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Special edition:
**Preparing Europe for future health
threats and crises**
February 2023

Featuring

- **Preparing Europe for future health threats and crises – key elements of the European Centre for Disease Prevention and Control's reinforced mandate**
- **Preparing Europe for future health threats and crises – the European Medicines Agency; ensuring safe and effective medicines and medical devices**

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Preparing Europe for future health threats and crises: the European Health Union

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It has been a little over 3 years since a novel coronavirus, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), spread across Europe and the world. During that time, health systems were put under pressure like never before. The coronavirus disease (COVID-19) pandemic revealed that most health systems were ill-equipped for a crisis disproportionately affecting the most vulnerable communities. The pandemic also uncovered the persistent inequality in prevention and care between and within countries in the European Union (EU) and between different population groups. Economies and societies continue to face uphill battles in coping with the lingering effects of a disease that led to too many lives lost.

Faced with an unprecedented challenge, the European Union (EU) took action; for example, during the COVID-19 pandemic, closer coordination and collaboration at EU level, with and between countries, resulted in the EU Vaccines Strategy [1] and the EU COVID-19 digital certificate [2]. Moreover, recognising the limitations of the early response to the pandemic at EU level, the European Commission (EC) presented a set of proposals in November 2020, to substantially strengthen health security by creating a strong European Health Union.

The aim of the Health Union is to reinforce coordination at EU level to build healthier, more resilient and more sustainable societies for the future. The building blocks of this Health Union are steadily being put into place with major developments achieved in the last year. These include a revised and stronger mandate for the European Centre for Disease Prevention and Control (ECDC) [3] and the European Medicines Agency (EMA) [4], the new Health Emergency Preparedness and Response Authority (HERA) [5], the Pharmaceutical Strategy for Europe [6], Europe's Beating Cancer Plan [7], the European Health Data Space [8] and the Global Health Strategy [9].

To shield present and future generations against the worst effects of future health threats, it is important to be properly equipped to face health challenges. This starts by relying on fit for purpose legislation that can affect real change. The Decision No 1082/2013/EU on serious cross-border threats to health [10] has thus far worked well but in a post-pandemic world, a limited legal framework will no longer do. The Health Union package entails a new overarching framework for health security: a Regulation on serious-cross border threats to health that entered into force on 26 December 2022 [11]. This Regulation aims to ensure a robust preparedness planning, a more integrated surveillance system and a better capacity for accurate risk assessment and targeted response. It allows to set up solid mechanisms for joint procurement of medical countermeasures and includes the possibility to adopt common measures at the EU level to address future cross-border health threats. The Regulation also strengthens the role of the Health Security Committee (HSC) as coordinating body of the EU level response. The HSC assumes additional responsibilities in the adoption of guidance and opinions to better support countries in the prevention and control of serious cross-border threats to health. To further promote an effective and coordinated EU response, the EC, in cooperation with countries and the relevant EU agencies, will develop an EU Prevention, Preparedness and Response Plan and facilitate stress tests to ensure it is operable. Countries should develop their own national plans seeking coherence and compatibility with the EU plan. The scope of public health risk assessments will be broadened to support an all-hazards approach. Consequently, depending on the type of health threat, one or several EU agencies may contribute to the risk assessment.

An important new aspect included in the Regulation on serious-cross border threats to health is the possibility to declare a public health emergency at EU level. Such declaration will provide the basis to identify and

ensure the availability of relevant critical medicines and coordinate associated measures to address the public health emergency [4], flexible mechanisms to develop, procure, manage and deploy medical countermeasures [5], as well as the activation of support from the ECDC to mobilise and deploy the 'EU Health Task Force' [3].

Any future path for health must be taken together with global partners. The European Global Health strategy [12] emphasises the role of the EU in global health, with a One Health and a 'health in all policies' approach at its very core. The EU will support strong multilateral systems around the World Health Organization. It actively participates in the negotiation of the future pandemic agreement and in the revision of the International Health Regulations, and it will engage in the Pandemic fund hosted by the World Bank. To improve equity in the access to vaccines and other countermeasures, the EU will boost local manufacturing capacities and strengthen health systems.

Further pillars of the European Health Union are Europe's Beating Cancer Plan that aims to improve cancer detection and treatment, to ensure better integrated and comprehensive cancer care and to address unequal access to quality cancer care and medicines [6], as well as the Pharmaceutical Strategy [7]. The latter, adopted on 26 November 2020, aims to give all Europeans equal access to affordable, safe and effective medicines and treatments. It will drive innovation in unmet medical needs and help secure access to affordable, high quality, safe and greener medicines in the EU. The Pharmaceutical Strategy should also boost EU resilience by promoting global and diversified supply chains. To secure supply in the EU, it includes stronger obligations for supply, transparency and earlier notification of shortages. The strategy modernises the existing regulatory framework and supports research and technologies that can be applied in healthcare. It addresses several antimicrobial resistance challenges, including the lack of investment in antimicrobials and the inappropriate use of antibiotics, and also covers actions on improving healthcare professionals' and European citizens' awareness on antimicrobial resistance.

The COVID-19 pandemic has uncovered the need for improvement in the digital realm. However, there has been much progress with accelerated development and use of digital tools and electronic health records. To further harness the benefits of digital tools to inform health policy, the EC is building the European Health Data Space (EHDS) [8]. The EHDS is both a health-specific data sharing framework establishing clear rules, common standards and practices, and a governance framework. By offering a consistent, secure, trustworthy and efficient framework for the use of health data, it will allow individuals to have digital access to and control of their personal health data. It will support their free movement by ensuring that health data

follows them. Furthermore, EHDS will enable the use of electronic health data for research, innovation, policy making, patient safety, statistics and regulatory purposes.

A strong European Health Union can only survive and thrive with committed investment. The EU4Health programme will add €5.3 billion in health promotion, diagnosis and treatment, and care to help countries boost their health systems, strengthen their healthcare workforce, invest in trainings and advance their digital transformation.

Multi-sectoral and cross-border coordination are needed to effectively face the health threats that may lie ahead. The new European Health Union will respond to this need. Its complementary pillars support EU countries in preparing for and responding to European and global health crises. Working together to improve prevention and treatment of diseases and guarantee availability of affordable and innovative medical supplies is of major importance. With a stronger European Health Union, we should be better prepared to face any future health threat with confidence.

Note

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Conflict of interest

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Preparing Europe for future health threats and crises – key elements of the European Centre for Disease Prevention and Control's reinforced mandate

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The COVID-19 pandemic has taught us many lessons and several of these have now been captured in European Union (EU) legislation. In order to be better prepared for future health threats and crises, the mandates of the European Centre for Disease Prevention and Control (ECDC) [1] and the European Medicines Agency (EMA) [2] have been reinforced, the European Commission's Directorate General European Health Emergency Preparedness and Response Authority (HERA) [3] was created and the Regulation on serious cross border threats to health came into force [4]. The lessons from the past 3 years also have implications for public health preparedness beyond the current pandemic, and many of them are transferable to other cross-border health threats, such as the risk of the emergence of new pathogens, resistance to antimicrobials and to vaccine preventable diseases.

ECDC's reinforced mandate [1], was adopted by the European Parliament on 4 October 2022 and by the Council on 24 October 2022. It further strengthens the capacity of ECDC to provide the robust and independent scientific expertise necessary to support actions related to the prevention, preparedness, and response planning to prevent and control serious cross border threats to health in accordance with Regulation (EU) 2022/2371 [4]. Since 26 December 2022, ECDC is mandated to provide non-binding science-based recommendations setting out options for both the management and control of communicable diseases in humans and related special health issues. ECDC will work closely with the EU countries to determine how to effectively monitor the capacity of their health systems to detect, prevent, respond, and recover from outbreaks. Further, the Centre will provide science-based recommendations to strengthen the health systems in the EU countries, and to support them in the implementation of projects to fill in any identified gaps.

Secure and interoperable digital platforms and applications in support of epidemiological surveillance are crucial at EU level. Following its reinforced mandate, ECDC has the task to develop such systems and it will seek solutions that allow a better use of the data by applying new digital technologies, such as artificial intelligence and computer modelling in data compilation and analysis.

Improving epidemiological surveillance through digitalisation of integrated surveillance systems in the EU countries, will constitute the basis for an EU-level digitalised surveillance system of communicable diseases, with interoperability across borders. Interconnected systems would ease monitoring of the impact of communicable disease crises (e.g. pandemics) on the healthcare system/hospitals in the future. The enhanced capacity to obtain a comprehensive overview of the epidemiological situation at EU level, to monitor the impact of communicable disease events on the healthcare system, and the possibility to anticipate future trends should be the EU-added value of surveillance of which the outcomes will be made available to decision-makers at EU and national levels.

Further, future-oriented information to decision-makers at EU and national levels will be provided through an ECDC programme on epidemiological modelling, anticipation, and scenario development for response. Based on the future scenarios, this programme will support prioritisation and preparedness at ECDC-, EU-, and country level. ECDC will also support and complement similar efforts of other EU entities, including HERA's intelligence gathering and threat assessment activities, towards a more resilient EU. ECDC will leverage its biostatistics, disease modelling, and health economics capacity to provide in-depth analyses, risk assessments, and recommendations for policy and actions to prevent and control communicable diseases and other special health issues.

Box

Scope of the European Union Health Task Force

Timely emergency response during outbreaks and crises

Communicable diseases or diseases of unknown origin;
Remote support and rapid in-country field deployment;
Outbreak investigation/response, operational research, guidance, resources, and tools.

Strengthening countries emergency preparedness

Development, testing, and updating of preparedness protocols and plans;
Assessment of preparedness gaps;
Simulation exercises and in- and after-action reviews;
Tailored capacity building activities and training.

In addition to the current network for epidemiological surveillance, ECDC will operate and coordinate two new networks: the network of EU reference laboratories for public health, and a network of national services supporting the use of substances of human origin.

To provide hands-on technical support to the EU countries and to third countries in outbreak situations, or to support countries in their preparedness and response planning, ECDC will also establish a permanent EU Health Task Force (EUHTF) (Box). The EUHTF will consist of an ECDC team coordinating the set up and future routine operations. An Enhanced Emergency Capacity will be composed of EUHTF public health experts from EU/EEA (European Economic Area) countries on voluntary basis, ECDC experts, and fellows during their two-year placement in the ECDC Fellowship Programme. They will support outbreak investigations or preparedness and response activities using their knowledge and practice related to preparedness and response during deployments and, to the benefit of their own countries, when not deployed. To enable smooth deployments and logistics support in particular in third countries, ECDC will establish arrangements with the EC Directorate General for European Civil Protection and Humanitarian Aid Operations and with the Global Outbreak Alert and Response Network.

As part of the EU commitment to reinforce partners' preparedness and response capacity to communicable diseases, laid out in the recent EU Global Health Strategy [5], as well as through the amended mandate, ECDC will focus on wider global health considerations. The Centre will cooperate with public health actors in third countries, and international organisations competent in the field of public health.

ECDC is one of the building blocks of the new European Health Union, together with EMA and HERA. Coordination of work between the two EU agencies and the EC, including HERA, and the World Health Organization Regional Office for Europe is of utmost

importance to avoid duplication of actions, enhance efficiency and effectiveness, and create synergy.

During the COVID-19 pandemic, the coordination mechanisms between the EC and ECDC have been further strengthened. The mandates of HERA and ECDC are well defined; HERA provides solutions to pandemic preparedness and response by focusing on the whole value chain of medical countermeasures and ECDC is tasked to identify, assess, and communicate current and emerging threats from communicable diseases and related special health issues. With the reinforced mandate, ECDC is also tasked to monitor the prevention, preparedness and response plans of countries and support them in addressing identified gaps. Some of ECDC and HERA's areas of work are closely related and therefore alignment of actions and collaboration are necessary. ECDC and HERA will sign a Memorandum of Understanding outlining areas of enhanced collaboration and complementary actions.

ECDC and EMA have been working together since 2010 through a bilateral collaboration agreement. Over the years of close collaboration, the respective responsibilities and complementary areas of work have become clear. Joint work on the development of a post-authorisation vaccine monitoring platform goes back almost 10 years, and now with reinforced mandates this jointly operated platform became reality. Independent studies on effectiveness, safety, and the use of vaccines carried out through this joint vaccine monitoring platform will provide information at EU and national levels on how vaccines perform in real life. This will help national authorities to make decisions on immunisation programmes, which is essential to build and maintain trust of the general population in vaccines.

Looking ahead, there is a growing awareness that societies should be more alert to the impact of communicable disease outbreaks, as well as to the impact public health countermeasures might have on other sectors of society. ECDC's reinforced mandate bolsters

the agencies' possibilities to look at the interconnectivity of communicable diseases, non-communicable diseases, and health determinants. The next external evaluation of ECDC is foreseen in 2025. It will assess the possibility to expand ECDC's mandate to non-communicable health threats as well as the degree of the implementation of the reinforced mandate.

To implement the reinforced mandate, ECDC will enhance its ways of working both internally and with external partners. It will develop even closer relations with the EU countries to understand their context better and to set a joint level of ambition for the implementation of the legislation. ECDC will foster cooperation, take the lead when necessary, and support countries in every feasible way. However, for the large transformations such as building national digitalised integrated surveillance systems as prerequisites for an EU level system, coordinated efforts at different levels are necessary.

Through collaborative actions between ECDC, EU countries, other EU Agencies, and the EC, the new European Health Union which is built on solidarity and equity, could decrease health inequalities.

One of the main lessons from the COVID-19 pandemic for future health emergency preparedness planning is that we need to adopt a multi-sectorial and multi-disciplinary preparedness approach, with 'One Health' in focus and where we also acknowledge globalisation and climate change as drivers of risk. Experiences made during the past years need to be used to improve our surveillance systems and build capacity and resilience in the public health systems to be better prepared for future health crises in the 21st century. It is crucial that lessons learned lead to continued improvement and adaptation. To ensure this, continuous political will and sustained investment in public health at national and at EU level are needed.

Note

Maarit Kokki is Head of the Executive Office at the European Centre for Disease Prevention and Control (ECDC) and Andrea Ammon is the Director of ECDC.

Conflict of interest

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Preparing Europe for future health threats and crises – the European Health Emergency and Preparedness Authority; improving EU preparedness and response in the area of medical countermeasures

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On 24 October 2022, the adoption of the Regulation on serious cross-border threats to health, the Regulation on the extended mandate of the European Centre for Disease Prevention and Control (ECDC), and the Council Regulation on the emergency framework regarding medical countermeasures (hereinafter, the Emergency Framework Regulation), which provides extra powers to the European Health Emergency Preparedness and Response Authority (HERA), concluded the creation of the European Health Union [1]. Other building blocks of this new EU health security framework are the Regulation on the extended mandate of the European Medicines Agency (EMA) adopted in March 2022 [2] and the creation of an entirely new permanent structure for health emergency preparedness and response. Established within the European Commission (EC) as a shared resource for both the European Union (EU) and its member countries, HERA was set up in September 2021 to further strengthen Europe's ability to prevent, detect, and rapidly respond to cross-border health emergencies by ensuring the development, manufacturing, procurement and equitable distribution of key medical countermeasures. HERA's governance ensures an extensive coordination and cooperation with EU countries via the HERA Board and the HERA Advisory Forum. In addition, structured exchanges with representatives of the civil society and industry are organised through subgroups of the HERA Advisory Forum.

With a budget of EUR 6 billion for the 2022–2027 period, HERA's mandate covers all serious cross-border health threats and related medical countermeasures, including crisis-related vaccines, medicines, personal protective equipment (PPE), diagnostics, active pharmaceutical ingredients (API) and critical raw materials. To further target its preparedness activities, in 2022, HERA has conducted a thorough threat prioritisation exercise, in consultation notably with ECDC and EMA, which resulted in the identification of the following three threat categories, namely: (i) pathogens with

high pandemic potential; (ii) chemical, biological, radiological, and nuclear (CBRN) threats originating from accidental or deliberate release; and (iii) antimicrobial resistance (AMR) [3]. The inclusion of AMR in the top three priority threat categories shows that HERA does not aim solely at preventing or addressing acute public health events, but also more slowly evolving, silent pandemics with high associated public health burden.

In full respect of the subsidiarity principle, HERA operates in two modes: the preparedness mode to anticipate and respond to threats before they turn into crises, and the crisis mode empowering HERA to coordinate and take action against health emergencies. This differentiation allows for a high level of flexibility as well as extended coordination and cooperation with EU countries, other EC services and EU agencies, as well as external actors to contribute to the identification of EU priorities, mutualise efforts and leverage resources.

As long as the emergency framework as defined by the Emergency Framework Regulation is not activated [4], HERA operates in preparedness mode in synergy with EU countries, ECDC and EMA, and international partners. Activities focus on intelligence gathering and threat assessment; promoting advanced research and development of medical countermeasures; and ensuring sustainable access to medical countermeasures through the coordination of purchase, manufacturing, and stockpiling activities.

Intelligence gathering and threat assessment encompasses both short- and long-term activities, including the continuous monitoring and assessment of signals to rapidly identify the health events requiring medical countermeasure response. The function also covers horizon scanning to guide policy, research, and innovation planning as regards medical countermeasures. In addition, HERA is developing a comprehensive mapping of medical countermeasures that are critically

important to address the three identified priority threats. This mapping will help HERA rapidly draw the list of crisis-relevant medical countermeasures to be established in case of the activation of the Emergency Framework Regulation.

To support HERA's intelligence gathering and threat assessment function, the HERA IT platform is currently being developed. It will be a highly accurate digital system which will make use of a wide range of data to guide decision-making on the medical countermeasures response, including by forecasting, developing and testing specific scenarios. Data processed by the HERA IT platform will include the outputs of the networks for epidemiological surveillance and the epidemic intelligence systems operated by ECDC, as well as forecasts and information gathered by EMA on existing medicines, including shortages, and those in development.

Via Horizon Europe and EU4Health funding, HERA is further investing in pandemic preparedness research and development, for instance by setting up sustainable networks, platforms and infrastructures that can be adapted quickly to emerging or previously unknown pathogens. As one example, the pandemic clinical trials platforms that were set up by the EC during the COVID-19 pandemic on vaccines and therapeutics (VACCELERATE [5] and EU-RESPONSE [6], respectively) will be further developed. Coordination mechanisms between the different clinical trials within the platforms are being established, and close cooperation with the EMA-Emergency Task Force (ETF) [7] is foreseen for scientific, regulatory and technical guidance regarding protocol design as well as coordination for larger, multinational clinical trials. Further integration of clinical research in threat preparedness is envisaged by the targeted development of and access to specific medicinal products with the potential to improve preparedness and response to serious cross-border threats to health, such as broad-spectrum antivirals and a new generation of COVID-19 vaccines.

Rapid and equitable access to medical countermeasures is essential in responding to health emergencies. At any time, HERA can mobilise EU funding to organise and coordinate development, manufacturing and procurements (including stockpiling) of relevant medical countermeasures. Through the COVID-19 Vaccines Strategy [8], the EC was able to speed up the development and manufacturing of safe and effective COVID-19 vaccines, and to secure up to 4.2 billion doses of COVID-19 vaccines. In addition to the vaccine contracts, a number of framework contracts for COVID-19 therapeutics were put in place to facilitate access to those for the EU countries. HERA continues to manage all these contracts and also carries out horizon-scanning for new vaccines or therapeutics which may be of interest to countries.

A new mechanism to improve Europe's overall preparedness for response to health crises established by HERA is the EU FAB. This network of facilities ready to be operational at all times for vaccine production in the EU and European Economic Area (EEA) can be activated in case of a health emergency to scale up production of different types of vaccines.

As regards stockpiles of medical countermeasures, HERA is defining a coordinated strategy to enhance their effectiveness and sustainability. In parallel, HERA is building stockpiles under rescEU to address high impact and low probability threats [7], such as CBRN events, with relevant medical countermeasures. A first call for proposal was launched in March 2022 and was further expanded in light of the current geopolitical situation.

HERA has a strong international dimension, through which it contributes to reinforcing global health security while also ensuring availability and access to critical medical countermeasures for all. This includes engaging with strategic global partners, such as the United States Biomedical Advanced Research and Development Authority, the World Health Organization Hub for Pandemic and Epidemic Intelligence, Coalition for Epidemic Preparedness Innovations, and Africa Centres for Disease Control and Prevention among others, to reinforce global surveillance and intelligence gathering, address international supply chain bottlenecks and expand global production capacity.

The Emergency Framework Regulation provides the basis for HERA to shift into crisis mode. The declaration of a public health emergency at EU level could trigger the activation of the emergency framework and allow for increased coordination and enable HERA to take necessary measures for sufficient and timely availability and supply of crisis-relevant medical countermeasures. To be effective and operational in times of public health emergencies, a new configuration will be rapidly convened within HERA. The so-called Health Crisis Board, co-chaired by the EC and the country holding the rotating presidency of the Council of the EU, will guide decision-making on medical countermeasures. EMA and ECDC will be represented by their respective Directors and will play a crucial role. EMA will regularly report information on the monitoring of medicinal products and medical devices, including their demand and supply, and ECDC will provide information on epidemiological surveillance outcomes and countries' health system capacity.

Based on the information collected, HERA will provide a comprehensive overview of the needed crisis-relevant medical countermeasures and the EU's capacity to meet those needs. While HERA and EMA will both have the mandate to monitor supply and demand of certain medical countermeasures in the event of public health emergencies, their focus will differ based on the respective expertise. In particular, EMA's monitoring of

After the ECDC epidemic intelligence picked up signals of a monkeypox outbreak in the EU in May 2022 [9], HERA, advised by EMA, identified the available authorised and unauthorised treatments and vaccines for monkeypox. Only one authorised therapeutic and only one vaccine was available to address this emerging threat in the EU. Thus, in accordance with its mandate and after consultation of the HERA Board, HERA then collected, on a voluntary basis, data from national competent authorities and the industry on supply and demand for the therapeutic and the vaccine. The intelligence gathered allowed HERA to rapidly purchase over three hundred thousand vaccine doses and donate them to EU/EEA countries, as well as to organise joint procurements for purchasing antivirals. Looking ahead to the medium and long-term needs, HERA signed a Joint Procurement Framework contract for the supply of up to 2 million doses of the monkeypox vaccine during 2023 and 2024 [10].

EMA provided scientific opinion and recommendations regarding the safety and quality of the purchased monkeypox vaccines and antivirals as well as a recommendation on the dose-sparing administration of monkeypox vaccines [11]. ECDC organised surveys on vaccination strategies and vaccine acceptance which provided evidence to assess and update the needs for vaccines in EU countries [12] and adjust HERA's purchase and procurement activities accordingly.

Once the outbreak was declared a public health emergency of international concern by the World Health Organisation [13], both drugs were included in the list of critical medicines established by EMA, which then organised regular and mandatory collection of supply and demand data. EMA could swiftly implement this data collection, building on the work carried out by HERA in preparedness time to collect similar data, but on a voluntary basis, for the purpose of its procurement activities.

To ensure a common approach, HERA and EMA jointly discussed with countries in the HERA Advisory Forum a European strategy for additional clinical data collection on the safety and efficacy of monkeypox treatment and vaccines. Scientific advice on clinical trial protocols was provided by EMA Emergency Task Force. The EC initiated the mobilisation of Horizon Europe emergency funding to support two complementary, multinational therapeutic clinical trials, which were submitted in the Clinical Trials Information System under the Clinical Trials Regulation (EU/536/2014) and that use the EU-RESPONSE pandemic trial platform.

supply and demand will focus on selected authorised critical medicines, including the gathering of information on their API, and certain types of medical devices. HERA will complement this monitoring by covering a broad range of crisis-relevant medical countermeasures, including both authorised and unauthorised medicines and medical devices, but also raw materials, diagnostics and PPE. Using the intelligence gathered, HERA would then advise on the activation and the implementation of the EU FAB facilities, emergency research and innovation plans and access to emergency funding.

HERA, ECDC and EMA work closely to leverage resources and expertise across their respective mandates and to contribute to a proportionate and efficient crisis response within Europe and globally. While HERA is the major player in the identification, development, procurement, stockpiling and deployment of medical countermeasures for health emergencies, this area also requires close collaboration between HERA, ECDC and EMA. HERA builds on and supplements the activities carried out by the ECDC and EMA on monitoring, prevention, and control of serious cross-border health

threats and on development and authorisation of medical countermeasures.

For example, HERA uses the outputs of ECDC activities – notably from the networks of epidemiological surveillance, the ECDC epidemic intelligence system, and the ECDC risk assessments as regards communicable diseases and threats of unknown origin – and combines them with outputs of other surveillance systems and its own data collection in order to rapidly identify threats requiring a medical countermeasures response.

Further, independent of the special mode of cooperation in public health emergencies as described above, in preparedness time HERA closely cooperates with EMA on availability of medicines identified as potential countermeasures as well as to identify products not authorised in the EU and products in development that could be potentially of interest in case of public health emergencies. HERA complements the information received from EMA with its own intelligence gathering. Conversely, the outputs of HERA's intelligence gathering and threat assessment relevant to medical countermeasures are shared with ECDC and EMA to feed ECDC's risks assessments and guide EMA scientific

advice and regulatory support for the relevant medical countermeasures.

The rapid and coordinated response to the ongoing monkeypox outbreak in Europe has shown that HERA, ECDC, and EMA have set up mechanisms to avoid duplications and ensure efficient cooperation across their respective mandates (Box).

One year after the creation of HERA and with the completion of the European Health Union, the EU has better tools, capacities and structures to respond to health crises. The EU pandemic preparedness and response system needed a fundamental transformation. The EC and the co-legislators have – judiciously and in full respect of the EU countries’ competences – addressed this need by creating a legislative framework and reinforced permanent structures to face the challenges ahead. HERA, ECDC and EMA are at the heart of this new and still evolving set-up. Their concerted and determined efforts, in close partnership with countries, will make the EU better prepared for and able to respond quickly to future cross-border health threats.

Note

Pierre Delsaux is the Director General of the Health Emergency Preparedness and Response Authority (HERA).

Conflict of interest

None declared.

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Preparing Europe for future health threats and crises – the European Medicines Agency; ensuring safe and effective medicines and medical devices

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When coronavirus disease (COVID-19) spread rapidly across Europe in early 2020, the European Medicines Agency (EMA), together with the European Centre for Disease Prevention and Control (ECDC) and the European Commission, was at the forefront of the European Union (EU) response to the COVID-19 pandemic.

Despite the absence of an explicit legal mandate and appropriate resources, EMA quickly introduced a structure to coordinate activities and established processes which were crucial for an effective EU-wide response. For example, EMA coordinated the exchange of information and actions to identify and mitigate medicine shortages between EU countries when global pharmaceutical supply chains were disrupted almost overnight because of border closures and lockdowns and there was an increased demand for medicines, particularly in the intensive care unit setting. However, it became clear early in the pandemic that EMA needed stronger legal tools to help ensure the availability of medicinal products and medical devices and to support the development of new therapeutics to protect the health of Europeans in times of crisis.

EMA's timely efforts and successes were subsequently recognised and codified in a new framework for a European Health Union put forward by the European Commission [1]. The framework includes three pillars: extending the mandate of both EMA and ECDC and establishing the European Commission's new Directorate General HERA, the European Health Emergency Preparedness and Response Authority. Today, ECDC, EMA and HERA form part of a European preparedness matrix, in which each actor has its own role, while working closely together. This matrix aims to ensure a comprehensive approach to cooperation, coordination and communication across countries and EU bodies to protect EU citizens and address cross-border health threats.

The reinforced role of EMA in crisis preparedness and management is defined in Regulation (EU) 2022/123 [2]. The new responsibilities enable EMA to improve the availability of medicines and medical devices, whether it is dealing with shortages to ensure that already authorised medicines or devices remain available for EU patients in time of crisis, or whether it is supporting the development and authorisation of medicines and/or vaccines to address new public health emergencies [3].

Improving the availability of medicines authorised in the EU is a key priority for EMA and the European Medicines Regulatory Network, comprised of EMA, the EU countries' national regulatory authorities and the European Commission.

Shortages of medicinal products became a major issue long before the COVID-19 pandemic. They often have complex root causes and have a serious impact on healthcare systems and infringe on the right of patients to access appropriate medical treatment. The extended mandate is an important step to address this growing threat to public health [2]. It builds on the work EMA started on a voluntary cooperative basis during the pandemic. While EMA had no formal role in managing these shortages, the agency set up an executive level steering group and engaged with single points of contact in each EU country and worked closely with companies, wholesalers and distributors to gain essential intelligence on the scope and underlying causes of the issues.

The extended mandate has provided EMA with the tools to officially deal with shortages. There is a new executive body, the Medicine Shortages and Safety Steering Group (MSSG), which comprises representatives from EMA and from countries, to respond robustly to medicine supply issues caused by major events or public health emergencies and to coordinate swift actions within the EU when needed [4] (Box).

Box

European Medicines Agency new mechanisms following the extension of its mandate on 25 January 2022

- Medicine Shortages and Safety Steering Group (MSSG)
- Industry Single Point of Contact network (iSPOC)
- European shortages monitoring platform (ESMP)
- Data Analysis and Real-World Interrogation Network (DARWIN EU)
- Medicines Shortages Single Point of Contact (SPOC) Working Party
- Emergency Task Force (ETF)

Source [2].

In practice, the MSSG establishes lists of critical medicines needed during a major event or a public health emergency that require close monitoring of supply and demand with a view to identifying any actual or potential shortages of those medicinal products. EMA has already published lists of critical medicines for COVID-19 [5] and monkeypox [6]. These lists impose obligations on the marketing authorisation holders, who are required to update EMA for example on potential or actual shortages of the medicines listed.

The pharmaceutical industry plays an important role in the prevention and management of shortages, which is reflected in the updated and formalised Industry Single Point of Contact network (iSPOC). By 2 September 2022, every marketing authorisation holder in the EU had to register an iSPOC to enable rapid communication between EMA and companies [7]. Companies that market products included on specific lists of critical medicines now have new monitoring and reporting responsibilities in respect to forecasts of stock or demand. Regulation (EU) 2022/123 also foresees the development of a centralised electronic platform for pharmaceutical companies and countries to report on shortages, the European shortages monitoring platform (ESMP), by 2025. The ESMP is expected to induce better coordination, monitoring and prevention and could serve as the basis for extended EU-wide monitoring also in normal times [8].

The rapid spread of COVID-19 led to a sharp increase in demand for medical devices such as ventilators, surgical masks and COVID-19 test kits. However, the limited capacity to increase production and the vulnerability of the global supply chains caused severe supply disruptions and serious shortages. EMA's new mandate aims to establish a solid and effective monitoring of medical devices shortages that can occur during a public health emergency [2].

Medical devices do not have a centralised authorisation procedure, but EMA is involved in the regulatory process [9]. The new mandate transfers the coordination of the medical device expert panels from the European Commission to EMA. This will lead to a more integrated approach, with one scientific agency managing both medicines and certain types of medical devices [10]. In the future, the panels' opinions will be published in the dedicated European database on medical devices (EUDAMED) [11].

When confronted with a new disease, such as COVID-19, the ability to bring together all relevant actors and facilitate the processes of medicine development and regulation is key to accelerate the development and evaluation of new medicines. The need for integration across all regulatory fields is embodied in the Emergency Task Force (ETF), which pools the necessary scientific expertise across the EU [12]. The ETF provides scientific advice and reviews evidence on medicines that could be used for prevention or treatment during a public health emergency. It also offers scientific support to facilitate clinical trials, particularly large, well-designed multinational trials, and supports EMA's scientific committees with the authorisation and safety monitoring of medicines and with recommendations on the use of medicines before authorisation.

The COVID-19 pandemic put a spotlight on the need to invest in and leverage real-world evidence to support crisis preparedness and response. The EMA new mandate provides a legal basis for the establishment of the Data Analysis and Real-World Interrogation Network (DARWIN EU), which will provide EMA's scientific committees with real-world evidence from healthcare databases across the EU. EMA will be the principal user of DARWIN EU [13].

In the area of medical countermeasures, the scientific advice and regulatory support provided by EMA will be complemented by the financial support provided by HERA, which will leverage funding to support both basic, translational and clinical research and development susceptible to bring innovative medical countermeasures on the EU market.

The EU institutions have demonstrated considerable resilience in the face of COVID-19 [14], but more needs to be done. A large-scale emergency response requires a wide pool of expertise that can be drawn on at any time. The pandemic exposed the challenge of retaining sustainable human resources to answer to the increased and urgent demand for evaluation, as it is not feasible to rapidly recruit many new specialists in the specific area of infectious diseases while a crisis is ongoing. An agile network needs to be established to ensure that sufficient resources in terms of both staff and finances are available. Further, EMA will need to ensure planning and resourcing in new areas of expertise such as medical devices and diagnostics.

In a pandemic, nobody is safe before everyone is safe. EMA has to ensure that the needs and expectations of partners and stakeholders are carefully listened to. Acknowledging the uniqueness and complexity of the EU context, the agency will collaborate across the European medicines regulatory network and with public health authorities to strengthen EU-wide communications in a way that is transparent and strengthens trust.

The pandemic has highlighted the power of science and international cooperation. EMA has been working at high speed and in close cooperation with regulators, scientists and governments to respond effectively to the public health emergency. The European Health Union is based on the reinforced cooperation between EMA, ECDC and HERA.

Already during the pandemic, EMA has deepened its cooperation with ECDC, in particular in epidemiological forecasting, as this supports EMA's regulatory processes. Further, regular communication at different levels feeds into the agencies' strategic planning and decision-making and ensures aligned messaging during a health crisis. Together, EMA and ECDC are responsible for an initiative to strengthen post-marketing monitoring of the safety, effectiveness and impact of COVID-19 vaccines in the EU/European Economic Area [15]. The jointly coordinated, EU-wide effectiveness and safety studies are essential tools to monitor how novel vaccines perform in real life.

COVID-19 was the first public health emergency where countries agreed to pool their powers and budget and purchase medicines and vaccines in a joint and coordinated manner. The cooperation and information exchange between HERA and EMA is crucial for effective EU action.

The extended mandate makes EMA better equipped to deal with future emergencies. A practical example: EMA will work with ECDC to obtain epidemiological data to help forecast medicines needs and to request specific data from countries and supply-chain stakeholders [16]. The forecasts provide important input for HERA to build surge EU manufacturing capacities and stockpiles as well as launch emergency procurements and emergency deployment of medical countermeasures such as vaccines [17]. The ongoing monkeypox outbreak is the first instance in which all the new tools are applied.

Further, regular discussions between EMA and HERA collaborate within the Medicines Shortages Single Point of Contact (SPOC) Working Party, which is responsible for monitoring and reporting events that could affect the supply of medicines in the EU. In joint meetings, HERA regularly presents their surveys and studies on medicine availability and supply chain vulnerabilities, which provide important information from and for countries. Having HERA on board helps to

implement these critical activities and has clarified the scope of the surveys.

COVID-19 will not be the last pandemic Europe will face [18]. In addition, there are already other threats to health, such as antimicrobial resistance and the effects of climate change. The cooperation and interaction between EMA, ECDC and HERA as envisaged by the EU Health Union should lead to better preparedness and more resilience to overcome new challenges together.

Note

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Conflict of interest

None declared.

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EPI-NEWS
Department of Infectious Disease Epidemiology and Prevention, Statens Serum Institut, Copenhagen.
Weekly, via e-mail subscription and online. In Danish and English (one week later).
<https://en.ssi.dk/news/epi-news>

ESTONIA

Health Board, Tallinn
Estonian Communicable Disease Bulletin
Monthly, online. In English
<https://www.terviseamet.ee/en/communicable-diseases/communicable-disease-bulletins>

FINLAND

National Institute for Health and Welfare (THL), Department of Health Security. In Finnish
<https://thl.fi/fi/web/infektiaudit>

FRANCE

Bulletin épidémiologique hebdomadaire (BEH)
Santé publique France, Saint-Maurice
Bi-monthly, online. In French, with abstracts in English
Bi-monthly, online. In French, with abstracts in English
<https://www.santepubliquefrance.fr/revues/beh/bulletin-epidemiologique-hebdomadaire>

GERMANY

Epidemiologisches Bulletin
Robert Koch-Institut, Berlin
Weekly, print and online. In German.
www.rki.de/epidbull

GREECE

National Public Health Organization
Updates, online. In Greek.
<https://eody.gov.gr/e-enimerosi-ioynios-2019/>

HUNGARY

Epinfo (az Országos Epidemiológiai Központ epidemiológiai információs hetilapja)
National Center For Epidemiology, Budapest
Weekly, online. In Hungarian.
<http://www.oek.hu/oek.web?to=839&nid=41&pid=7&lang=hun>

ICELAND

EPI-ICE
Landlknisembtti, Directorate Of Health, Seltjarnarnes
Monthly to quarterly, online. In Icelandic and English.
<https://www.landlaeknir.is/english/epi-ice/>

IRELAND

EPI-INSIGHT
Health Protection Surveillance Centre, Dublin
Monthly, online. In English.
<http://www.hpsc.ie/epi-insight/>

ITALY

Notiziario dell'Istituto Superiore di Sanita
Istituto Superiore di Sanita, Reparto di Malattie Infettive, Rome
Monthly, online. In Italian.
<http://www.iss.it/publ/noti/index.php?lang=1&tipo=4>
Bolletino Epidemiologico Nazionale (BEN)
Istituto Superiore di Sanita, Reparto di Malattie Infettive, Rome
Monthly, online. In Italian.
<http://www.epicentro.iss.it/ben>

LATVIA

Epidemiologijas Biļeteni
Sabiedrības veselības agentūra

Public Health Agency, Riga
Online. In Latvian.
<http://www.sva.lv/epidemiologija/bileteni>

LITHUANIA

Epidemiologijos žinios
Užkrečiamųjų ligų profilaktikos ir kontrolės centras
Center for Communicable Disease Prevention and Control, Vilnius
Online. In Lithuanian.
<http://www.ulac.lt/index.php?pl=26>

MALTA

IDCU notifiable infectious disease tables
Infectious Disease Prevention and Control Unit, Department of Health
Promotion and Disease Prevention
Monthly and annually, online. In English.
https://ehealth.gov.mt/HealthPortal/public_health/idcu/library/library_menu.aspx

NETHERLANDS

Infectieziekten Bulletin
Rijksinstituut voor Volksgezondheid en Milieu
National Institute of Public Health and the Environment, Bilthoven
Monthly, online. In Dutch.
<http://www.infectieziektenbulletin.nl>

NORWAY

Nytt om smittevern
Folkehelseinstituttet, Oslo.
Online. In Norwegian.
<http://www.fhi.no/tema/smittevern-og-overvaaking>

POLAND

Meldunki o zachorowaniach na choroby zakaźne i zatruciach w Polsce
Panstwowy Zakład Higieny
National Institute of Hygiene, Warsaw
Fortnightly, online. In Polish and English.
http://www.pzh.gov.pl/epimeld/index_p.html#o1

PORTUGAL

Portugal Saúde em Números / Health by Numbers Portugal
Ministério da Saúde,
Direcção-Geral da Saúde, Lisbon.
Digital only. In Portuguese and English.
<https://www.dgs.pt/publicacoes/revista-cientifica-da-dgs.aspx>

ROMANIA

Centrul pentru Prevenirea și Controlul Bolilor Transmisibile, National Centre
of Communicable Diseases Prevention and Control, Institute of Public Health,
Bucharest
Sporadic, print only. In Romanian.
<http://www.cnscbt.ro/>

SLOVENIA

eNboz - Elektronske novice s področja nalezljivih bolezní in okoljskega
zdravja /
Intitit za varovanje zdravja, Center za nalezljive bolezni
Institute of Public Health, Center for Infectious Diseases, Ljubljana
Monthly, online. In Slovene.
<http://www.nijz.si/sl/e-nboz-o/>

SPAIN

Boletín Epidemiológico Semanal
Centro Nacional de Epidemiología, Instituto de Salud Carlos III, Madrid
Fortnightly, print and online. In Spanish.

<http://revista.isciii.es/index.php/bes/issue/current>

SWEDEN

Nyheter och press
Folkhälsomyndigheten, Stockholm.
Weekly, online. In Swedish.
<https://www.folkhalsomyndigheten.se/nyheter-och-press/>

UNITED KINGDOM

ENGLAND AND WALES

Health Protection Report
Public Health England, London
Weekly, online only. In English.
<https://www.gov.uk/government/collections/health-protection-report/latest-infection-reports>

NORTHERN IRELAND

Transmit: Health protection service bulletin
Public Health Agency, Belfast.
Monthly. In English.
<http://www.publichealth.hscni.net/search/node/transmit>

SCOTLAND

Health Protection Scotland Weekly Report
Health Protection Scotland, Glasgow.
Weekly, print and online. In English.
<http://www.hps.scot.nhs.uk/ewr/index.aspx>

EUROPEAN UNION

“Europa” is the official portal of the European Union. It provides up-to-date
coverage of main events and information on activities and institutions of the
European Union.
<http://europa.eu>

EUROPEAN COMMISSION - PUBLIC HEALTH

The website of European Commission Directorate General for Health and
Consumer Protection (DG SANCO).
<http://ec.europa.eu/health/>

HEALTH-EU PORTAL

The Health-EU Portal (the official public health portal of the European Union)
includes a wide range of information and data on health-related issues and
activities at both European and international level.
<http://ec.europa.eu/health-eu/>

EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

European Centre for Disease Prevention and Control (ECDC)
The European Centre for Disease Prevention and Control (ECDC) was
established in 2005. It is an EU agency with aim to strengthen Europe’s
defences against infectious diseases. It is seated in Stockholm, Sweden.
<http://www.ecdc.europa.eu>

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