of the ECDC role

The European Centre for Disease Prevention and Control (ECDC)[15] was set up in 2004 as a decentralised EU agency based in Stockholm, Sweden, with the mission to "identify, assess and communicate current and emerging threats to human health from communicable diseases"[16]. The COVID-19 pandemic has revealed the limitations faced by the agency both in terms of regulatory powers and resources.

Currently, ECDC's annual expenditures are around €60.5 million (including staff, infrastructure and operating expenditure). Its budget has a 7-year time horizon (corresponding to the Multi-annual Financial Framework for the EU budget) and therefore the agency has limited flexibility to shift activities and resources[17].

The agency's main focus is on risk assessment activities, along with surveillance and monitoring, and to a certain extent, the provision of non-binding scientific recommendations. While the ECDC can provide recommendations based on its monitoring and risk assessment activities, it does not have the power or resources to implement public health measures. Moreover, the efficiency of such measures ultimately depends on capacities at national and regional level (e.g. health systems),

[14] https://ec.europa.eu/info/sites/info/files/proposal-mandate-european-centre-disease-prevention-control_en.pdf

[15] The European Parliament Regulation (EC) no 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control.
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R0851&from=EN

[16] Ibid.

[17] https://www.ecdc.europa.eu/en/publications-data/strategic-and-performance-analysis-ecdc-response-covid-19-pandemic p. 14.

which are widely dissimilar across the EU, as well as on the coordination of such responses, another area where the EU has limited powers. Risk management falls within the remit of Member States, and at EU level, coordination of responses involves the Health Security Committee (HSC), which is composed of representatives of Member States and the EU Commission, and is in charge of preparedness, planning, risk and crisis communication, and response[18].

While the core activities of the ECDC are similar to those of other similar institutions at national level, its regulatory powers and resources (e.g. staff, budget) are quite limited when compared, for instance, to the US CDC, Public Health England or the German Robert Koch Institute[19]. Over the years, the ECDC has been confronted with significant limitations in pursuing its objectives, during past outbreaks, and more recently in relation to the COVID-19 outbreak. These limitations help to explain why the agency's (as well as the European Commission's) first steps in the COVID-19 crisis have been criticised as insufficient[20]. Despite this, the ECDC has demonstrated that it has the potential to tackle future crises[21]. Therefore, FEAM believes that an enlargement of the ECDC's mandate accompanied by appropriate resources is a positive step towards better EU preparedness and response for future outbreaks.

Over the past years, external evaluations of the ECDC[22], including those carried out by the European Court of Auditors[23] and more recently, the views from diverse stakeholders, have supported an extension of the mandate of the ECDC[24]. FEAM joins these voices, while calling for an ongoing system to fine-tune and improve the new mandate of the agency, as well as the EU's powers and competences in public health. We also highlight the importance of building synergies with the European Commission and the other agencies, including the future EU Health Emergency Preparedness and Response Authority (HERA), to address future challenges.
In particular, FEAM Academies have discussed the potential for strengthening the ECDC to improve action and coordination at EU level regarding the following aspects.

Scope of the ECDC

The new Regulation extending the mandate of the ECDC maintains its focus on communicable diseases. Long-standing discussions have focused on whether the

[18] Eleanor Brooks, Anniek de Ruijter and Scott L. Greer, Chapter 2 COVID-19 and European Union health policy: from crisis to collective action, in Brooks, Eleanor, Anniek de Ruijter, and Scott L. Greer. "COVID-19 and European Union health policy: From crisis to collective action." Social Policy in the European Union: State of Play (2020).
[19] Representatives of the German Presidency of the EU Council have presented ideas to model a "new ECDC" on the basis of the Robert Koch Institute or its US counterparts: https://www.bundesgesundheitsministerium.de/en/en/eu2020.html
[20] https://www.politico.eu/article/coronavirus-europe-failed-the-test/
[21] https://www.ecdc.europa.eu/en/publications-data/strategic-and-performance-analysis-ecdc-response-covid-19-pandemic
[22] See last external evaluation in 2019, https://www.ecdc.europa.eu/sites/default/files/documents/third-independent-external-evaluation-of-ECDC-report.pdf
[23] European Court of Auditors special report no 28, Dealing with serious cross-border threats to health in the EU: important steps taken but more needs to be done (Luxembourg, Publications Office of the European Union 2016).
[24] https://www.ecdc.europa.eu/en/publications-data/strategic-and-performance-analysis-ecdc-response-covid-19-pandemic

ECDC's scope should be broadened to encompass non-communicable diseases. All diseases are intertwined, and a dichotomy between non-communicable diseases and communicable diseases should be avoided as there are multiple overlapping areas (e.g. long-term COVID-19 symptoms or viral diseases leading to chronic conditions).

Therefore, the ECDC should focus on 'health' as an integrated concept, especially as the agency will continue to focus on socioeconomic and environmental determinants of health to address health inequalities and to continue to pay attention to the needs of vulnerable groups.

While dichotomies should be avoided and an integrated approach to health should be recognised, for the moment it would be preferable if the agency were to continue to focus on the coordination and surveillance of communicable diseases throughout the EU (given the core mission and current resources of the ECDC including in terms of skills of its core staff). New communicable diseases and other cross-border health threats will continue to pose important threats for EU citizens in the future and it is expected that the ECDC will need to focus on these issues. In this sense, an efficient ECDC on infectious diseases would be much better than one with a broader scope that would not be able to cover all these complex areas with sufficient resources and expertise. Currently the ECDC is monitoring only a list of diseases and this list should be continuously updated as well as complemented through foresight and anticipatory research.

Nonetheless, the ECDC and other EU and national agencies and institutions should work closely together, including by fostering data sharing on health inequalities with institutions working on non-communicable diseases.

In the current proposed extension of its mandate, the ECDC is now required to engage in several new activities, including more foresight and anticipatory exercises to prepare for the future. For this and other new competences, it would be important that the agency's new tasks are matched by sufficient resources and that potential duplications of efforts are avoided. Given that another new agency, HERA, is currently being proposed to accelerate and boost advanced medical research for health emergencies, and that foresight and anticipatory exercises have also been included in the proposal for the creation of HERA[25], a clarification of the scope and roles of each agency should also be envisaged in the near future.

Surveillance, Early Warning Response System and Data Integration

The ECDC has played an important role in the surveillance of communicable diseases

[25]https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12870-European-Health-Emergency-Preparedness-and-Response-Authority-HERA-

and other health issues falling within mandatory surveillance at EU level. In this area, the ECDC operates a surveillance network in close collaboration with Member States.

As highlighted by the COVID-19 crisis, the availability of reliable data that can be aggregated and analysed at EU level is a necessary condition for strong surveillance and early warning systems. The COVID-19 crisis has further underlined the limitations of the ECDC as an agency lacking regulatory powers and relying on cooperation with Member States, including for the transmission and sharing of critical data:

"*ECDC is unable to collect data from Member States themselves, but relies heavily on Member States providing them with the requested data. ECDC does issue guidelines on data collection, but has no authority to enforce standards in how data should be reported, currently enforced by the database and reporting control, or quality assure the source of surveillance and data reporting within Member States*"[26].

A critical issue faced during the COVID-19 crisis has been the lack of reliability and comparability of data at EU level (e.g. due to a variety of criteria for testing[27], or divergent case or death definitions)[28]. The harmonisation of health indicators across the EU to make them comparable is a complex but critical step that may be facilitated by EU institutions and by the ECDC. So far, only a limited number of important health indicators have been defined in the same way across EU countries[29].

Countries might also face additional difficulties in obtaining data (and sharing it with the ECDC), and this is the case for instance in highly decentralised countries where data must be shared by regions. Potential obstacles for countries to share data with the ECDC must be addressed and capacities built to enable the fast and accurate sharing of vital data.

Beyond formal networks for data exchange, the existence of informal scientific networks is also key to drive data exchanges across researchers, and such networks are particularly relevant for data sharing during emergencies. Scientific advisory groups are key enablers of informal exchanges of information that are sometimes unavailable to organisations and therefore, collaboration should be enabled via these informal groups too.

The proposal by the European Commission highlights the need to strengthen the capacities of the ECDC to integrate surveillance and monitoring systems at EU level, including research data as well as data on the capacity of health systems with regard

[26] https://www.ecdc.europa.eu/en/publications-data/strategic-and-performance-analysis-ecdc-response-covid-19-pandemic
[27] https://analysis.covid19healthsystem.org/index.php/2020/04/16/how-do-covid-19-testing-criteria-differ-across-countries/
[28] https://apps.who.int/iris/bitstream/handle/10665/336295/Eurohealth-26-2-45-50-eng.pdf
[29] Fehr, A., Lange, C., Fuchs, J., Neuhauser, H., & Schmitz, R. (2017). Health monitoring and health indicators in Europe. *Journal of Health Monitoring*, *2*(1).

to diagnosis, prevention and treatment of communicable diseases. Therefore, it underlines the need for cooperation on a common framework for the European Commission and the Member States to define disease-specific European surveillance standards with key support from the ECDC[30] and extends the mandate of the ECDC regarding the following critical data areas[31]:

- epidemiological surveillance of communicable diseases;
- progression of epidemic situations;
- unusual epidemic phenomena of new communicable diseases;
- molecular pathogen data;
- health systems data.

Whilst it is not clear whether genetic surveillance would be covered under "*molecular pathogen data*", monitoring activities directed at identifying changes in pathogens (including new mutations) as well as any differences in host susceptibility should clearly be included.

The proposal envisages that the ECDC shall make use of modern technologies for processing data, in particular for the Early Warning and Response System (EWRS), and incentives are given for utilising digital mobile applications, artificial intelligence model and automated contact tracing[32]. The EWRS should be sufficiently flexible to incorporate context as well as "*hard data*". For example, contact tracing is often best undertaken with local knowledge and can lead to identification of "*places*" of transmission rather than simply a list of "*direct contacts*".

Beyond the extension of its mandate, the ECDC can be expected to play an important role in the EU Health Data Space with regard to the TESSy and EPIS platforms, and overall, with all data platforms and spaces supporting surveillance, early warning strategies and other data-related tasks under its new mandate.

The development of an EU Health Data Space provides further opportunities for improving the surveillance of communicable diseases as well as the use of health data for research, both in communicable diseases as well as in the capacity of health systems, and socioeconomic as well as environmental determinants of health. The compilation and sharing of data in a manner that protects personal data and privacy is an essential element for advanced research and for targeted solutions to current public health issues.

[30] Ibid. Article 13, it is proposed that 'the ECDC monitor Member States' adherence to surveillance standards and share regular monitoring reports with the HSC and the Commission. The ECDC shall regularly inform the HSC on the timeliness, completeness and quality of the surveillance data reported to the ECDC'.
[31] Ibid. Article 11 on Collection and Analysis of data
[32] Ibid. Article 8 on Early Warning and response system and Article 11 on Collection and Analysis of Data.

Sharing epidemiological and other health data with researchers and public health authorities is key for public health and for the advancement of health research. Within the European Economic Area, the General Data Protection Regulation (GDPR) aims at ensuring protection of personal data while it also facilitates the use and sharing of data.

In a joint report of ALLEA, EASAC and FEAM, these three European Academy networks examine the importance of sharing personal health data for research in the public sector also outside of the EU/EEA[33]. The expert group found that the implementation of GDPR rules on international transfer of data outside of the EEA/EU has created problems for academic researchers, health care professionals and other involved actors in the public sector. Such problems affect international organisations such as the WHO within the context of studies by the International Agency for Research on Cancer (IARC). While exchange of data in the context of the current COVID-19 pandemic has been facilitated by the use of specific exemptions for these cases, the European Data Protection Board (EDPB) has also restated that such exemptions "must be interpreted restrictively and on a case-by-case basis"[34]. Lack of effective mechanisms to facilitate the sharing of health data for research between public sector institutions ultimately affect patients and citizens as beneficiaries of public sector health research. Therefore, the joint report recommends actions to ensure that sharing of pseudonymised health data for public sector research is enabled while data is shared safely and efficiently, and with due respect of privacy concerns. The report also calls for the development of additional guidance by the EDPB applicable to health research by public sector authorities and institutions. Trust in existing mechanisms should also serve to increase the use of shareable data to enhance surveillance activities and to advance research.

Problems related to the exchange of data with countries outside of the EU/EEA are now compounded by the outstanding issues remaining between the EU and the UK after Brexit. A preliminary decision on the adequacy of the UK's privacy framework has now been issued and a final decision is expected in 2021 to ensure that the flow of data exchanges will not be affected by similar obstacles as those described above[35] (for collaboration with the UK after Brexit, see also the section *"Cross-border and global collaboration beyond the EU"* below)".

Overall, the proposal outlines an ambitious role for the ECDC – especially with regard to surveillance and data – including for the correlation of disease incidence with societal and environmental factors. It mandates that the ECDC plays a role in monitoring and assessing not only communicable diseases but also health systems' capacities and mandates it to identify population groups at risk and in need of targeted

[33] https://www.feam.eu/wp-content/uploads/International-Health-Data-Transfer_2021_web.pdf
[34] https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_guidelines_202003_healthdatascientificresearchcovid19_en.pdf
[35] https://ec.europa.eu/commission/presscorner/detail/en/ip_21_661

prevention and response measures. The ECDC has had a strong focus on vulnerable populations (e.g. migrants, minorities) and this focus, which has been critical to deal with health inequalities, should be maintained. While the proposal is accompanied by increased budgetary resources, it is important to assess whether such increased resources would be sufficient for the ECDC to fulfil its extended mission.

Cross-sectoral integration and collaboration

Early warning and prevention strategies need to be well integrated with other alert systems and responses[36]. Because many pandemics, including the one caused by SARS-CoV-2, are zoonoses, an integrated One Health approach that enables collaboration between the animal health, human health and environment sectors is critical[37].

The integration of data from the veterinary and human health sectors via the collaboration between the ECDC and the European Food Safety Authority (EFSA) in the European Food and Waterborne Diseases and Zoonoses Network (FWD-Net) is an example of such cross-sectorial collaboration. Collaborations between both sectors (e.g. via EFSA and for vector-borne diseases) including joint meetings of veterinarians and the HSC committee to enhance cooperation seem to work well[38]. This has also been the case with joint activities between the EFSA and the ECDC to monitor SARS-CoV-2 infection in mustelids[39].

The current EU proposal on a new Regulation on serious cross-border health threats, recognises people's interconnectedness under an integrated One Health approach: "*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*" [40]. However, neither this instrument, nor the Regulation on the extended mandate of the ECDC, provide further details about how such cooperation and interoperability across sectors should function or be expanded in the future. Moreover, lack of resources and limited information exchange might hamper data exchanges and early warnings at the intersection of animal and human health, and therefore, national capacities could also need reinforcement.

We recommend that details about how cooperation between the animal and human

[36] See European Court of Auditors, 2016 highlighting the need to: "further enhance the EWRS and develop integrated solutions for situational awareness and incident management for serious cross-border threats to health", and also mentioning that "the procedural or technical interfacing with other rapid alert systems at Union level was not yet completed" at that time. See also ECDC, Towards One Health preparedness, Technical Report, Expert consultation 11–12 December 2017, highlighting that "One Health implementation was made more difficult by poor communication of early warning signals and surveillance results".

[37] ECDC, Towards One Health preparedness, Technical Report, Expert consultation 11–12 December 2017, highlighting that "One Health implementation was made more difficult by poor communication of early warning signals and surveillance results".

[38] Webinar with stakeholders organized by DG Sante on 29 October 2020. A video recording is available: https://vimeo.com/474117689

[39] https://www.efsa.europa.eu/en/efsajournal/pub/6459#abstract

[40] https://ec.europa.eu/info/sites/info/files/proposal-regulation-cross-border-threats-health_en.pdf p. 9, recital (8).

health sector will be facilitated, and the resources that need to be dedicated to this, as well as the potential incorporation of the third element of the "One Health triad" – the environment – should be better outlined in the proposals. Details may be incorporated via implementing acts and therefore collaboration with stakeholders and institutions from all sectors will be vital to better define and address the necessary requirements for such cross-sectorial collaborations to function smoothly.

Laboratory capacities

During the COVID-19 crisis, the diversity of testing strategies has been an important obstacle to coordinated responses at EU level. The proposal addresses this problem by emphasising the EU role in coordinating and supporting national laboratories and also through the creation of EU networks of laboratories. Under the current proposal, the ECDC, along with the European Commission, will assume a leading role with a new network of EU reference laboratories to align diagnostics, serological tests, and testing methods. Another new network that integrates Member States services that support transfusion, transplantation and medically assisted reproduction allowing rapid access to sero-epidemiological data is also foreseen.

As crucial pillars to the preparedness and response against health threats, limited (and dissimilar) national laboratory capacities, including their ability to react in response to an emergency, would also need to be addressed:

"*The European Centre for Disease Prevention and Control (ECDC) published a comparison of values for a composite index of national public health laboratory capacities as of 2016. France, the United Kingdom, Sweden and Belgium were among the countries with the highest scores, scoring significantly higher than Germany, for example, which ranked only 18th amongst European countries (ECDC, 2018a). However, Germany reacted rapidly in the early stages of the COVID-19 pandemic. It was one of the first countries to develop a diagnostic test developed at Berlin's Charité hospital, and the government mobilised both public and private laboratories to rapidly scale up testing capacity*"[41].

It will be crucial that Member States further invest in developing such capacities and that the EU facilitates this. Building a network of qualified laboratories will be key to prepare for future challenges, supporting efficient surveillance and monitoring of infectious diseases, and allowing the early warning system to detect threats as early as possible. National capacities, including laboratory capacities, are critical to enable a rapid and effective response to future health threats.

[41] Group of Chief Scientific Advisors to the European Commission, European Group on Ethics in Science and New Technologies (EGE), Special advisor to President Ursula von der Leyen on the response to the coronavirus and COVID-19, Improving pandemic preparedness and management Joint Opinion, November 2020.

The ECDC could function as a network that facilitates the exchange of knowledge (e.g. techniques, validation, logistics) but also sharing of reagents and antibodies rapidly and efficiently. Data from biobanks could also be integrated with the potential collaboration of the BBMRI-ERIC (a consortium of EU biobanks). Furthermore, the integration of new technologies and digital solutions in surveillance and monitoring systems as well as more in general in health systems, will be key to ensure that countries are better prepared for future challenges. Co-creation of this and other networks with Member States, including through the incorporation of Member States staff, will be key to their success.

Risk assessment

Risk assessment is one of the core competences of the ECDC [42]. It has also been one of the key contributions of the ECDC during the COVID-19 outbreak, deemed useful by many stakeholders:

"*Risk assessments issued by ECDC are perceived very positively by external stakeholders and are described as timely and very useful by some. More specifically, the RRA (rapid risk assessment) outputs 'Coronavirus disease in 2019 in the EU/EEA and UK – tenth update' and 'Novel coronavirus disease 2019 pandemic: increased transmission in the EU/EEA and UK' were considered relevant, of high quality and useful*"[43].

Others have nonetheless criticised the initial risk assessments carried out by the ECDC, highlighting that, at least until early March 2020, it failed to acknowledge the severity of the threat[44]. For instance, on its first update on 22 January 2020[45], the ECDC reached the conclusion, that the "*likelihood of a case reported in the EU resulting in secondary cases within the EU/EEA*" was low. As part of the criticism directed towards the agency during the early stages of the outbreak, it is also reported that at that time, the ECDC reassured ministers about Europe's capacity to test for the coronavirus, and that such capacities were later confronted with the real laboratory capacities (and gaps) across Member States[46].

While it is important to mention that these early risk assessment exercises were done in the face of significant uncertainty, and this element was explicitly acknowledged in the initial assessment of 22 January 2020 ("*there are considerable uncertainties in*

[42] Article 10 of the Decision No. 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health.

[43] Report Strategic and performance analysis of ECDC response to the COVID-19 pandemic, November 2020, https://www.ecdc.europa.eu/en/publications-data/strategic-and-performance-analysis-ecdc-response-covid-19-pandemic

[44] https://www.politico.eu/article/coronavirus-europe-failed-the-test/

[45] Risk assessment: Outbreak of acute respiratory syndrome associated with a novel coronavirus, Wuhan, China; first update, 22 January 2020, https://www.ecdc.europa.eu/en/publications-data/risk-assessment-outbreak-acute-respiratory-syndrome-associated-novel-coronavirus

[46] https://www.politico.eu/article/coronavirus-europe-failed-the-test/

assessing the risk of this event, due to lack of detailed epidemiological analyses"), it is also important to identify any limitations that the ECDC might have faced and that should be addressed as part of the proposals.

The current proposal reinforces the competences of the ECDC with regard to risk assessment of communicable diseases and antimicrobial resistance and healthcare-associated infections related to communicable diseases, and adds assessments regarding threats to substances of human origin, such as blood, organs, tissues and cells potentially impacted by communicable diseases, or by threats of unknown origin. This is accompanied by increased budgetary allocations for monitoring and assessing risks. While the allocation of sufficient budget is a necessary condition, it is also important to acknowledge that risk assessment heavily relies on the availability and quality of data. Therefore, addressing gaps in the consistency and availability of data, the obligations and capabilities to share such data early on, the capacities of laboratories, and the ability to cooperate widely and deeply with other countries and institutions within and outside of the EU, should also contribute to improve risk assessment capacities in the future.

Scientific advice and risk communication

During the COVID-19 outbreak, citizens across Europe have been faced with a discordance of voices from the scientific community[47]. This is despite the critical importance of science and risk communication during similar crises:

"Knowledge, motivation, and trust are important requirements for behaviour, which is why transparent and comprehensible communication about the risk of infection and possible consequences are key. This includes communicating key figures and the reference values for such figures in a clear way, while admitting to uncertainties concerning interpretation, and explaining the possible effects of preventive measures"[48].

Scientific advice has been provided at national level through different mechanisms and the processes have faced important obstacles. With significant uncertainties and knowledge gaps, establishing the best available evidence during an outbreak is a daunting task[49]. To make things worse, the lack of certainty often leads to public policies based on incomplete and sometimes inexact or even incorrect information.

[47] See Rosenkötter, Nicole, Timo Clemens, Kristine Sørensen, and Helmut Brand. "Twentieth anniversary of the European Union health mandate: taking stock of perceived achievements, failures and missed opportunities–a qualitative study." *BMC Public Health* 13, no. 1 (2013): 1074, finding through a qualitative study that: "Questions were raised on whether the ECDC' s responsibility in surveillance, risk assessment and training are sufficient or if additional responsibilities in risk communication and management were needed to assure full stewardship during and in the prevention of health crises."

[48] https://www.leopoldina.org/uploads/tx_leopublication/2020_Leopoldina_Statement_Corona_Autumn_EN_01.pdf

[49] Alwan, Nisreen A., Rochelle Ann Burgess, Simon Ashworth, Rupert Beale, Nahid Bhadelia, Debby Bogaert, Jennifer Dowd et al. "Scientific consensus on the COVID-19 pandemic: we need to act now." *The Lancet* 396, no. 10260 (2020): e71-e72.

The failure of such policies further contributes to distrust in policymakers and also to distrust in science.

It is in this complex context that further cooperation for the production and validation of scientific evidence at EU and global levels could be beneficial, while respecting the space for political decisions at national level.

Following the COVID-19 crisis, the European Commission set up a scientific task force[50], chaired by Prof. Peter Piot, and the ECDC issued regular risk assessments as well as numerous recommendations (e.g. on the validity of diagnostic tests, the use of protective measures such as masks). In spite of these activities, there is significant room for improvement at EU level for the production of sound scientific advice and the communication of such advice to the public during health crises.

In their joint opinion on the response to COVID-19, the European Commission's Group of Chief Scientific Advisors, the European Group on Ethics in Science and New Technologies, and the Special Advisor to the President of the European Commission, recommended the creation of a standing EU Advisory body:

"This body should have a multidisciplinary and inclusive membership so it can advise on biomedical, behavioural, social, economic, cultural, ethical, legal, technological and international aspects. Its composition and functioning should also respond to the challenges and requirements involved by its role in advising on new and surprising questions and complex and changing situations, as it will need to be expert, farsighted, rapid, flexible and creative, while often facing the unknown, uncertainties and chaos. It should have liaisons to representatives from relevant advisory bodies in the Member States, at EU-level, including the ECDC, and internationally to ensure EU-wide and global sharing and exchange of information. The result should be a shared evidence-base about effective and socially and economically sustainable mitigation and management strategies for health threats and crises, including epidemics and pandemics. The envisaged EU advisory body would also ensure that the advice provided to Member State governments and the European Commission is consistent, with differences in advice to different Member States clarified and clearly communicated. It would also ensure that key criteria guide EU coordination regarding international concerns such as travel, ensuring coherence and non-discrimination among Member States"[51].

The proposed new Regulation on serious cross-border health threats creates an

[50] On 17th March 2020, the European Commission set up an Advisory Panel on the coronavirus composed of 7 epidemiologists and virologists with the mission to formulate science-based EU response guidelines and to coordinate risk management measures, https://ec.europa.eu/health/advisorypanel_covid19_en

[51] https://op.europa.eu/en/publication-detail/-/publication/a1016d77-2562-11eb-9d7e-01aa75ed71a1/language-en/format-PDF/source-171481573

Advisory Committee on public health emergencies composed of independent experts selected by the European Commission, as well as representatives of the ECDC and the EMA as observers[52]. However, such a mechanism is likely to be insufficient due to different reasons. Rather than a standing committee, as recommended by the joint opinion, the Advisory Committee has been designed as a mechanism that would be put in place in the context of the recognition of a public health emergency at EU level[53]. The agencies (ECDC and EMA) are incorporated only as observers.

Under the new proposed Regulation on serious cross-border health threats, the Advisory Committee can declare a public health emergency at Union level (article 23), in a similar way to how the WHO can declare a public health emergency of international concern (PHEIC) at global level under the International Health Regulations (IHR). Such a declaration triggers the possibility of using emergency mechanisms in response to the crisis at EU level without the need to wait for a declaration from the WHO.

Therefore, the newly proposed Advisory Committee will be an *ad-hoc* mechanism. While a similar committee operates under the International Health Regulations (IHR) to declare public health emergencies of international concern (PHEIC), the IHR establishes the need to maintain a roster of experts as well as Regulations for Expert Advisory Panels and Committees. It is not clear from the current proposal whether a similar roster would be maintained at EU level to facilitate the availability of a diverse group of experts as well as a balanced representation of diverse disciplines in an emergency situation, as envisaged by the same proposal.

Moreover, current proposals allow, but do not necessarily require, the ECDC director to invite experts from professional or scientific bodies or from non-governmental organisations to sit on its Advisory Forum. Such representation is key to ensure that a variety of views are taken into consideration.

For the above-mentioned reasons, while the proposal moves towards a more adequate incorporation of scientific advice at EU level during and in-between health crises, the proposed mechanisms could be improved. Moreover, clear coordination with the WHO should be envisaged. While the proposal establishes that the EU Commission should liaise with the WHO before declaring a public health emergency at Union level and notify it of its intention to adopt this decision, a more detailed plan to avoid mismatches with the WHO and the global framework of the International

[52] 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 (article 24 on the creation of an Advisory Committee on public health emergencies). "The director may invite experts or representatives of professional or scientific bodies, or non-governmental organisations with recognised experience in disciplines related to the work of the Centre to cooperate in specific tasks and to take part in the relevant activities of the Advisory Forum. In addition, the Commission may suggest to the director experts or representatives of professional or scientific bodies, or non-governmental organizations to be invited on an ad-hoc basis".

[53] See article 24 of the proposed Regulation on serious cross-border health threats.

Health Regulations should also be put in place.

The current proposal also envisages a wider role for the ECDC to issue recommendations, advices and response measures. According to Article 6 of the proposal, the ECDC will "provide concrete analyses and recommendations for actions to prevent and control communicable disease threats upon request of the European Commission". Based on the ECDC's recommendations, the European Commission will have the possibility to adopt recommendations on common temporary public health measures for Member States[54].

It is important to consider how this new role for the ECDC would function in practice and whether and to what extent it could overlap with national bodies and the WHO as providers of normative guidance during health emergencies. Potential overlaps need to be carefully managed to ensure consistent messages from all levels of governance, something that has been particularly challenging throughout the current pandemic. Overall, while the proposal facilitates the involvement of the ECDC, it does not envisage a key role for the agency in providing or coordinating the provision of scientific advice and addressing the communication of science facts and risks to the public in the context of cross-border health threats. The ECDC shall provide recommendations upon request but such recommendations are not binding.

In carrying out an expanded yet limited role in providing recommendations on response measures upon request, the procedures for this should be carefully thought out in order to avoid any overlap between the ECDC, national bodies and the WHO, and also to ensure that clear messages are communicated to the public.

Preparedness and response plans

The limited preparedness for the ongoing crisis has further complicated the lack of a coordinated EU approach to pandemics. In spite of a current obligation for Member States to report every three years on their preparedness and response plans, the implementation of this obligation has been insufficient, also due to the lack of enforcement mechanisms at EU level.

With the current proposal, an EU preparedness plan will be established with the aim to complement national plans[55]. Member States shall also be obliged to produce a preparedness plan every three years, and the ECDC will audit the Member States along the same timeframe and propose corrective measures if needed. Article 8 of the cross-border health threat proposal states that following the audit, "the Member States

[54] 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, Article 22 on recommendations on common temporary public health measures: "The recommendation for measures adopted under paragraph 1 shall: (a) be based on in particular recommendations of the ECDC in particular (…)"

[55] Ibid. Article 5 on the Union preparedness and response plan.

shall present an action plan addressing the proposed recommendations of the audit and the corresponding actions and milestones"[56]. A more active role within the audits for the European Commission and the ECDC would allow for the identification of financial instruments, including the EU4Health Programme and structural funds, that could help to address existing gaps related to cross-border health threats.

The proposal also envisages a broader role for the ECDC through the Technical Support Instrument, which will include targeted training and exchange of knowledge activities for healthcare and public health staff regarding national preparedness plans, crisis preparedness, surveillance and laboratory capacities. As the ECDC has ample experience in running training schemes in public health, such training programmes, including the existing EPIET/EUPHEM 2-year programme, should also be complemented and strengthened.

The role of the ECDC in emergencies and crisis mechanisms at EU level

Before the COVID-19 crisis, the ECDC was already seen as a potential contributor to the EU and international emergency and crisis management mechanisms. A 2019 external evaluation of the ECDC highlighted the great potential for the agency to contribute to these activities, although recognising that this would require a "*strategic vision in coordination with the Commission services, ECDC governing bodies, and key stakeholders"*[57]*.*

On April 7, 2020, and during the first wave of the COVID-19 outbreak, the European Medical Corps was deployed to the north of Italy to help local medical staff, a measure that had been long expected by Italy. While the intervention was perceived as arriving very late, it was also qualified as "*an important symbol of European solidarity*". With its extended mandate, the ECDC will have the capacity to mobilise and deploy the EU Health Task Force to assist local response to outbreaks in Member States and third countries' territories[58].

Furthermore, by integrating its early warning and rapid alert systems to the early planning of resources in synergy with the EU Civil Protection Mechanism (under the coordination of the Directorate-General for European Civil Protection and Humanitarian Aid Operations ECHO), the ECDC could play a major role in anticipation of and/or in providing early warnings about potential outbreaks and their consequences in terms of shortage of medicines and other critical equipment as well as health staff shortages.

[56] 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, Article 8 on Auditing on preparedness and response planning.

[57] https://www.ecdc.europa.eu/sites/default/files/documents/ECDC%20International%20Relations%20Policy%202020-FINAL_1.pdf

[58] Proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control, Article 11 on support international and field response.

EU coordination of responses

An effective approach to prepare and respond to pandemics needs to rely on strong cooperation at transnational level, as well as strong health systems at national and local levels[59]. In 2017, a study found many gaps in Member States' legislation, and a lack of available and transparent information about national frameworks, in spite of clear information-sharing obligations at the EU and global levels (including through the International Health Regulations)[60].

The COVID-19 pandemic has shown that uncoordinated measures from Member States can lead to significant problems and unforeseen consequences aggravating health crises[61]. During challenging phases – such as the beginning of the outbreak, post-lockdown phases as well as subsequent waves – the role of the ECDC (and to a certain extent, that of the EU) has been limited in spite of its potential capacity in terms of providing scientific advice and leading the coordination of responses along with the European Commission. It is therefore crucial that some coordination takes place more effectively at EU level, even if this would require significant discussion between Member States before agreeing to a more centralised approach.

The main instrument for coordinating responses at EU level is the Health Security Committee (HSC), which is composed of representatives of the Member States and observers from the European Economic Area (EEA) countries, EU agencies and the WHO. While the HSC has played a pivotal role in the coordination and cooperation among European bodies and national authorities, current mechanisms provide limited opportunities to enforce or coordinate national measures or to coordinate risk communication activities[62].

Risk management, which includes the coordination of responses, has been outside of the mandate of the ECDC, which has focused on surveillance and risk assessment. The ECDC cooperates with "*coordinating competent bodies (CCBs)*" of Member States. However, one of the main obstacles faced by the ECDC relates to its lack of regulatory powers, which prevents the ECDC from effectively coordinating Member States – for instance in their surveillance activities, where the ECDC does not have a mechanism to ensure that Member States provide the information in the "prescribed

[59] Renda, Andrea, and Castro, Rosa. "Towards Stronger EU Governance of Health Threats after the COVID-19 Pandemic." *European Journal of Risk Regulation* 11, no. 2 (2020): 273–82. doi:10.1017/err.2020.34.

[60] Speakman, Elizabeth M., Scott Burris, and Richard Coker. "Pandemic legislation in the European Union: Fit for purpose? The need for a systematic comparison of national laws." *Health Policy* 121, no. 10 (2017): 1021-1024.

[61] For instance, the enactment of unilateral actions by some Member States such as export restrictions on personal protective equipment (PPE) or the introduction of travel bans within the EU.

[62] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats, COM/2020/724 final.

manner"[63]. This reduces its ability to obtain timely information from Member States, which are also necessary for coordinated responses.

As the coordination of responses falls within the competences of the European Commission (in coordination with Member States) via the Health Security Committee (HSC), the current proposal partially addresses the limitations faced by existing mechanisms through the expansion of the HSC. It foresees that the HSC can adopt guidance and opinions integrated by recommendations from the European Commission and such recommendations can translate into measures that can be implemented at national level[64]. However, the relevance of the HSC would ultimately depend on the commitment of Member States to implement their measures.

The ECDC's expanded mandate also partially addresses these gaps, as the agency will be granted a coordinating role within several platforms:

- it will have an advisory role within the Health Security Committee[65]; and
- it will coordinate the network of surveillance of communicable diseases within which the European Commission, the ECDC and the competent MS authorities work closely together[66].

Although limited, such coordination roles would also be accompanied by an increased capacity in responses including in operating and coordinating the following activities:

- the network of EU reference laboratories[67];
- the network for substances of human origin[68];
- the EU Health Task Force ECDC[69].

In addition, the proposal fosters collaboration with the EMA and with the new EU

[63] See Greer, Scott, and Anniek de Ruijter. "EU health law and policy in and after the COVID-19 crisis." European Journal of Public Health (2020), arguing that: "The ECDC can provide common methodologies for information gathering, but it has no way to ensure that Member States indeed provide information in the prescribed manner. To make information flows more integrated and useful, the EU could direct resources and create obligations for Member States to improve surveillance and reporting (e.g. by reducing the time it takes for data to get from a lab to capitals to the ECDC)".

[64] Ibid. Article 4 on the establishment of the Health Security Committee.
"The HSC shall have the following tasks:
(a) enabling of coordinated action by the Commission and the Member States for the implementation of this Regulation;
(b) coordination in liaison with the Commission of the preparedness and response planning of the Member States in accordance with Article 10;
(c) coordination in liaison with the Commission of the risk and crisis communication and responses of the Member States to serious cross-border threats to health, in accordance with Article 21;
(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."

[65] 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, Article 13 on epidemiological surveillance and Article 14 on the Platform for surveillance.

[66] Ibid. Article 13.

[67] Ibid. Article 15 on EU Reference laboratories.

[68] Ibid. Article 16 on a Network for substances of human origin.

[69] Proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control, Article 11-a on support international and field response.

agency HERA. When situations of emergency arise, epidemiological forecasts shall be made available by the ECDC to the EMA[70]. Also, in terms of prevention of communicable diseases, joint work should be undertaken with the EMA for the coordination of independent monitoring studies on post-vaccine effectiveness and safety[71].

It is clear that collaborations between Member States, the European Commission and the ECDC should function as smoothly as possible. One important limitation highlighted during the COVID-19 crisis is that the ECDC can provide an analysis and risk assessment of the situation but cannot give binding recommendations. While the European Commission has certain competences for EU coordination mainly through the Health Security Committee, further coordination powers for the EU would need to be agreed upon by Member States and the COVID-19 crisis has brought this question into the spotlight.

A FEAM Board statement, issued in June 2020, advocated for stronger public health powers and better coordination of health policies at EU level. It is still to be seen whether the mechanisms included in the current proposal will be sufficient to ensure coordination of responses at EU and national levels during health crises. These questions should be the subject of wider discussions, possibly in the framework of the forthcoming Conference on the Future of Europe and ensuring that future proposed mechanisms of stronger cooperation are co-created with Member States[72].

Cross-border and global collaboration beyond the EU

By definition, health threats do not stop at EU borders. Therefore, truly European as well as global mechanisms of cooperation with non-EU countries (with special attention given to neighbouring countries) are critical. The ECDC has maintained important cooperation activities with third countries outside of the European Union and the proposal envisages several areas in which this cooperation will continue:

- global support of epidemic and outbreak responses;
- promotion of a steady and long-term cooperation with public health actors of third countries;
- broadening the ECDC's scope to collect and analyse data from third countries;
- strengthening preparedness capacities under the International Health Regulations (IHR), in particular in EU partner countries.

[70] Ibid. Article 11 on Collection and Analysis of Data
[71] Ibid. Article 5 on Prevention of communicable diseases'
[72] Communication from the Commission to the European Parliament and the Council shaping the Conference on the Future of Europe, Brussels, 22.1.2020, COM(2020) 27 final, https://ec.europa.eu/info/sites/info/files/communication-conference-future-of-europe-january-2020_en.pdf

The proposal addresses the need for more cooperation at global level – for instance through the EU Health Task Force of the ECDC and its contribution to the WHO Health Emergencies Programme Mechanism, the Global Outbreak Alert and Response Network (GOARN) – and the Union Civil Protection Mechanism, and with European countries for instance through the deployment of experts and staff from the EU and EEA countries, EU pre-accession and European Neighbourhood Policy countries.

Over the years, the ECDC has strengthened its collaboration with the WHO and especially with WHO Europe[73]. While WHO Europe and the EU cover different countries of the region, it is important that the geographical coverage of the European Commission, the ECDC and WHO Europe are coordinated, and especially that they are well understood by countries and do not lead to unnecessary duplication of efforts. Alignment and coherence between all organisations involved in tackling health threats is critical and this includes a clear definition of the geographical scope of each organisation as well as a clear understanding of their mandates and roles.

It is particularly important that the EU engages in cooperation mechanisms with European countries also with regard to its surveillance and early warning systems. While participation of countries belonging to the EEA has not been envisaged in the existing framework[74], their involvement has been key for a response to the COVID-19 crisis[75].

As mentioned above, the EU would now have the power to declare a public health emergency at Union level (article 23), in a similar way to how the WHO can declare a public health emergency of international concern (PHEIC) at global level under the International Health Regulations (IHR). The justification for this is that this would allow the EU to activate public health measures. While the proposal foresees that the European Commission should liaise with the WHO to share its intention to adopt a decision and inform the WHO once a decision is made, details of how this new mechanism could solve any potential mismatches between the EU and the WHO should be developed.

An additional problem for the EU is the extent of collaborations with the UK after Brexit. The long-awaited agreement on the future relationship between the UK and the EU was reached on 25 December 2020. Under this provisional agreement (ratification by European and national parliaments is still ongoing), both parties plan to adopt a cooperative approach on health security. In particular, article HS.1: Cooperation on health security (part four “thematic cooperation”, title I “health security”), foresees how

[73] See the 2014-2020 ECDC International Relations Policy https://www.ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/international-relations-policy-2014-2020.pdf

[74] Anderson, Michael, Martin Mckee, and Elias Mossialos. "Covid-19 exposes weaknesses in European response to outbreaks." BMJ (2020).

[75] https://www.reuters.com/article/us-china-health-swiss/swiss-seek-access-to-eu-early-warning-system-as-coronavirus-spreads-idUSKBN1ZR24M

the UK and the EU should continue working together in this key area. The agreement enables timely information exchange when necessary.

In case of emergency, following a written request, the UK might be temporarily granted access to the Early Warning and Response System (EWRS) by the Union. Cooperation between the ECDC and the relevant UK body should happen on a regular basis.

However, the details that will apply to the future UK-EU relationship after Brexit in the field of health security are still subject to mutual agreement by the parties, and in particular, a memorandum of understanding is planned between "the European Centre for Disease Prevention and Control and the relevant body in the United Kingdom responsible for surveillance, epidemic intelligence and scientific advice on infectious diseases" to "cooperate on technical and scientific matters of mutual interest to the parties" [76].

In general, further reflection is needed on the contribution of the ECDC to other international organisations (e.g. WHO and WHO Europe, and similar agencies, including the Africa CDC). The details of how this cooperation will be organised are very important and should be clarified in the proposal or in key documents that ensure the continuity of collaborations between institutions[77].

To prepare for future health threats, it is essential that the EU looks outside of its own borders, and a particular aspect that should be addressed is how to facilitate the potential work of the EU and the ECDC with low- and middle- income countries. This has acquired extreme importance for example in the context of access to COVID-19 and the possibility that the EU could send vaccines to Africa, but it is also critical to prepare for future health threats. In fostering cooperation with low- and middle- income countries, the EU should also recognise and facilitate learning from the experiences of these countries.

Recommendations

Make sure expectations and mandates allocated to the ECDC as well as to other institutions and EU agencies are matched by sufficient resources and competences. Overall, while the current proposal significantly expands the mandate of the ECDC as well as the resources that will be committed to the agency, it is critical that such an extended mandate is accompanied by adequate financial and other required resources such as the appropriate mix of skillsets and legal mandates that would

[76] https://ec.europa.eu/info/sites/info/files/brexit_files/info_site/tca-20-12-28.pdf, article HS.1: Cooperation on health security p. 370.
[77] A Memorandum of Understanding between the ECDC and the Chinese CDC exists, and an international network of similar institutions was put in place in June 2019: https://www.eca.europa.eu/Lists/ECADocuments/RW21_01/RW_public_health_resp_Covid-19_EN.pdf

enable the effective operation of the agency.

Facilitate synergies with other EU institutions and agencies, including the new EU agency HERA, and ensure coordination of approaches as well as minimize duplication of efforts. The current proposals for a European Health Union include plans for setting up a new agency, the EU Health Emergency Preparedness and Response Authority (HERA). While the details of this proposal will be released later in 2021, overlapping and duplication of efforts between EU agencies, the EU Commission, and the forthcoming agency HERA should be avoided. Consistency of the EU Health Union should include avoiding the loss of resources and ensuring that entities work in cooperation rather than in competition. A clear definition of roles would facilitate this.

Keep the focus of the ECDC on communicable diseases and cross-border health threats. While an extension of the mandate of the ECDC towards non-communicable diseases has been advocated for a long time, and a truly integrated approach to health would support this, the ECDC core mission focuses on the coordination and surveillance of communicable diseases throughout the EU as this area poses major challenges with important specificities. New communicable diseases and other cross-border health threats will pose important threats for EU citizens in the future and it is expected that the ECDC will need to focus on these issues at present. Nonetheless, the ECDC and other agencies should work closely together, including by fostering data sharing on health inequalities with institutions working on non-communicable diseases. The ECDC's strong focus on vulnerable population (e.g. migrants, minorities) should also be maintained.

Ensure the EU collaborates with Member States and regions as well as with other countries globally. It is essential that the EU looks outside of its own borders, with neighbouring countries in Europe as well as globally through the WHO, including collaborations with low- and middle- income countries.

Foster the wider positioning of ECDC within the global network of agencies by continuing to build connections and sharing data with other lookalike agencies. A network of similar agencies could be considered to exchange information and data rapidly so as to be better prepared for health emergencies. The ECDC should also promote and play a leading role in supporting responses to threats elsewhere.

Provide continuous monitoring and support for the ECDC, other involved agencies, the European Commission, and Member States to ensure fast learning and adaptation to changing circumstances, including new health threats as well as new technological solutions also via an external committee composed of independent experts. This would include for instance, the use and incorporation of genetic surveillance data on new mutations and differences in host susceptibility, and also the incorporation of "hard data" within the EWRS, for example, local knowledge which can be critical for

contact tracing.

The production and sharing of comparable data should be facilitated at EU level. Potential obstacles for countries to share data with the ECDC must be addressed and capacities built to enable the fast and accurate sharing of vital data. Beyond the formal exchange of data, the importance of informal scientific networks which also help with data exchange – especially during health emergencies – should be recognised and enabled.

The ECDC's role in facilitating the exchange of knowledge and providing training to support the development of surveillance, preparedness and laboratory capacities should be strengthened. Furthermore, the EU's support for the integration of new technologies and digital solutions in surveillance and monitoring systems as well as more generally in health systems, will be key to ensure that countries are better prepared for future challenges.

The proposed EU scientific advisory mechanism for health emergencies should be improved. An ad-hoc Advisory Committee offers only an impartial answer to the need for multidisciplinary and clear scientific guidance. Moreover, clear coordination with the WHO should be envisaged for the declaration of a health emergency at Union level to avoid divergence with the WHO and the global framework of the International Health Regulations.

In line with the One Health Approach, closer alignment with other EU agencies, such as EFSA, EEA or EMA, should be sought to facilitate a fluid interface between animal and human health. A four-party committee, composed of each EU agency linked to the One Health Approach, could also be set up to respond to the needs of increasing information exchange.

A long-term vision for the ECDC and the European Health Union

To prepare for future challenges, the ambitious goals of a European Health Union should be matched with an enabling regulatory framework and institutions endowed with sufficient powers and resources. This includes greater emphasis on preparation as well as anticipation and foresight as highlighted also by the 2020 Annual Strategy Foresight Report[78]. Such a forward-looking approach should be co-created with Member States and developed with the help of expertise from different sectors and disciplines under a truly integrated One Health approach, as well as a Health in All Policies approach.

The first steps for a European Health Union have now been outlined with the current

[78] https://ec.europa.eu/info/sites/info/files/strategic_foresight_report_2020_1.pdf

package of proposals examined in this statement, as well as with a few other pieces such as the new European Pharmaceutical Strategy, the creation of a EU Health Data Space and the new agency HERA. Against this background, and as expressed by the FEAM Board in June 2020, FEAM Academies are also supportive of the following long-term actions[79]:

- **More political and financial support is needed** for better coordination and cooperation of public health and health research at EU level. FEAM welcomes the approval of the EU4Health Programme for 2021-2027[80]. While the final approved budget is significantly lower than initially envisaged by the European Commission proposal, it is an improvement compared to the past programme. FEAM calls for sustained support for the EU Health Programme; it is critical that expectations and mandates are matched by sufficient resources. The EU's research initiatives, including Horizon Europe, should also devote sufficient attention to health research, not only in terms of funding but also in terms of the identification of priorities to build the necessary tools to fight future health threats through adequate research and innovation.

- **Launching an inclusive dialogue** to reflect and take stock of the lessons learned from the COVID-19 outbreak while preparing for the future. FEAM has recommended the creation of an expert Task Force to review challenges and opportunities to strengthen the role of the EU in coordinating emergencies such as the COVID-19 pandemic, antimicrobial resistance, shortages of medicines, or the complex effects of migration and climate change in health. A wide and inclusive dialogue with other stakeholders, Member States and EU institutions, is key to design suitable proposals and significantly improve the coordinating role of the EU. FEAM offers to be an active part of this Task Force, which could clearly identify and examine areas where the optimal provision of healthcare should be facilitated through cooperation between the EU and Member States. In addition to lessons from the pandemic, and other emerging health threats, the Task Force should also devote attention to ongoing issues such as the need for health economic evaluation of innovations (HTA) on a pan European level (avoiding duplication and waste of resources), enhancing equal access to medical innovations for all EU citizens, and decreasing health inequalities. The Task Force could also consider other areas where the EU could lead to stronger coordination with the appropriate funding and political will, including the use of artificial intelligence for large clinical databases and European clinical trials, and the EU's role in coordinating research and innovation (including for clinical research, defining optimal therapeutic strategies without commercial aim). Enhancing solidarity and tackling inequalities (including inequalities in research

[79] https://www.feam.eu/wp-content/uploads/FEAM-Board-Statement-EU-cooperation.pdf
[80] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0522&from=EN

and healthcare that translate into broad health and other inequalities) should be a core goal. This task force could be organised within the Conference on the Future of Europe[81].

FEAM join the voices of other stakeholders, civil society, and the European Parliament, calling for dialogue and the potential deepening of EU powers to coordinate public health and health research alongside EU Member States. There is substantial *de facto* EU integration in public health, including through the recognition of university degrees, the mobility of healthcare workers, and the major impact of health crises, which do not stop at borders. Healthcare approaches and requirements need to respond to the increasing need for coordination and orchestration at the EU level. Europe has a challenge but also an opportunity to contribute to a stronger, more sustainable and resilient global system to prepare for and respond to future pandemics.

[81] Communication from the Commission to the European Parliament and the Council shaping the Conference on the Future of Europe, Brussels, 22.1.2020, COM(2020) 27 final, https://ec.europa.eu/info/sites/info/files/communication-conference-future-of-europe-january-2020_en.pdf

Conclusions and way forward

While the COVID-19 crisis unfolds, this statement reflects on a few preliminary lessons emerging from the ongoing crisis that could help Europe prepare for future pandemics and health threats. We therefore offer some recommendations focused on the European Commission's proposals to extend the mandate of the European Centre for Disease Prevention and Control (ECDC) and on the new EU Regulation on serious cross-border health threats.

Our recommendations build upon the important role that the ECDC and the European Commission have played during the COVID-19 pandemic despite limited resources and mandates. This highlights the enormous potential of EU cooperation to enhance public health and health research. They are guided by the spirit of the One Health approach that envisages deep intersectoral cooperation between the human and animal health sectors, as well as an integration of knowledge and concerns about the environment. Tackling complex issues such as the impacts of climate change and inequalities in health also call for deeper cooperation between the medical and social sciences, and for the incorporation of expertise and scientific advice into key policy decisions to prepare or respond to health threats.

Beyond the recommendations provided in this statement, FEAM Academies believe that a broad dialogue to reflect on the possibilities to extend EU's competences and powers in public health, possibly within the framework of the forthcoming Conference on the Future of Europe, should follow soon.

As the EU begins to re-shape its institutions to build a stronger European Health Union, FEAM Academies stand ready to contribute with their expertise and to facilitate discussions with other EU and national health stakeholders.

About the Federation of European Academies of Medicine (FEAM)

FEAM is the European platform of national Academies of Medicine, Pharmacy and Veterinary Science, or national Academies via their medical division. It brings together 23 national Academies within the WHO European region. FEAM's mission is to promote cooperation among them; to provide them with a platform to formulate and express their common position on European matters concerning human and animal medicine, biomedical research, education, and health; and to extend to the European authorities the advisory role that they exercise in their own countries on those matters.

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