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State of Health Preparedness Report 2023

1. INTRODUCTION

The European Union (EU) has made important strides in strengthening its preparedness capacity to withstand serious cross-border health threats. December 2023 marks four years since SARS-CoV-2 was detected for the first time, eventually unleashing a full-blown pandemic and an unprecedented global health crisis. Since then, many initiatives and lessons learned have crystallised in new EU legislation to strengthen our collective defences and preparedness against pandemics and other major threats to health, such as those brought by climate change.

December 2023 also sees the first anniversary of the entry into force of a key legislative act in the EU health security framework: Regulation (EU) 2022/2371 on serious cross-border threats to health.[1] The Commission proposed the Regulation back in 2020 as part of the first pillar of the European Health Union, together with proposals for the expanded mandates for two key EU health agencies: the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA). The Regulation has upgraded the existing EU-level mechanisms for public health prevention, preparedness, surveillance, early warning and response, and has become the backbone of the EU's health security architecture. The European Health Union – whose foundations were laid while we were still undergoing the unprecedented COVID-19 crisis – is now operational and delivering results, including the Commission's Health Emergency Preparedness and Response Authority (HERA), created in September 2021[2]. This report outlines those major developments to date.

The political commitment to draft an annual state of health preparedness report to reflect the overall changing risk landscape in the EU and the state of health preparedness was announced in the 2021 Commission Communication 'Drawing the early lessons from the COVID-19 pandemic'[3]. The first edition of the State of Health Preparedness Report[4] was published in 2022 and focused on preparedness capabilities related to medical countermeasures. The primary objective of this year's report is to map the EU actions that have been put in place to address serious cross-border health threats, with a focus on those actions implementing Regulation (EU) 2022/2371 (such reporting is, in fact, a requirement according to Article 9[5]). As a second objective, the 2023 report outlines relevant ongoing initiatives and work that are closely related but that are, for example, coordinated by Commission services outside the public health policy area. By showing these interlinkages, the report takes stock of EU efforts in the area of stronger health security, emphasising the importance of taking a 'One Health' approach[6]. The value of the 'One Health' approach is recognised by the EU and by many governments, organisations and global industries due to its critical impact on overall prevention, preparedness and risk assessment processes.

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[1] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU, OJ L 314, 6.12.2022, p. 26 (https://eur-lex.europa.eu/eli/reg/2022/2371/oj).

[2] Commission Decision establishing the Health Emergency and Response Authority, COM(2021) 6712 final.

[3] COM(2021) 380 final.

[4] COM(2022) 669 final.

[5] Article 9 of Regulation 2022/2371 provides that the Commission shall, by 27 December 2023 and every 3 years thereafter, transmit to the European Parliament and to the Council a report on the state of play and progress on prevention, preparedness and response planning at EU level.

[6] As defined in Article 3(7) of Regulation (EU) 2022/2371:
'One Health' means a multi-sectoral approach which recognises that human health is connected to animal health and to the environment, and that actions to tackle threats to health must take into account those three dimensions.

2. PREVENTION

Prevention is one of the essential steps in the crisis management cycle, comprising all activities that aim to minimise the burden of health threats and mitigate their associated risk factors. Regulation (EU) 2022/2371 firmly codified the notion of prevention in addition to preparedness and response, thus providing a strong legal basis for strengthening work in this area. Regulation (EU) 2022/2371 covers a wide scope of serious cross-border public health threats: from communicable diseases to chemical and environmental threats and threats of an unknown origin[7], thus creating an overarching and flexible framework for preparedness and response.

Vaccination as a key prevention measure

Vaccination is key to preventing the spread of infectious diseases. As shown during the COVID-19 pandemic, the EU Vaccines Strategy[8] ensuring support to the development of vaccines and their availability to all Member States and the national vaccination campaigns were able to substantially alter the course of events, saving tens of millions of lives globally (an estimated 20 million lives were saved in the first year alone [9]). COVID-19 is no longer considered a public health emergency of international concern[10], but the ECDC stresses that the continued roll-out of COVID-19 vaccines by countries (particularly targeting older adults and other medically vulnerable groups) remains essential in order to reduce severe disease, hospitalisations and deaths from the virus[11]. The Commission is supporting Member States in ensuring continued access to adapted COVID-19 vaccines.

The Commission also continues to be active in the field of vaccination policy beyond COVID-19, by supporting the Member States in increasing their vaccination coverage. The Commission's Communication and the Council Recommendation of 2018 on strengthened cooperation on vaccine-preventable diseases[12] referred to a number of priorities in this field, which have been implemented by the Commission on the basis of a publicly available roadmap[13]. For example, to counteract vaccine hesitancy in the population, which is a growing risk to public health, the Commission has launched initiatives such as behavioural studies[14,15]; the Coalition for Vaccination, bringing together EU health professionals' and students' associations to advocate for vaccination; as well as the European Vaccination Information Portal[16], which is an accurate source of information on vaccination for the general public. To continue those efforts, a subgroup of the Commission's Public Health Expert Group (PHEG)[17] is dedicated to vaccination. Moreover, the ECDC now offers online training to the public on vaccine hesitancy and misinformation via its Virtual Academy[18] and continues to host the National Immunisation Technical Advisory Group (NITAG) Collaboration of countries in European Economic Area (EEA), which assesses vaccination needs and advises national governments on vaccination strategies.

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[7] See Article 2(1) of Regulation 2022/2371.
[8] https://commission.europa.eu/strategy-and-policy/coronavirus-response/public-health/eu-vaccines-strategy_en
[9] https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00320-6/fulltext
[10] https://www.who.int/publications/i/item/9789241580496
[11] https://www.ecdc.europa.eu/en/publications-data/interim-public-health-considerations-covid-19-vaccination-roll-out-during-2023
[12] Council Recommendation of 7 December 2018 on strengthened cooperation against vaccine-preventable diseases, OJ C 466, 28.12.2018, p. 1–7 (https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=OJ%3AJOC_2018_466_R_0001).
[13] https://health.ec.europa.eu/system/files/2022-12/2019-2022_roadmap_en.pdf
[14] https://op.europa.eu/en/publication-detail/-/publication/8ba3bd75-7c38-11ed-9887-01aa75ed71a1/language-en
[15] https://knowledge4policy.ec.europa.eu/projects-activities/behavioural-insights-eu-bi4eu_en
[16] https://vaccination-info.eu/en
[17] https://health.ec.europa.eu/non-communicable-diseases/expert-group-public-health_en
[18] https://eva.ecdc.europa.eu/

Moving forward, the Commission is developing a vaccine strategy targeting priority threats for which the development of new vaccines or improvement of existing ones would be needed. In addition, the Commission's work on vaccination also has strong ties to Europe's Beating Cancer Plan[19], which is illustrated by an upcoming proposal for a Council Recommendation on vaccine-preventable cancers.

Cross-border sharing of vaccination data with healthcare professionals in their language

The MyHealth@EU infrastructure was launched to allow health professionals to access, in their language, electronic health data, including vaccination records, of patients travelling or moving from their home country to another Member State. The objective is to ensure continuity of care. Participation is voluntary (based on Directive 2011/24/EU on patients' rights in cross-border healthcare). As of July 2023, 11 Member States were already connected to MyHealth@EU and more are planning to join in the future. Under the Commission proposal for a regulation on a European Health Data Space, which is currently under negotiation by the co-legislators, the participation of Member States in the MyHealth@EU infrastructure would become mandatory. Under the EU4Health work programme 2023, direct grants to Member States' authorities are planned for the development and enhancement of MyHealth@EU services, including vaccination card services.

Monitoring vaccines on the EU market

Experience with COVID-19 has reiterated the importance of post-marketing monitoring of vaccines. The Vaccine Monitoring Platform was therefore launched as a collaborative space between the ECDC and the EMA to address research questions through large-scale EU-wide independent studies on vaccine effectiveness and safety monitoring. It is necessary to build capacity in the Member States and create the infrastructures, at both national and subnational levels, to enable the sustainable and long-term monitoring that is required to inform public health and regulatory decisions regarding vaccines on the EU market and their use in real-life settings.

Addressing antimicrobial resistance

Antimicrobial resistance (AMR) is the ability of microbes like bacteria, viruses and fungi to develop resistance and to overpower the medicines designed to kill them. AMR threatens to unravel modern medicine as we know it. The coming years will be crucial to ensure prudent use, access and development of effective antimicrobials and thus require greater awareness of the fight against AMR. It is estimated that at least 35 000 people die each year in the EU/EEA as a direct consequence of resistant infections. This is more than the combined total of deaths due to influenza, tuberculosis and HIV/AIDS, and this number is growing[20]. AMR is not as acutely in the public eye as COVID-19 was, but it is no longer a silent pandemic and needs urgent action to prevent the currently projected catastrophic outcomes.

Building on the 2017 EU action plan on antimicrobial resistance[21], in April 2023 the Commission proposed a Council Recommendation, adopted in June 2023[22]. It recommends measures to combat

[19] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2021:44:FIN
[20] https://www.ecdc.europa.eu/sites/default/files/documents/Health-burden-infections-antibiotic-resistant-bacteria.pdf
[21] https://health.ec.europa.eu/system/files/2020-01/amr_2017_action-plan_0.pdf
[22] Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach (2023/C 220/01), OJ C 220, 22.6.2023, p. 1–20.

AMR in the fields of human health, animal health and the environment through the 'One Health' approach. For the first time in the EU, the Recommendation sets EU and national targets to reduce the consumption of antimicrobial medicine and control the spread of critical pathogens in human health. Devised with the support of the ECDC, these recommended targets should serve as a driver of national action and monitoring of progress in the coming years.

Highlight: joint Action on AMR

The EU is also mobilising its financial resources to support effective AMR policies and measures. Over EUR 57 million was invested under the EU4Health programme in its first 3 years (2021-2023) in tackling AMR – most notably a new joint action on AMR to be launched in 2024 to bring together all EU Member States, Iceland, Norway and Ukraine in common activities to combat AMR. across the One Health approach.

To address increasing AMR, it is essential to ensure both access to existing antimicrobials and the development of novel effective ones. On 26 April 2023, the Commission adopted proposals for a new directive and regulation to revise and replace existing Union general pharmaceutical legislation[23]. These proposals contain measures to improve innovation and access to medicines in the EU, including antimicrobials. Some measures specifically address AMR, in conjunction with the above-mentioned Council Recommendation, which aim to strengthen the prudent use of antimicrobials and include 'transferable data-protection vouchers'[24] to incentivise the development of novel antibiotics. Eligibility for the voucher scheme would be restricted to novel antimicrobials that address AMR and the priority pathogens recognised by the World Health Organization (WHO). The Council Recommendation on stepping up EU actions to combat AMR also welcomed the Commission's intention to design an EU multi-country 'pull' incentive scheme to improve innovation, the development of new antimicrobials and access to existing and new antimicrobials, with financial support from the EU4Health programme[25].

As regards the availability of existing antibiotics and prevention of their shortages during the 2023 autumn and winter season, the Commission together with the EMA monitor the supply and demand of key antibiotics used in the treatment of respiratory infections.[26] Based on the results of this monitoring, the EMA Executive Steering Group on Shortages and Safety of Medicinal Products issued recommendations to ensure the availability of antibiotics at potential risk of shortages. As announced in the Communication on addressing medicine shortages in the EU[27], the Commission and EMA will continue to closely monitor the situation.

The Commission is further supporting the development of and access to preventive, diagnostic and therapeutic medical countermeasures against AMR through its work. This support includes funding international bodies such as the WHO, the Global Antibiotic Research & Development Partnership[28] and their joint initiative SECURE[29], which is working to develop new antibiotics[30]

(https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023H0622%2801%29).

[23] https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union/reform-eu-pharmaceutical-legislation_en

[24] The voucher will offer to the developer an additional year of data protection from competition for the medicine that the voucher is used for.

[25] https://health.ec.europa.eu/funding/eu4health-programme-2021-2027-vision-healthier-european-union_en

[26] See also below section on safe and effective medicinal products and medical devices.

[27] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Addressing medicine shortages in the EU, COM(2023) 672 final (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2023:672:FIN).

[28] https://gardp.org/

and vaccines against AMR infections[31]. HERA Invest, an EUR 100 million top-up to the InvestEU programme, which is geared towards small and medium-sized companies that develop medical countermeasures, will also address AMR.

At the same time, the EU's framework programme for research and innovation, Horizon Europe, is delivering on the objectives of the 2017 EU action plan and the 2023 Council Recommendation on AMR. In the past year it has provided support through a coordination and support action, DESIGN OH AMR (DESIGN One Health AntiMicrobial Resistance)[32], for the development of a European co-fund partnership on OH AMR research and innovation, to be launched in 2025, to which the EU is expected to contribute EUR 100 million.[33] It has also continued to provide funding resources for research and innovation actions on OH AMR of nearly EUR 200 million since the start of the Horizon Europe programme.[34]

Besides its efforts in human and animal health, the Commission continues to recognise the environment as a reservoir of resistance that needs further understanding as recognised in the EU Strategic Approach to Pharmaceutical in the Environment[35]. Through initiatives under the European Green Deal [36] and in particular the Zero Pollution Action Plan[37], the Commission has acted in several environmental domains. Regarding water, the Commission proposes to revise the list of pollutants in groundwater and surface water[38], including a number of AMR substances and AMR genes. The Commission proposal for a recast of the Urban Wastewater Treatment Directive[39] also establishes, among other measures, the monitoring of health parameters in urban wastewater, including the mandatory surveillance of AMR to enhance the EU's preparedness against pandemics or other major public health threats, as is currently being done for COVID-19.

Regarding soil, the Commission is looking into AMR genes in microorganisms in agricultural soils through survey LUCAS Soil 2018[40], with reports expected by the end of 2023. Preliminary results show that over 600 samples contained detectable levels of AMR genes[41]. The Commission, through its proposal on the Nature Restoration Law, also aims to act on increasing resilience against such genes by restoring the health of ecosystems that can act as a barrier to the spread of AMR. In addition, through LUCAS Soil 2018, the Commission is looking into antibiotics synthesis (ABG) genes in soils which can contribute to new medicines. The results of both AMR and ABG genes will be hosted in the EU Soil Observatory (EUSO)[42].

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[29] https://www.who.int/groups/secure-expanding-sustainable-access-to-antibiotics

[30] A total of EUR 8 million was provided under the action CP-g-06.7: 'Strengthening preparedness and response to cross-border health threats at global level' (EU4Health Work Programme 2021).

[31] The Commission has issued an EUR 82 million call for tenders: 'Speed up the Development of and Access to Innovative Medical Countermeasures'.

[32] https://www.jpiamr.eu/activities/one-health-amr/design-oh-amr/

[33] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-hlth-2024-disease-09-01

[34] Horizon Europe (europa.eu)

[35] eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52019DC0128

[36] https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal_en

[37] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021DC0400

[38] https://environment.ec.europa.eu/publications/proposal-amending-water-directives_en

[39] https://environment.ec.europa.eu/publications/proposal-revised-urban-wastewater-treatment-directive_en

[40] The Land Use and Coverage Area frame Survey (LUCAS) is a regular harmonised survey organised by the European Statistical Office (EUROSTAT) in cooperation with other Commission services, to gather information on land use and land coverage across all Member States.

[41] https://esdac.jrc.ec.europa.eu/projects/lucas

[42] https://esdac.jrc.ec.europa.eu/

Preventing zoonotic diseases such as avian influenza

Over 60% of emerging infectious disease threats are of zoonotic origin[43], so we must remain vigilant about the possibility of a next pandemic coming from an animal source.

The EU has relied on two main pieces of legislation to address infectious disease risks coming from animals. These are Directive 2003/99/EC[44], ensuring proper monitoring and evaluation of zoonoses, zoonotic agents and food-borne outbreaks, and Regulation (EU) 2016/429[45] (the 'Animal Health Law') which lays down rules for the prevention and control of zoonoses, including their early detection, notification and reporting.

The One Health approach has already been considered in EU actions for decades, but the COVID-19 pandemic underlined once again the importance of this approach for prevention, preparedness and response and the need for optimal coordination across sectors. Regulation (EU) 2022/2371 now explicitly calls for the One Health approach in addressing current and emerging crises.

Within months of the adoption of Regulation (EU) 2022/2371, the Health Security Committee[46] – the key EU body dealing with public health threats – held several joint meetings with the EU's Chief Veterinary Officers to discuss the threat of Highly Pathogenic avian influenza (HPAI) and the animal and human health measures needed to prevent the risk of zoonotic spillover to humans. HPAI is a major health threat and requires vigilance, early detection and a rapid and early response to any spillovers early on. The 2022/23 season saw one of the largest HPAI epidemics in wild birds and poultry in the EU to date and large outbreaks among mammals. The relevant EU legislation[47] provides that all Member States must carry out surveillance, to allow early detection of HPAI in birds and mammals. Animal health law ensures harmonisation of the measures that all Member States have to implement once the HPAI virus is detected in kept birds in order to prevent and control its spread; and provides the legal basis for the competent authorities to take the necessary measures when the virus is detected in mammals.

Since September 2017, the European Food Safety Authority (EFSA) and the ECDC have been mandated by the Commission to regularly assess, jointly with the EU Reference Laboratory for avian influenza in animal health[48], the HPAI epidemiological situation and the evolution of the genetic characteristics of HPAI viruses detected in animals. Scientific reports with the results of these assessments are published every 2 to 3 months[49] and present options for responding to the identified risks for animal and public health.

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[43] https://www.nature.com/articles/nature06536

[44] Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424EEC and repealing Council Directive 92/117/EC, OJ L 325, 12.12.2003, p. 31–40 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32003L0099).

[45] Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2006 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law'), OJ L 84, 31.3.2016, p. 1–208.
(https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R0429&qid=1699617422821).

[46] See also below section on Health Security Committee.

[47] https://eur-lex.europa.eu/eli/reg_del/2020/689/oj

[48] https://www.izsvenezie.com/reference-laboratories/avian-influenza-newcastle-disease/

[49] Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases, OJ L 174, 3.6.2020, p. 211–340 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020R0689&qid=1699963567960).

Together with some Member States, the Commission is working on the possibility of securing vaccines against zoonotic influenza in humans via the Joint Procurement mechanism. First shipments of such a vaccine to the Member States are planned for early 2024. The common purchase of zoonotic vaccines would strengthen the preparedness of the Member States in face of an (Avian) Influenza pandemic by adding up to the two existing framework contracts – also concluded under the Joint Procurement mechanism – for the reservation of over 110 million pandemic vaccine doses. The pandemic vaccine doses would be distributed to the Member States participating in the reservation contracts after the declaration of an influenza pandemic by the WHO.

Preventing climate-change- and environment-related health threats and preparing for them

The effects of climate change and environmental degradation were felt heavily in the summer of 2023, as extreme weather events caused devastating floods in Bulgaria, Croatia, Greece, Spain, Italy, Romania and Slovenia and a heatwave brought some of the hottest temperatures ever recorded in the EU. Public health action is needed to protect the most vulnerable in particular, and to prevent as many heat-related deaths as possible. The EU's fast-warming climate is also becoming increasingly suitable for certain climate-sensitive infectious diseases, notably vector-borne ones. Furthermore, climate change is accelerating permafrost thawing, which may release long-dormant microorganisms of concern.

Pandemic-prone pathogens that are also vector-borne, such as yellow fever, dengue, zika, chikungunya and West Nile fever, have been identified by HERA as priority threats and work is ongoing to expand the medical countermeasures arsenal by investing in the research and development of innovative medical tools for pandemic preparedness through the Horizon Europe and EU4Health programmes. For instance, the Commission is funding the Coalition for Epidemic Preparedness Innovations (CEPI) through the Horizon Europe Programme to carry out effectiveness and further scientific studies to expand the potential use of licensed chikungunya vaccines to children, immunocompromised people and pregnant women. The Commission is also exploring ways to support different vector-control measures (e.g. sterile insect techniques).

Other recent work to support health preparedness in relation to climate change and environmental risks includes *inter alia*:

- new products of the **European Climate and Health Observatory**[50]**,** operated by the European Environment Agency and the European Commission, released in 2023 (notably indicators, fact sheets and forecasts on heat health, infectious diseases, occupational health and air pollution);
- the **Declaration of the Seventh Ministerial Conference on Environment and Health (Budapest Declaration)**[51] of July 2023, which formulates political commitments and actions to address the health risks posed by climate change, pollution and biodiversity loss;
- the **COP28 Declaration on Climate and Health**, signed on the occasion of the first Health Day at the 28th session of the Conference of the Parties to the United Nations Framework Convention on Climate Change (COP28) on 2 December 2023[52];
- the launch of a major update of the **guidance on heat health action plans for the WHO European Region**[53], which the EU supports under its LIFE programme[54];

[50] https://climate-adapt.eea.europa.eu/en/observatory
[51] https://www.who.int/europe/publications/i/item/EURO-Budapest2023-6
[52] https://www.cop28.com/en/cop28-uae-declaration-on-climate-and-health
[53] https://www.who.int/publications/i/item/9789289071918

- the development of the first-ever **EU Climate Risk Assessment**[55], which would include dedicated chapters on health and is scheduled to be published by the European Environment Agency in spring 2024;
- publication of an integrated **zero pollution monitoring and outlook** report in December 2022, whose bi-yearly updated data will regularly feed the Cancer Inequalities Registry and the Atlas of Demography, to better identify trends in relation also to other pollution-related diseases, enable people to compare how much pollution affects their health across EU regions and help targeting interventions at EU, national and local level to enhance cost-effectiveness and preparedness.

In the framework of the zero-pollution action plan, the Commission has taken further action to tackle air, water and soil pollution. Despite significant improvements in air quality during the past few decades, air pollution continues to be the largest environment-related health risk, with significant associated mortality (with estimated more than 230.000 premature deaths in the EU each year) and morbidity.[56] The Commission on 26 October 2022 proposed to align EU air quality standards more closely with WHO recommendations as key element to its zero-pollution policy package.[57]

In addition to the already mentioned proposals on wastewater treatment and water pollutants[58], the Commission has also adopted proposals on the revision of the Industrial Emissions Directive[59], as well as a new Soil Health and Resilience Directive[60] that both aim to bring tangible health benefits.

3. PREPAREDNESS

Preparedness – having the structures and capacities in place at national and EU level to effectively anticipate, respond to and recover from public health threats – is an essential element in the EU's health security framework. Failing to prepare is preparing to fail.

Preparedness, reporting and assessment: stronger requirements

The recent adoption of Regulation (EU) 2022/2371 has allowed preparedness activities to be strengthened at EU level and both within and across Member States. Most notably, the Regulation requires expanded reporting on national preparedness planning and introduces the possibility of EU review and assessment of national preparedness capacities to ensure that they are adequately maintained. A new reporting cycle has been introduced: expanded reporting on preparedness capacities of Member States to the Commission, followed by assessments carried out by the ECDC and a Commission report to the European Parliament and the Council. The first implementing act under the Regulation was adopted in September 2023, providing the specifications for the Member States reporting on prevention, preparedness and response planning at national level[61].

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[54] https://cinea.ec.europa.eu/programmes/life_en

[55] https://www.eea.europa.eu/en/about/who-we-are/projects-and-cooperation-agreements/european-climate-risk-assessment

[56] See, for example, https://www.eea.europa.eu/publications/air-quality-in-europe-2022/health-impacts-of-air-pollution

[57] https://ec.europa.eu/commission/presscorner/detail/en/ip_22_6278

[58] See section on AMR above.

[59] https://environment.ec.europa.eu/publications/proposal-revision-industrial-emissions-directive_en

[60] https://environment.ec.europa.eu/topics/soil-and-land/soil-health_en

[61] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2023:234:TOC

The Regulation also introduces the Union Prevention, Preparedness and Response plan, which will be developed in 2024. The plan will cover work and activities related to health preparedness and response, across all Commission services, the Council and EU agencies and bodies, as well as interactions and coordination with relevant international bodies.

In close cooperation with the Member States, the Commission is also strengthening emergency health planning via the Union Civil Protection Mechanism (UCPM)[62]. This is done by developing specific emergency health preparedness and response plans, such as the burns preparedness plan[63], which outlines the medical evacuation guidelines to follow in the event of a disaster involving mass burn patients. In addition, the Commission is developing, under the UCPM and in close cooperation with Member States, two EU-wide disaster scenarios focusing entirely on the scenario of a health emergency, such as a pandemic or nuclear disaster[64].

The Commission has also, in its Communication adopted in the context of the 2023 European Semester on the Annual Sustainable Growth Survey 2023[65], underlined the need for increased vigilance and investment in all Member States to ensure that health systems are suitably prepared to deal with future health crises.

Training and testing of preparedness capacities

Training and capacity building

The EU PREPAREDNESS project, which is funded by the EU4Health programme, is intended to develop and deliver a training programme in 30 countries. It will help strengthen crisis preparedness and surveillance capacities and facilitate cross-country collaboration between experts in public health and other sectors.

Moreover, under the UCPM, a number of medical field exercises have been organised to test the coordination and inter-operability of Emergency Medical Teams.

A training programme on management of medical countermeasures needed for preparedness for and response to serious cross-border health threats is also being developed. Initial training activities are focusing on stockpiling, procurement and supply-chain constraints and will be complemented with simulation exercises to test and improve coordination and response frameworks.

Training and capacity-building in the Member States are aspects of preparedness where the EU can offer added value. Training activities are organised by the Commission in close cooperation with the relevant EU agencies and bodies, as well as professional and patient organisations. These activities provide healthcare and public health staff with the knowledge and skills necessary to develop and implement the national prevention, preparedness and response plans.

In addition, resilience-testing of health systems against specific shock scenarios (e.g. pandemics, heat waves and shortage of health workers) can improve crisis preparedness. A project, co-led by the Organisation for Economic Co-operation and Development (OECD) and the European Observatory on Health Systems and Policies and supported by the EU4Health programme, is

[62] The UCPM includes both Member States and 10 non-EU participating states.
[63] SWD(2020) 3 final.
[64] Europe-wide disaster scenarios are one of the flagship initiatives from the Commission's EU Disaster Resilience Goals introduced in February 2023: https://civil-protection-humanitarian-aid.ec.europa.eu/what/civil-protection/european-disaster-risk-management/european-disaster-resilience-goals_en.
[65] COM(2022) 780 final.

developing a resilience-testing methodology for health systems. The methodology will enable Member States to regularly review health crisis preparedness and test their health systems' resilience against specific high-pressure scenarios and long-term structural challenges.

Preparedness in medical countermeasures

Preparedness in medical countermeasures entails strategic coordination for their development. In July 2022, the Commission concluded the first prioritisation exercise to identify the top three health threats for which medical countermeasures should be available in case of need, and that require coordination of measures at EU level: (1) pathogens with high pandemic potential; (2) chemical, biological, radiological, and nuclear threats; and (3) threats resulting from antimicrobial resistance[66]. The Commission's HERA has been tasked to contribute to the development, production and distribution of medical countermeasures in case of emergency. Ensuring efficient procurement and stockpiling of medical countermeasures remain key elements of a good preparedness strategy.

The Joint Procurement Agreement for Medical Countermeasures (JPA), which was concluded in 2014 as a response to the A/H1N1 influenza pandemic, has played an essential role in helping Member States to obtain critical medical products and supplies during the COVID-19 pandemic (therapeutics against COVID-19, personal protective equipment, ventilators, vaccination supplies, testing devices, etc.) through more than 200 contracts with a total value exceeding EUR 12 billion[67]. The Commission, Member States and other JPA signatory countries are now building on this experience of cooperation during an emergency in order to enhance the use of the JPA for preparedness and response. As announced in the Communication on addressing medicines shortages in the EU, the Commission will also look at using joint procurement for antibiotics and treatments for respiratory viruses ahead of winter 2024/2025.

Joint procurement for influenza vaccines

15 JPA signatory countries are taking part in the joint procurement of highly pathogenic influenza vaccines. The purpose is to vaccinate vulnerable target groups, such as farm workers, in order to help prevent the transfer of the virus from birds and animals to humans, and, thereby, a potential avian influenza outbreak.

The JPA also remains an important instrument for jointly reserving and securing the pandemic influenza preparedness vaccines. There are currently two standing contracts under the JPA for such vaccines. The Commission will by the end of 2024 consult the Member States and other JPA signatory countries on their willingness to renew such contracts within the framework of the JPA.

The JPA can be used flexibly and thereby, play an important role in health crisis preparedness by facilitating access for the Commission and the Member States to preparedness-relevant medical countermeasures, including novel or rare medical countermeasures.

Regulation (EU) 2022/2371 introduced a refined framework for joint procurement, including the possibility for the Commission to propose an exclusivity clause for a particular joint procurement (i.e. once countries have opted to participate in an EU joint procurement, they must refrain from carrying out a parallel national procurement for the same medical countermeasure). In justified

[66] https://health.ec.europa.eu/publications/hera-factsheet-health-union-identifying-top-3-priority-health-threats_en
[67] https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health_en#ensuringtheavailabilityofsuppliesandequipment

cases (and if all participating Member States and other JPA countries agree), applying the exclusivity clause should strengthen the EU negotiating position and security of supply. The Commission will have to carry out a preliminary joint procurement assessment indicating the general envisaged conditions of the joint procurement procedure, including as regards the possible need for exclusivity on a case-by-case basis.

Anticipating potential threats to, and vulnerabilities of, the supply chains of medical countermeasures is an important factor in preparedness, as is stockpiling and facilitating the development of new and improved medical countermeasures. In 2022, the Commission launched EU FAB, a network of 'ever-warm' vaccine production capacities that can be quickly activated in the event of a public health emergency. On 30 June 2023, four EU FAB contracts were signed with pharmaceutical manufacturers to reserve the capacity to produce up to 325 million vaccines of different types annually. The Commission also stockpiles medical countermeasures under rescEU – an EU-funded strategic reserve of last resort, from which Member States and associated countries can request assistance. To date, EUR 1.2 billion has been invested in building up stockpiles against serious cross-border health threats, including chemical, biological, radiological and nuclear (CBRN) threats. The first call for tender in 2022 led to France, Croatia, Poland and Finland being chosen to host the stockpiles. The results of the second call will be announced in late 2023.

3. SURVEILLANCE AND EARLY WARNING SYSTEMS

Public health surveillance of communicable diseases

Without public health surveillance, we would be unable to monitor trends of communicable diseases, to detect outbreaks early on or to evaluate the effectiveness of public health measures and policies. This was yet another key aspect of public health whose importance was emphasised during the COVID-19 pandemic. A recent study [68] has looked into lessons learnt from surveillance in the EU during the COVID-19 pandemic. There remains some variation in the quality of the data reported by the Member States across disease areas, despite the ECDC's efforts to provide methodological support to the Member States and reporting protocols. There is also room for improvement when it comes to technological advances, such as digital platforms for surveillance, notwithstanding the major efforts made during the pandemic years.

Regulation (EU) 2022/2371 introduces a new high-performing epidemiological surveillance system at EU level. This incorporates using artificial intelligence and digital tools for data validation, analysis and automated reporting, ensuring accurate modelling and risk assessments. To complement epidemiological surveillance of communicable diseases, Regulation (EU) 2022/2371 requires Member States to step up their reporting of health systems indicators, including health system capacity (e.g. hospital bed availability, specialised treatment and intensive care capacity, and the number of medically trained staff). The Commission is revising the list of communicable diseases and special health issues (e.g. AMR) that are notifiable at EU level. The updated list is planned to be in place by mid-2024. The Commission is supporting the upgrade of the Member States' national surveillance systems by providing nearly EUR 100 million in direct grants for infrastructure development, capacity-building and specific national priorities.

[68] See 'Surveillance during the COVID-19 epidemic and other epidemics: lessons learnt', https://www.nivel.nl/en/project/1920.

Strengthening laboratory capacities for surveillance and development of medical countermeasures

EU reference laboratories in the area of public health

Another novelty brought by Regulation (EU) 2022/2371 is the creation of EU reference laboratories (EURLs) for public health, to provide support to national reference laboratories and to promote good practice and alignment on a voluntary basis regarding diagnostics, testing methods and the use of certain tests for the uniform surveillance, notification and reporting of diseases by Member States. The Commission and the ECDC are working closely together in the implementation of the EURLs. The first six EURLs will be designated in early 2024 and funded under the EU4Health programme[69].

DURABLE

The Commission launched the DURABLE laboratory network project (2023-2027)[70] composed of public health and academic laboratories to support the research and development of medical countermeasures. DURABLE, funded under the EU4Health programme, mobilises the experimental capacities of its members to speed up the development of medical countermeasures, including diagnostics, therapeutics, and vaccines. DURABLE has a global focus, thanks to the participation of members with laboratory capacities around the world and is complementary to the EURLs.

Modern enhanced digital platforms for surveillance

The rapid development of digital tools is facilitating timely data-collection and sharing. To strengthen EU surveillance systems, Regulation (EU) 2022/2371 also enhances the use of digital platforms.

In June 2021, the ECDC launched the European surveillance portal for infectious diseases (EpiPulse), a platform for enabling real-time surveillance of infectious diseases[71]. EpiPulse is an online portal for EU/EEA public health authorities and partner organisations to collect, analyse, share and discuss infectious disease data. It supports threat detection, monitoring, risk assessment and outbreak response. EpiPulse will be further developed to take into account the requirements of Regulation (EU) 2022/2371 and will also integrate other reporting tools such as the European Surveillance System for indicator-based surveillance (TESSy)[72]. The ECDC is working on integrating Epidemic Intelligence from Open Sources (EIOS) – a key threat-detection tool that has been developed in collaboration with the WHO[73] – with EpiPulse in order to streamline the threat-detection, monitoring and assessment process.

The Commission is developing the ATHINA (Advanced Technology for Health INtelligence and Action)[74] IT system to support its daily threat-assessment activities and to generate useful insights for decision-making. ATHINA will help the Commission to detect relevant signals on possible

[69] https://health.ec.europa.eu/health-security-and-infectious-diseases/surveillance-and-early-warning/eu-reference-laboratories-public-health-calls-application_en
[70] https://www.pasteur.fr/en/home/institut-pasteur/institut-pasteur-throughout-world/international-research-programs/durable-large-scale-project-emerging-diseases-within-eu4health-european-program
[71] https://www.ecdc.europa.eu/en/publications-data/epipulse-european-surveillance-portal-infectious-diseases
[72] https://www.ecdc.europa.eu/en/publications-data/european-surveillance-system-tessy
[73] https://www.who.int/initiatives/eios
[74] https://health.ec.europa.eu/latest-updates/hera-it-system-athina-collect-intelligence-and-assess-threats-call-tender-published-2023-04-25_en

health threats that require a medical countermeasure response based on supply chain analysis and identified vulnerabilities in the supply of medical countermeasures, including the risk of shortages and strategic dependencies. To this end, ATHINA will gather intelligence by exchanging data on medical countermeasures and public health threats with relevant databases (e.g. those of the ECDC and the EMA); reusing existing systems (e.g. the WHO's EIOS platform) and other sources; and ensuring interoperability among digital solutions.

Unlocking the power of health data

The proposal for a regulation on a European Health Data Space is intended to unlock the power of health data by enabling the reuse of electronic health data for research, innovation, official statistics, policy-making and regulatory activities. This includes the reuse of health data for surveillance purposes in order to protect against health threats or ensure high standards of quality and safety of healthcare and of medicinal products and medical devices. To develop and deploy the EU's infrastructure for the secondary use of health data, HealthData@EU was launched in October 2022 as a two-year pilot project. It will test the infrastructure for the secondary use of health data on use cases. Examples include focusing on AMR surveillance and test use, hospitalisations, and vaccination adherence in vulnerable subpopulations. The ECDC will also participate in the project by assessing the use of the infrastructure for public health surveillance.

Boosting integrated One Health surveillance systems

The Commission is supporting integrated One Health surveillance systems that cover the links between human and animal health and the environment. One of these is the EUR 7.8 million joint action 'Union and National Capacity Building for IntegraTED Surveillance (UNITED4Surveillance)'[75], funded under the EU4Health programme and launched in February 2023 with national competent authorities to promote the integration of surveillance systems at EU level by supporting improvements in national surveillance systems. UNITED4Surveillance focuses on defining guidelines for integrating different sources of electronic health data and digital registers/databases, surveillance capacity-building within the EU and beyond, and improving global health security.

In addition, another EUR 20 million direct grant has been made available to Member States for a coordinated surveillance system under the One Health approach for cross-border pathogens[76]. This grant will help Member State authorities to contribute to the setting-up and scaling-up of animal and environmental surveillance system for zoonoses, including the systematic ongoing collection and assessment of data by EFSA in collaboration with the ECDC. It will provide the animal health and environmental elements to complement the above action on the human side, for a One Health integrated surveillance.

The Commission will be launching a feasibility study in early 2024 on integrated surveillance systems for AMR and antimicrobial use from the human, veterinary and environmental sectors. This study will support Member States in developing integrated surveillance systems to efficiently and rapidly detect emerging resistant infections and outbreaks; and also to determine trends in, and the toxicity of, the presence of AMR genes and antimicrobials in soils and waters. This will enhance the understanding of the complex epidemiology of AMR to guide future policy recommendations to respond to AMR risks before they become large-scale emergencies.

[75] https://united4surveillance.eu/

[76] CP-g-22-04.01. The singnature of the grants is expected towards the end of 2023.

Wastewater: a source for public health surveillance

During the COVID-19 pandemic, wastewater-based surveillance of SARS-CoV-2 and its variants emerged as a powerful supplementary source of information on the presence of the virus and for an epidemiological investigation of the virus's spread in the EU, enabled through the Digital European Exchange Platform (DEEP). HERA and the Joint Research Centre (JRC) are supporting a joint action to strengthen national capacities for pathogen prioritisation, sampling and integration of wastewater data into surveillance for public health decision-making and the establishment of an EU sentinel system to test wastewater samples when needed. Moreover, HERA is leading the process of setting up a global consortium for wastewater surveillance for public health – a network of stakeholders and authorities worldwide to provide comprehensive real-time monitoring in strategic locations that can help identify emerging risks and enable prompt action.

Horizon 2020 research projects like MOOD[77] and VEO[78] have contributed to the development of innovative approaches to improving disease surveillance through a One Health approach, using multisource big data and data on drivers of disease emergence, including human movements and climate change. PHIRI[79] has developed a health information portal that centralises health and healthcare data and allows researchers to link and use different data sources from across the EU.

Early warning systems

The EU's Early Warning and Response System (EWRS) was set up in 1998 (Decision No 2119/98/EC)[80]. It is a restricted access tool used to notify alerts and monitor public health threats. Over the years, it has been the channel for the rapid notification of thousands of alerts. The Commission posted the first alert on COVID-19 back in early January 2020. To align with Regulation (EU) 2022/2371, the EWRS is to be restructured according to the main categories of health threats, i.e. related to biological, chemical and environmental sources as well as those of unknown origin.

A preparatory action[81] for the EWRS's new development is currently being implemented. The aim is to address the priorities for further development of the EWRS in line with Regulation (EU) 2022/2371: introducing new governance, architecture and functionalities to support the expansion of structures and new user-groups and roles; reinforcing security and data protection following a data-protection impact assessment; developing new modules to support preparedness and response planning and reporting and crisis management capabilities; and improving user-support services (training and integrated user guidance). Under this action, the feasibility assessment for interlinkage with the EU and other international alert and information systems is currently being finalised. 13 such systems were assessed and 10 will be prioritised for interlinkage with EWRS. To ensure interoperability with other alert information systems, the EWRS taxonomy for biological, chemical and environmental threats is also under review.

Coordination with other alert systems is essential when faced, for example, with food-borne pathogens (e.g. the case of resistant salmonella in chocolate eggs in 2022) or zoonoses, such as

[77] https://mood-h2020.eu/
[78] https://www.veo-europe.eu/
[79] https://www.phiri.eu/
[80] Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community, OJ L 268, 3.10.1998, p.1–7 (https://eur-lex.europa.eu/eli/dec/1998/2119/oj).
[81] Specific contract with Alboris Consortium under the BEACON FWC DIGIT/2020/OP/0005 – BEACON Lot 2.

avian influenza (as mentioned earlier in this report). Upcoming changes called for by Regulation (EU) 2022/2371 include EWRS interoperability with other systems such as (i) the EU Animal Diseases Information System (ADIS) in order to monitor infectious animal diseases; (ii) the Rapid Alert System for Food and Feed (RASFF) for risks to public health resulting from the food chain; (iii) WebECURIE, the EU early notification and information exchange system in the event of a radiological emergency including nuclear accidents; (iv) RASCHEM for threats of a chemical nature; and (v) the safety-gate for threats of a biological or chemical nature in non-food consumer products. The EWRS is also to be interoperable with EpiPulse for the notification of alerts and exchange of epidemiological summaries or risk assessments as part of the EWRS situation awareness module.

Within the Commission, ARGUS is the main crisis management and coordination mechanism. It ensures that relevant information from Commission services and EU agencies, as well as from the Member States, is collected and used to form a timely and up-to-date situational picture to help contingency planning, appropriate coordination and decision-making. During the COVID-19 pandemic, ARGUS was instrumental in coordinating the Commission's participation in meetings of the Council's Integrated Political Crisis Response mechanism (IPCR), where the Commission and Member States extensively discussed key issues such as the use of the Emergency Support Instrument, green lanes, health protocols for transport and contact-tracing, measures for travel into and within the EU, Re-Open EU, joint procurement for vaccines and vaccines-sharing, the EU Digital COVID Certificate, and communication and fighting disinformation. ARGUS and EWRS interlinkage has been effective since 2022, ensuring the exchange of information on serious cross-border threats to health with the EU crisis managers. ARGUS was also the channel for coordinating the Integrated Situational Awareness and Analysis (ISAA) reports, which were a key instrument to promote shared situational awareness during the COVID-19 pandemic.

Contact-tracing: the European Federation Gateway Service and Passenger Locator Forms

At the time of the COVID-19 pandemic, 22 public health authorities launched national tracing and warning apps as part of a package of measures to prevent the spread of the virus. In October 2020, EU Member States and the Commission launched the European Federation Gateway Service (EFGS) to allow for the interoperability of national apps throughout the EU. By autumn 2021, 19 Member States were exchanging risk contact information through the EFGS, representing tens of millions of active users in the EU and the rest of Europe.

In April 2022, the EFGS was transferred to the ECDC. This reinforced the EU's digital contact-tracing capabilities, in line with the ECDC's new mandate, by pooling the necessary expertise at the ECDC. The EFGS has since been withdrawn from service, but the ECDC and the Commission have prepared a reactivation procedure to make it available to the EU Member States should the need arise.

Between 1 June 2021 and 31 May 2022, a Passenger Locator Forms' Exchange Platform (ePLF)[82] was made available to connect Member States and enable the secure exchange of passenger data for cross-border contact tracing in all transport modes in the EU.[83] Based on feedback from Member States, the Commission started to work with the ECDC on the technical integration between the

[82] Established through the two implementing acts adopted by the Commission in May (C/2021/3921) and July 2021 (C/2021/5595).

[83] At its peak, the ePLF connected five Member State: Italy, Malta, Slovenia, Spain and – for a short period – France. Yet its actual use remained very limited, with only 256 messages exchanged between end 2021 and early 2022.

EWRS selective exchange functionality and the ePLF, thereby enabling their interoperability.[84] While the ePLF as such has been terminated, the insights gained through its development and the integration with the EWRS selective exchange functionality make the EU better equipped in case of future needs.

4. RESPONSE

During the very early phases of the COVID-19 pandemic, the Crisis Coordination Committee (CCC) was convened through ARGUS on 23 January 2020 to discuss situational updates as well as possible courses of action. These CCC meetings were chaired by Commissioner Lenarčič and the Secretary-General and attended by all relevant Directorates-General and EU Agencies. Numerous additional coordination meetings have been subsequently called in the framework of the Commission crisis management response mechanism at all levels, from daily calls of the President with relevant Commissioners, to more operational coordination at Directors-General or services level.

In the aftermath of the COVID-19 pandemic, a number of improvements were made to the EU's mechanisms for responding to serious cross-border threats to health. Key ones are based on Regulation (EU) 2022/2371 and include a strengthened role for the EU Health Security Committee and a newly established EU capacity to declare a public health emergency at EU level.

EU Health Security Committee

The EU Health Security Committee (HSC) is a key forum for exchanging information on serious cross-border health threats at EU level. It is made up of representatives from the Member States' health authorities. Created back in 2001 in the aftermath of the 9/11 attacks, the HSC has been facilitating the coordination of public health measures across the EU over the years, culminating in weekly meetings during the height of the COVID-19 pandemic[85]. The HSC played a key role in decisions regarding public health measures. Examples during the COVID-19 pandemic include coordination on vaccination strategies, testing and surveillance and risk communication. Subsequent health crises in which the HSC met regularly and made an important contribution to the coordination of response include the Ebola outbreak in Uganda and the MPOX outbreak in the EU in 2022, as well as close coordination on the threat of avian influenza in 2023 (often jointly with the HSC's counterparts in animal health such as the EU Chief Veterinary Officers).

A change introduced by Regulation (EU) 2022/2371 is the empowerment of the HSC to formally adopt opinions and guidance. During the pandemic, the HSC issued a number of opinion papers, crystallising the views of the Member States on particular topics. These opinions contributed to the decisions of the Council's IPCR, such as it established coordinated measures on travel from China into the EU in response to a deterioration in China's COVID-19 situation.

[84] As a result of this effort, messages sent by Member States connected to the ePLF could be technically delivered to Member States using the EWRS selective messaging functionality. Work is still ongoing within the ECDC to enable messages sent through the EWRS selective exchange functionality to be received by the Member States using the ePLF if the system is to be activated again during a future crisis.

[85] https://health.ec.europa.eu/health-security-and-infectious-diseases/crisis-management/list-authorities-represented-health-security-committee/health-security-committee-reports_en

First HSC opinion, only days after the entry into force of Regulation (EU) 2022/2371

The first test for the newly empowered HSC came with the record levels of COVID-19 cases in China at the end of 2022 that resulted from relaxation of Chinese domestic measures. The HSC issued its first opinion under the Regulation as early as 5 January 2023, only 10 days after the Regulation's entry into force. It contained several proposed steps for a staged, phased and proportionate common EU approach to mitigate any potential risks, which served to underpin further political decisions in the Council's IPCR.

The latest opinion[86] of the HSC focuses on the need for continued vigilance around COVID-19, seasonal flu and other viruses that are circulating in the autumn/winter season.

Public health emergency at Union level

Until 2022, the EU relied entirely on the WHO's assessment of pandemic situations and declaration of a public health emergency of international concern. Regulation (EU) 2022/2371 has now empowered the Commission to formally recognise a public health emergency at Union level, when a serious cross-border threat to health is considered to endanger public health in the EU. Once a public health emergency at Union level is recognised, one or more measures of Regulation (EU) 2022/2372 may be activated if that is appropriate to the economic situation, which includes the establishment of a Health Crisis Board to ensure coordination and integration of approaches to crisis-relevant medical countermeasures at EU level, and which may include the establishment of mechanisms for the monitoring, activation of emergency funding, procurement and purchase of crisis-relevant medical countermeasures and raw materials; the activation of EU FAB facilities, the activation of emergency research and innovation plans, and the use of Union-wide clinical trial networks and provisions and platforms for the rapid sharing of data; and measures concerning the production of crisis-relevant medical countermeasures. The recognition of public health emergency also enables the introduction of measures related to medicinal products and medical devices, provided for in Regulation (EU) 2022/12, activation of support from the ECDC to mobilise and deploy experts to the affected areas under an EU Health Task Force, and activation of the Council's IPCR.

Public health risk assessment

The first step in responding to an emerging cross-border health threat is to assess its magnitude and associated risks. Regulation (EU) 2022/2371 expands the scope of EU agencies and bodies involved in public health risk assessments and defines their role and input. The Regulation references the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA), the European Food Safety Authority (EFSA), the European Chemicals Agency (ECHA), the European Environment Agency (EEA), the European Monitoring Centre for Drugs and Drug Addiction and the European Union Agency for Law Enforcement Cooperation (EUROPOL).

To support the Commission in the decision-making process regarding the formal recognition of such an event, Article 24 of Regulation (EU) 2022/2371 envisages the establishment of an Advisory Committee on public health emergencies. The Commission decision setting up the Advisory Committee was adopted in September 2023[87] and the final designation of the committee is planned

[86] https://health.ec.europa.eu/publications/preparing-winter-20232024-address-respiratory-infections-caused-sars-cov-2-and-other-viruses_en

[87] Commission Decision of 11.9.2023 setting up the group of experts 'Advisory Committee on public health emergencies' (C(2023) 6017) (https://ec.europa.eu/commission/presscorner/detail/en/mex_23_4442).

for spring 2024. The Advisory Committee will be a multidisciplinary expert group that can advise the Commission and the Health Security Committee on public health, biomedical, behavioural, social, economic, cultural and international aspects. It will include representatives of the ECDC and the EMA as permanent observers. Representatives of the WHO may also participate as observers. The representatives of other EU agencies and bodies relevant to the specific threat may participate in the Advisory Committee as non-permanent observers. In addition, and on an ad hoc basis, the Commission may invite, or Member States may propose, the appointment of experts with relevant expertise to take part in the committee's work, in particular from the countries where the threat has arisen.

In addition, EU emergency response capacities, not limited to public health, are maintained under the UCPM where the Commission, in close cooperation with the Member States, not only ensures emergency response coordination for products and medicinal devices, but also coordinates fully equipped and self-sufficient emergency medical teams at EU level. If the medical capacities of a country affected by an emergency are insufficient, the UCPM can mobilise different emergency medical support from its European Civil Protection Pool (ECPP), including emergency medical teams (EMTs).

As part of rescEU, EUR 106.2 million has been allocated to eight countries to develop new rescEU EMTs. The objective is to boost emergency medical support to populations affected by large-scale natural or human-induced disasters. This rescEU EMT capability will gradually become operational as of 2024 and will allow a response to a wide range of disaster scenarios. The teams will be able to operate autonomously and support existing national healthcare facilities in case the latter are not able to cope with a given emergency. Furthermore, rescEU also entails medical evacuation MEDEVAC) capacities in case of emergency needs for patients affected by highly infectious diseases, including dedicated planes.

Safe and effective medicinal products and medical devices

The COVID-19 pandemic reiterated the importance of ensuring the safety and the effectiveness, as well as the availability, of medical devices, diagnostics and medicines at times of health crisis.

Even outside emergency situations, Regulations (EU) 2017/745 and 2017/746 on medical devices and diagnostics have created a robust regulatory framework, which harmonises and strengthens requirements for manufacturers. These regulations ensure that medical devices on the EU market are safe and effective. During the COVID-19 pandemic, the EU market was flooded with rapid antigen tests, which were not required to undergo independent third-party review. With the new regulatory framework (applicable since May 2021 for medical devices and May 2022 for diagnostics), medical devices must undergo a more stringent conformity assessment before they can be placed on the EU market. At the same time, Member States may in exceptional situations grant derogations from conformity assessment if this is in the interest of public health (Article 59 of Regulation (EU) 2017/745 and Article 54 of Regulation (EU) 2017/746).

In addition, supply issues of medicines are an ongoing concern in the EU and affect all EU Member States outside a declared public health emergency or a major event. A multifaceted system is in place to mitigate shortages. That system was also activated when the EU suffered shortages of antibiotics in the winter of 2022/2023. To ensure that a similar situation does not recur, the Commission and EMA continuously monitor the planned supply of, and estimated demand for, a set of key antibiotics, in order to proactively identify any gaps in supply capacities. In October 2023, the Commission adopted a communication on addressing medicine shortages in the EU, which aims

to strengthen security of supply in the EU with complementary actions to further improve the availability and security of supply of medicines.

Since the introduction of a strengthened mandate for the EMA in 2022[88], the EMA has put in place new bodies and structures to provide a quick response to medicine shortages. The Executive Steering Group on Shortages and Safety of Medicinal Products and the Executive Steering Group on Shortages of Medical Devices were created to coordinate EU actions to mitigate supply issues with medicines and medical devices. In addition, there are now two Single Point of Contact (SPOC) Working Parties to monitor and report on shortages, for both medicine and medical device shortages. There is also an industry single point of contact (i-SPOC) network to provide guidance to holders of marketing authorisations. A European Shortages Monitoring Platform is expected in 2025, to facilitate the collection of information on shortages and on the supply of and demand for medicinal products.

EU stockpiles for emergency response

Under the UCPM's rescEU reserve, the Commission has established since 2020 stockpiling capacities of medical countermeasures for preparedness and response to serious cross-border health threats as well as CBRN threats. The medical stockpiling reserve enables the swift delivery of medical equipment such as ventilators and personal protective equipment. More than 3 million protective masks, ventilators and other equipment from the strategic rescEU distribution centres were distributed to Member States that needed them most. 10 Member States (Belgium, Croatia, Denmark, Germany, Greece, Hungary, Romania, Slovenia, Sweden, and the Netherlands) currently host the rescEU medical stockpiles.

In parallel, in February 2023 the Commission awarded EUR 545.6 million in grants for rescEU stockpiles for chemical, biological and radiological (CBRN) emergencies. These will include antidotes, antibiotics, vaccines, sedatives and prophylactic treatments and specific CBRN response equipment, such as iodine thyroid blocking (ITB) tablets, detectors and decontamination supplies and personal protective equipment. The stockpiles will be progressively available from 2023 onwards. To further bolster preparedness, there is currently an open call to develop further medical and CBRN stockpiles with an indicative budget of EUR 636 million, with 9 proposals currently under evaluation.

Protecting critical infrastructure and enhancing the resilience of critical entities

Directive (EU) 2022/2557 on the resilience of critical entities[89] (the CER Directive) entered into force in January 2023 and will replace Directive 2008/114/EC on the identification and designation of European critical infrastructures[90] as of 18 October 2024. The CER Directive applies to 11 sectors, enhancing the resilience of the entities operating essential services within those sectors, including health.

[88] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, OJ L 20, 31.1.2022, p. 1–37 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0123).

[89] Directive (EU) 2022/2557 of the European Parliament and of the Council on the resilience of critical entities and repealing Council Directive 2008/114/EC, OJ L 333, 27.12.2022, p. 164 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022L2557&qid=1699961915719).

[90] Council Directive 2008/114/EC of 8 December 2008 on the identification and designation of European critical infrastructures and the assessment of the need to improve their protection, OJ L 345, 23.12.2008, p. 75 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008L0114&qid=1699961985226).

In September 2023, the Commission adopted a proposal for a Council recommendation[91] on a blueprint to coordinate an EU-level response to disruptions of critical infrastructure with significant cross-border relevance. This will complement the current framework on critical infrastructure protection and resilience of critical entities by explaining the interplay between different existing EU-level arrangements and putting forward the elements of a coordinated EU-level response in the event of a significant critical infrastructure incident.

Emergency task forces

EU Health Task Force

Under Regulation No 851/2004 establishing a European centre for disease prevention and control as amended by Regulation (EU) 2022/2370, the ECDC is to set up the EU Health Task Force to provide rapid on-demand support in the event of emergencies along with assistance to Member States with the preparation of plans related to prevention, preparedness and response planning, local responses to outbreaks of communicable diseases and after-action reviews in EU and non-EU countries, in cooperation with the WHO. The EU Health Task Force will include experts from the Member States, ECDC staff, current and former fellows of the European Programme for Intervention Epidemiology Training and a newly established list of experts. The EU Health Task Force can provide assistance to both EU and non-EU countries.

The ECDC has created an ad hoc working group (composed of Member State experts, representatives of the Commission and the WHO) to advise the ECDC on the establishment of the EU Health Task Force. Once operational, the ECDC will set up a permanent advisory group and a team to coordinate the work of the Health Task Force.

EMA Emergency Task Force

The EMA Emergency Task Force (the ETF) is an advisory and support body that carries out regulatory activities in preparation for and during a public health emergency, such as a pandemic. Regulation (EU) 2022/123, which strengthened the mandate of the EMA[92], and became applicable as of 1 March 2022, established the ETF as a formal advisory and support body focusing on medicines for public health emergencies and preparedness. In April 2022, the ETF took over the activities of the COVID-19 EMA Pandemic Task Force, which the EMA had convened in March 2020 to address the COVID-19 pandemic. Regulation (EU) 2022/123 made the group permanent and entrusted it with an important role in crisis preparedness. In 2023, the ETF continued supporting EMA scientific committees with the authorisation and safety-monitoring of medicines and with recommendations on the use of medicines prior to authorisation. The ETF looked into available treatment options to combat the COVID-19 pandemic and the MPOX outbreak, such as facilitating clinical trials and working with EU partners.

5. RECOVERY

The effects of a serious health crisis can be profound and long-lasting. The COVID-19 pandemic placed health systems under severe strain, and even at risk of collapse. It is essential to support the recovery of Member States and their respective health systems at all levels. This can be done not only through financial help, but also through direct help to those most affected by the measures put

[91] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023DC0526
[92] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022R0123

in place in times of crisis. In the case of COVID-19, it is known that the mental health of many people deteriorated as a result of the pandemic and that many are still suffering from long COVID. At the same time, recovery also entails taking stock of past events, so that we learn how to further improve our prevention and preparedness for, and response to, serious cross-border health threats.

Recovery and effectiveness of public health measures

The ECDC is continuing to assess the evidence base from the COVID-19 pandemic by carrying out systematic literature reviews on various operational and scientific questions that arose during the pandemic, including the efficiency and cost-effectiveness of non-pharmaceutical interventions, aircraft transmission of SARS-CoV-2, long COVID, use of masks in community settings, etc. The ECDC has conducted several after-action reviews on evidence-based decision-making in EU/EEA and EU Neighbourhood countries during the COVID-19 pandemic, focusing on long-term care facilities and school closures. It has also published relevant guidance [93] to help countries design their own after-action reviews.

Health system recovery

Under the Recovery and Resilience Facility, over EUR 43 billion has been earmarked across 27 national Recovery and Resilience Plans (RRPs) to strengthen healthcare. This includes more than EUR 14 billion dedicated to measures for advancing the digital transition of health systems. In addition, health system reform challenges (such as those identified in the 2019 and 2020 European Semester Country Specific Recommendations (CSRs)) that are not sufficiently tackled under the Recovery and Resilience Plans can be addressed via the European Semester CSRs. These CSRs also guide investment priorities for cohesion funds. Under the most recent European Semester (2023), six Member States received a healthcare CSR, including on challenges related to access, workforce and primary care. In addition, Member States are planning to invest around EUR 16 billion in healthcare[94], including more than EUR 2 billion in the digital transition of health systems. As mentioned in Health at a Glance: Europe 2022[95], it is important that health systems overcome the big shock and reduction in care delivery during the pandemic. The surgery backlog remains significant in some countries.

Mental Health and long COVID

Mental health problems are known to be affecting more and more people in the EU. Even before the COVID-19 pandemic, mental health problems affected about 84 million people (1 in 6 individuals) at an estimated cost of over EUR 600 billion (more than 4% of GDP). Moreover, the consequences of the pandemic and other global crises continue to increase the prevalence of anxiety and depression worldwide. The devastating effects of the COVID-19 pandemic, the Russian full-scale invasion of Ukraine, the climate crisis, increased digitalisation, unemployment and rising living costs have further exacerbated the already poor levels of mental health. Vulnerable groups and people in socio-economically disadvantaged situations suffer more than others. The Health at a Glance: Europe 2022 report underlined that the pandemic had affected the mental health of young people particularly hard: one in two young Europeans reported unmet needs and depression among

[93] https://www.ecdc.europa.eu/en/publications-data/conducting-after-action-reviews-public-health-response-covid-19-update-0

[94] https://cohesiondata.ec.europa.eu/2021-2027-Categorisation/2021-2027-Finances-details-categorisation-multi-fu/hgyj-gyin

[95] https://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-europe-2022_507433b0-en;jsessionid=-ZyVma6ABAN0VaaG5paqz-epR3sPXjuLlFsJ5MXW.ip-10-240-5-108

young people had more than doubled. In 2022, the WHO launched a global wake-up call to all countries to step up mental health services and support [96].

The EU has set a clear recovery path by launching a comprehensive approach to mental health[97] and supporting research activities for better health preparedness[98]. Following the announcement of 'a new initiative on mental health' by President von der Leyen in her 2022 State of the European Union address, the Commission adopted a communication on a comprehensive approach to mental health on 7 June 2023[99]. This marks the starting point for a new approach to mental health: it looks beyond health, strongly involving areas such as education, digitalisation, employment, research, urban development, environment and climate. The Communication has 20 flagship initiatives, identifies EUR 1.23 billion in funding opportunities and places a focus on vulnerable groups (children, young people, the elderly). For example, one key flagship addresses mental health support for people displaced from Ukraine, and another supports the dissemination of a minimum service package to deliver quality care in humanitarian emergencies. In the implementation phase, the Commission is continuing to work closely with the Member States (the mental health subgroup of the Public Health Expert Group) and stakeholders (the network in the EU Health Policy Platform). In addition, the Council's Trio Presidency has put mental health high on its agenda and the Spanish Presidency will prepare a set of four Council conclusions (one setting out a general approach and three addressing the specific policy areas of precarious work, drugs and youth).

The Commission has created the high-level Network of Expertise on long COVID (NELC), which brings together national institutions that function as a reference centre to other healthcare institutions. The aim of the NELC is to facilitate an exchange of the most relevant information and best practices of long COVID management in response to the latest scientific developments relating to long COVID as a growing public health crisis [100]. It will also contribute to coordinating initiatives at national, EU and WHO level. The NELC met for the first time on 2 May 2023 to discuss initial ideas and its priorities. The identification of research needs and gaps, together with the sharing of guidelines and intelligence on diagnosis and treatment, were identified as the two most urgent topics to address. Moreover, the NELC highlighted the need for guidelines and clinical recommendations.

The Horizon Europe programme supports projects (including large cohort studies on COVID-19) to determine the long-term consequences and symptoms of SARS-CoV-2 infections for a better understanding, diagnosis and potential treatment of long COVID.

6. RESEARCH

The Commission funds innovation and research of relevance to health security via Horizon Europe and HERA Invest[101] across a range of domains, such as preparedness and response.

[96] https://www.who.int/news/item/02-03-2022-covid-19-pandemic-triggers-25-increase-in-prevalence-of-anxiety-and-depression-worldwide

[97] https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union/comprehensive-approach-mental-health_en

[98] https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/european-partnerships-horizon-europe/health_en

[99] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023DC0298

[100] https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(23)00268-0/fulltext

[101] https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/hera-invest_en

Research in preparedness

The Horizon Europe programme is supporting projects to increase knowledge on vaccine-induced immunity to viruses with a high epidemic or pandemic potential as well as to define optimal design of vaccines against pathogens, where information on host-pathogen interaction and viral surface structures is known. Other research actions for medical countermeasures focus on advancing broad-spectrum antiviral compounds and developing novel approaches to the development of such compounds, which target viruses with high epidemic or pandemic potential for the EU.

The Commission has also launched HERA Invest to promote advanced research and development of medical countermeasures and related technologies for tackling priority cross-border health threats. Part of InvestEU[102] - the EU programme that supports sustainable investment, innovation and job creation in Europe, HERA Invest fills a vital gap in the field with EUR 100 million to support innovative SMEs in the early and late phases of clinical trials. HERA Invest aims to reduce market failures and to enhance the EU's strategic autonomy.

The Horizon Europe programme is also supporting the development of, and access to, *in vitro* diagnostics for the detection and characterisation of pathogens with pandemic potential as well as supporting access to medical devices and *in vitro* diagnostic medical devices for cross-border health threats. In addition, the Commission is, through the European Innovation Council [103] - Europe's flagship innovation programme established under Horizon Europe, promoting the development and commercialisation of technological solutions for epi/pandemic management, (including, for example, advanced systems for aerosol capture, pathogen deactivation and air circulation optimisation, next generation face masks and rapid surface decontamination devices).

Response and emergency research

The Horizon Europe work programmes for health continue to envisage the possibility to mobilise research funds in case of public health emergencies. This option was used in 2022 to support the EU RESPONSE[104] network for the implementation of a clinical trial to assess treatment for MPOX, as well as the cohorts from the VERDI[105] project for a better understanding of the disease.

The Commission, through Horizon Europe, will also build on existing adaptive platform trials and cohort studies to maintain and strengthen strategic coordination mechanisms in the EU and beyond. These networks make possible the conduct of perpetual platform trials, the pivoting of perpetual strategic cohorts to emerging diseases if an epidemic strikes, and the generation of scientific evidence on different possible medical countermeasures.

The Commission, in cooperation with Member States, is involved in the preparatory phase of the EU Partnership on Pandemic Preparedness, which will develop a consolidated pandemic preparedness research agenda strengthening the collaboration between Member States as well as prepare for the management of the research response during a crisis by establishing an EU network of ever-warm clinical trial sites and align investments for pandemic preparedness and response, from basic research, to preclinical and clinical research.

[102] https://investeu.europa.eu/index_en

[103] https://eic.ec.europa.eu/system/files/2023-08/EIC-WP2023-amended.pdf

[104] https://eu-response.eu/

[105] https://verdiproject.org/

Considering that in a pandemic 'nobody is safe until everybody is safe everywhere', the EU Global Health Strategy[106] launched in November 2022 represents the external dimension of the European Health Union. The EU is investing in improving the pandemic prevention preparedness and response capacity in Lower and Middle Income Countries with a particular focus on sub Saharan Africa through various instruments as part of the Global Gateway strategy[107]. The European and Developing Countries Clinical Trials Partnership Joint Undertaking[108] is funding research for the development and testing of medical countermeasures as well as developing clinical trial networks and cohorts, linking the outcome of this research with the Team Europe Initiative on Manufacturing and Access to Vaccines, medicines and health technology in Africa (MAV+) and the EU–LAC Partnership on vaccine production and health systems resilience.

7. INTERNATIONAL DIMENSION

International partnerships to strengthen the global health security framework

Past health emergencies have shown that diseases do not respect borders. The EU is involved in addressing health emergencies at international level in order to mitigate the possible spread of health risks in the EU. The external dimension of the European Health Union, the EU Global Health Strategy, was adopted on 30 November 2022 and is intended to guide all EU action for ensuring better health and well-being of people across the life course through, on the one hand, strengthening health systems and advancing universal health coverage, and on the other, preventing and combating health threats, including pandemics, applying a One Health approach.

The three health-related political declarations passed during High Level Meetings at United Nations General Assembly in New York during September 2023 on Tuberculosis, Universal Health Coverage and Pandemic Prevention, Preparedness and Response highlighted the urgency for actions to strengthen national health systems and improve global health security to achieve the sustainable development goals related to health. In this context, the EU continues to be strongly engaged in the ongoing negotiations for the adoption of a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response ("Pandemic Agreement") and in the complementary negotiations on the revision of the International Health Regulations. The EU has made ambitious proposals that promote equity and include operative provisions on the entire prevention, preparedness and response cycle, with a view to delivering significant and concrete improvements in the interest and for the benefit of all. Achieving a successful outcome for both processes by the May 2024 World Health Assembly is a priority for the EU.

In addition, the Commission is a founding member of and contributor to the Pandemic Fund launched by the G20 in 2022 and hosted by the World Bank. The Fund provides long-term financing to strengthen pandemic prevention, preparedness and response (PPR) capacity and capabilities in low- and middle-income countries and addresses critical gaps through investments and technical support at the national, regional, and global levels.

Recognising the important opportunity to strengthen global commitments against antimicrobial resistance, the EU has put forward a comprehensive proposal for concrete AMR provisions as part of the negotiations for a WHO international agreement on pandemic prevention, preparedness and

[106] https://health.ec.europa.eu/system/files/2023-03/international_ghs-report-2022_en.pdf
[107] https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/stronger-europe-world/global-gateway_en
[108] https://research-and-innovation.ec.europa.eu/research-area/health/edctp_en

response. The EU is committed to global cooperation on AMR and hosted an in-person meeting of the Transatlantic Task Force on Antimicrobial Resistance on 14-15 November 2023 that brought together authorities from the EU, the US, Canada, Norway and the UK, to collaborate and share best practices to strengthen domestic and global efforts. The EU is also supporting international efforts to combat AMR within the G7 and G20 contexts and is involved in preparations for a successful United Nations General Assembly high-level meeting on AMR in 2024. Through its financial contribution to the AMR Multi-Partner Trust Fund, the EU is supporting efforts in low- and middle-income countries to strengthen their capacities to fight AMR.

EU Civil Protection Mechanism (UCPM)

The UCPM is committed to providing assistance to any requesting country, inside and outside the EU. So far in 2023, 10 requests have been received through the UCPM from non-EU countries for COVID-19 related items (vaccines, medical equipment, etc.) and all were fully met with offers from EU Member and UCPM-participating States. Furthermore, if needed, the Commission can also directly support humanitarian health partners through the European Humanitarian Response Capacity with the provision of complementary emergency kits (i.e. shelter, hygiene and cholera kits) as well as the deployment of health experts (in close collaboration with the ECDC) in the event of a health emergency in a humanitarian context.

International dimension in EU-funded research and innovation

To better coordinate research on pandemic preparedness and response, the EU has helped set up and is funding the global research collaboration for infectious disease preparedness (GloPID-R). Its living roadmap for clinical trial coordination defines epidemic-ready clinical trial networks and platforms, an agile and effective clinical trial response and an equitable research environment as the core of guidance to funders. GloPID-R's regional hubs in Africa and the Asia-Pacific support stronger coordination at a regional level.

To promote global collaboration on clinical trials, the EU-funded EDCTP Association brings together 26 countries in Africa and 15 in Europe in a clinical trial partnership that was established in 2003 to promote multi-country clinical trial networks in Africa and collaboration with Europe. The EDCTP is currently in its third iteration, as a Joint Undertaking, and has enhanced research capacity and accelerated the development of new or improved medical interventions for the identification, treatment and prevention of poverty-related infectious diseases, including emerging and re-emerging diseases in sub-Saharan Africa, through all phases of clinical trials and with an emphasis on phase II and III trials.

Engagement and close collaboration with international stakeholders are fundamental to strengthening pandemic preparedness and response efforts globally. Over the past year, implementation of the 2022 administrative arrangement with the United States' Administration for Strategic Preparedness and Response (ASPR) has continued, including through an exchange of experts and a developing partnership on funding innovation in the diagnostics sector, specifically on technologies for early-outbreak detection. HERA is also expanding cooperation with partners in Asia and recently signed administrative arrangements with the Ministry of Health and Welfare of the Republic of Korea and the Japan Agency for Medical Research and Development.

Close cooperation is also continuing with Ukraine and other neighbouring countries, as well as partners in the global South, particularly in Africa. Key objectives in the preparedness phase are improving surveillance-sequencing capacity, facilitating data exchange and supporting sustainable production and distribution capacities for relevant medical countermeasures so that partners can in

times of crisis rapidly identify and characterise pathogens of concern and have broad and quick access to medical countermeasures.

This includes work through international partnerships (e.g. GH-EDCTP3JU to advance the development of medical countermeasures for infectious diseases affecting Africa). With particular regard to global, regional or national initiatives in the field of pandemic preparedness, the Commission has invested around EUR 25 million from the EU4Health programme. Actions include support for late-stage clinical trials of vaccines and treatments against priority health threats (e.g. Ebola and Marburg virus); the enhancement of sequencing capacities in Africa, in collaboration with the African Centre for Disease Control (CDC); and collection of data on emerging pathogens in Africa in collaboration with the WHO pandemic hub and WHO AFRO.

EU Digital COVID Certificates and the WHO Global Digital Health Certification Network

The development and use of EU Digital COVID Certificates have been key in the fight against the COVID-19 pandemic. During the pandemic, the EU Digital COVID Certificate facilitated travel within the EU when travel restrictions were deemed necessary. It also allowed for a coordinated lifting of these restrictions once this became possible.

The EU Digital COVID Certificate also had an important international dimension. Based on open-source technologies and standards, it allowed connection with non-EU countries that issued certificates according to EU Digital COVID Certificate standards and specifications. With 78 countries and territories connected, the EU Digital COVID Certificate system became the most widely used solution for the issuance and validation of digital COVID-19 certificates. Through this system, more than 1.8 billion people had access to interoperable digital certificates, and more than 2.3 billion certificates were issued in the EU alone.

From the onset of the pandemic, the WHO engaged with all WHO regions to define overall guidelines for COVID-19 certificates, recognising an existing gap and continuing need for a global mechanism that would support bilateral verification of the provenance and authenticity of health documents for pandemic preparedness and continuity of care. Leveraging the experience of the EU Digital COVID Certificate, the WHO launched in June 2023 a Global Digital Health Certification Network (GDHCN), which builds on the solid foundations of the EU Digital COVID Certificate framework, principles, specifications and open technologies. The WHO and the Commission have agreed on a partnership to facilitate the uptake of the EU Digital COVID Certificate and on collaboration in the GDHCN's operation and further development. The GDHCN will allow the world to benefit from convergence of digital certificates, while respecting and promoting common values and the principles of transparency and openness, inclusiveness, accountability, data protection and privacy, security, scalability at a global level and equity. The Commission/WHO partnership aims to work to technically develop the WHO system with a staged approach to cover additional use cases in the future (this may include, for example, the digitalisation of the International Certificate of Vaccination or Prophylaxis). Expanding such digital solutions will be essential to delivering better health for citizens throughout the world.

EU response in support of Ukraine

Russia's war against Ukraine has been a major humanitarian crisis that has affected Ukraine's healthcare system and created risks for public health both within Ukraine and beyond. The EU's Member States and the Commission have sent medical countermeasures via the UCPM to protect against chemical, biological, radiological and nuclear attacks and emergencies in Ukraine. The

Commission has also set up a scheme to facilitate the logistics for donations of medical goods from EU companies to Ukraine via the UCPM.

A medical evacuation (MEDEVAC) system established by the UCPM has been operational since March 2022. It has so far enabled the safe evacuation of over 2 800 wounded and critically ill Ukrainian patients, from both Ukraine and neighbouring countries to hospitals in 21 European countries. Such a collective MEDEVAC system is unprecedented at EU level. The Commission has also established a medical facility in a dedicated hub in Poland to increase the well-being of patients awaiting transport to European hospitals and to increase the reliability and predictability of MEDEVAC. From the rescEU strategic reserve and since the beginning of Russia's full-scale invasion of Ukraine, more than EUR 56 million's worth of medical and CBRN items and equipment have been deployed to Ukraine, including masks, potassium iodide tablets, ventilators and other items.

8. CONCLUSIONS

This report has mapped the EU actions and capacities put in place to address serious cross-border health threats in the aftermath of the COVID-19 pandemic and building on the pre-COVID-19 EU health security architecture. The focus was on those actions that implement Regulation (EU) 2022/2371, in response to the requirement of its Article 9 to report on EU prevention, preparedness and response planning. In addition, this report outlined ongoing initiatives and work that are closely related to public health in other EU policy areas, e.g. research, emergency assistance, international cooperation, etc.

The COVID-19 pandemic triggered a major upheaval in our health systems and life as we know it; but it also brought an unexpected opportunity to improve our health security framework so that it is better prepared to withstand major future health threats. While we may not know what the future holds – despite our best efforts to anticipate and plan – the EU has introduced upgraded structures for prevention, preparedness and response, which have greatly enhanced our collective capacities to react to any future emergency. The EU-level health security framework adds an important additional layer to the core functions of Member States in the field of health and the provision of healthcare. Health threats do not respect borders, but we are, collectively, better prepared to combat them, including by engaging in partnerships at global level.