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#### **COVER NOTE**

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#### COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Preparing the EU for the next health crisis : a Medical Countermeasures Strategy

#### **INTRODUCTION**

Vaccines, therapeutics, diagnostics, and other medical devices, as well as personnel protective equipment (PPE) are geostrategic products, essential to keep people, societies and economies healthy and safe. The need for such medical countermeasures has never been more pressing, at a time of rising health threats stemming from both natural and man-made origins.

The COVID-19 pandemic demonstrated that medical countermeasures are one of the backbones of EU preparedness and response to health threats. Their rapid development and supply were pivotal in saving millions of lives and in supporting frontline responders throughout the world. At the same time, their development, production at scale and fast deployment helped to mitigate the devastating impacts on our societies and economies, while highlighting the need to be better prepared to respond to the next health crisis when this occurs.

Joint and coordinated, concerted actions at EU level and reinforced global cooperation are essential to ensure availability and access to medical countermeasures. Building on this lesson learned, the European Union reinforced its health security framework through strengthened legislation on serious-cross border threats to health in the form of a new Regulation<sup>1</sup>, and the European Commission established the Health Emergency Preparedness and Response Authority (HERA), as a watchtower for preparedness and response in the area of medical countermeasures, working closely with other Commission services, the strengthened European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA). In this robust health security framework, which will be further strengthened through the Union prevention, preparedness and response plan for health crises,<sup>2</sup> EU institutions and Member States work closely together to address health threats that transcend national borders.

Today the EU is better prepared than five years ago, yet Europe and the world remain exposed to a wide range of growing health threats for which medical countermeasures often remain scarce or unavailable. The dynamic challenges posed by emerging threats and structural barriers, including fragmented and insufficient investments in innovation, regulatory burdens, limited commercial viability, supply chain vulnerabilities, as well as the lack of manufacturing capacities and insufficient international collaboration, result in significant gaps in the availability of medical countermeasures to address the threats we face.

An innovative and competitive medical countermeasures sector is essential for our preparedness for health threats. Supporting innovation and the development of promising and cutting-edge technologies and medical countermeasures will not only ensure that products are available when the next crisis strikes but these breakthroughs will yield broader public health, social, and economic benefits beyond health emergency preparedness. The rapid progress of mRNA platforms observed during the COVID-19 pandemic and their subsequent application in cancer treatments best exemplify this potential. Strengthening the medical countermeasures sector

<sup>&</sup>lt;sup>1</sup><u>Regulation (EU) 2022/2371 on serious cross-border threats to health</u>

 $<sup>^{2}</sup>$  According to Article 5 of Regulation (EU) 2022/2371 on serious cross-border threats to health, the Commission shall establish a Union prevention, preparedness and response plan to promote an effective and coordinated response to cross-border threats to health at Union level.

will further enhance innovation and competitiveness of a strategic sector of the EU economy and provide quality jobs.

Preparedness and response save lives when diseases with epidemic or pandemic potential spread within hours or days. That is why ensuring that medical countermeasures are rapidly, sufficiently and equitably available, to protect people from health emergencies is a prerequisite for our readiness for the next crisis. This relies on a rapidly scalable manufacturing capacity, robust distribution systems and resilient workforce to deliver and administer medical countermeasures to those in need, being mindful of the specific needs of women and diverse groups<sup>3</sup>. A change of mindset is also needed, in line with the Preparedness Union Strategy's allhazard, whole-of-government and whole-of-society approach, and recognising that preparedness does not come for free: the costs incurred today are long-term investments in resilience to crises.

The Medical Countermeasures Strategy embraces this change of mindset to proactively prepare and protect people from health threats, acknowledging the fact that medical countermeasures are strategic assets to make EU stronger, healthier and better prepared. With this strategy, the EU aims to reinforce its preparedness for the next health emergency, irrespective of its origin, from pandemics to human-made biosecurity threats or conflicts, by ensuring access to and availability of medical countermeasures at all times. This will be achieved through the following objectives:

- 1. Stimulating and fostering innovation in the area of medical countermeasures, as well as their development, production and availability by following a One Health and full value chain approach to ensure a comprehensive and complete end-to-end approach from threat and identification, prioritisation, and assessment, through the research and development pipeline, to manufacturing, and deployment.
- 2. Driving **joint priority setting, close cooperation with Member States** and collaboration with EU candidate countries and global partners.
- 3. Scaling-up **public and private partnerships** and enhancing cross-sectoral collaboration including **civil-military cooperation**.

Such a strategy will not only be beneficial to counter public health threats but should also fortify our preparedness for other types of crises requiring medical countermeasures while also contributing to enhancing the EU's technological leadership and competitiveness in the health sector. As such, this strategy is built at the interface between the Niinistö<sup>4</sup> and Draghi<sup>5</sup> reports and is embedded in the overarching framework provided by the Preparedness Union Strategy<sup>6</sup> and the Competitiveness Compass<sup>7</sup>.

<sup>&</sup>lt;sup>3</sup> In particular, attention should be paid to the needs of persons with disabilities, younger and older persons, and racial or ethnic minorities. The <u>Union of Equality framework</u> promotes equal access to health for all.

<sup>&</sup>lt;sup>4</sup> Safer Together Strengthening Europe's Civilian and Military Preparedness and Readiness.

<sup>&</sup>lt;sup>5</sup> The future of European competitiveness - A competitiveness strategy for Europe.

<sup>&</sup>lt;sup>6</sup> The European Preparedness Union Strategy.

<sup>&</sup>lt;sup>z</sup> <u>A Competitiveness Compass for the EU</u>.

The Strategy is accompanied by two supporting annexes, one presenting a list of priority health threats requiring medical countermeasures and the other on an EU strategic plan for stockpiling of medical countermeasures which is the first sectoral deliverable of the EU Stockpiling Strategy<sup>8</sup>.

#### I. <u>PRIORITY HEALTH THREATS REQUIRING MEDICAL</u> <u>COUNTERMEASURES</u>

Climate change, globalisation, conflicts, and humanitarian crises are increasing the complexity, frequency and probability of health emergencies, rendering Europe and the world more vulnerable to rapidly evolving health threats for which medical countermeasures are needed. To ensure agility and robust actions at EU-level, complementing Member States' interventions, the Commission, in collaboration with Member States<sup>9</sup>, has currently prioritised four categories of severe and serious health threats posing the greatest risk and requiring coordinated EU interventions in the area of medical countermeasures (See Annex 1).

The Commission will, together with Member States, continuously review and update this prioritisation and related medical countermeasures. As with any threat analysis this is a dynamic process which will be continuously informed by multidisciplinary scientific evidence and intelligence sources.

#### Respiratory or contact-based viruses with pandemic potential

Outbreaks of infectious diseases with the potential to cause widespread, sustained transmission are becoming increasingly frequent, complex and severe. The drivers include among others, the accelerating effects of climate change, environmental degradation, as well as biodiversity loss, globalisation, geopolitical instability and conflicts.

Recently, the world has experienced the global impact of *Coronaviridae* viruses such as COVID-19, recurring *Filoviridae* outbreaks, such as Ebola, and is now facing the rapid spread of avian influenza among birds and mammals, with occasional transmission to humans. These threats also include the so-called 'Pathogen X', referring to yet unknown pathogens that may become responsible for the hypothetical 'Disease X' in the future. Addressing these health threats requires a strong and integrated One Health approach, along the human, animal, and plant health continuum, and dedicated medical countermeasures.

### Vector-borne or animal-reservoir viruses with epidemic potential

Climate change, rising temperatures, and changing precipitation patterns are enabling the emergence and expansion of vector-borne diseases<sup>10</sup> in regions that were considered low-risk, this includes the EU<sup>11</sup>. The establishment and spread of mosquitoes and ticks across the EU is facilitating the transmission of tropical diseases like dengue, West Nile virus, chikungunya.

<sup>&</sup>lt;sup>8</sup> EU Stockpiling Strategy COM(2025)528

<sup>&</sup>lt;sup>9</sup> Consultations with Member States have been carried out via the HERA Board

<sup>&</sup>lt;sup>10</sup> Vector-borne diseases account for more than 17% of all infectious diseases, causing more than 700 000 deaths annually with most deaths occurring in children under the age of 5 years. (WHO, 2024).

<sup>&</sup>lt;sup>11</sup> The first <u>European Climate Risk Assessment</u>, published in March 2024, highlights mosquito- and tick-borne diseases recently emerged or expanded their range in the EU, including West Nile virus, chikungunya, dengue, Lyme disease, tick-borne encephalitis and Crimean-Congo haemorrhagic fever.

Similar environmental changes influence the spread of rodents, acting as reservoirs of viruses such as Hantaan or Lassa viruses. These growing threats in the EU require preparedness for and investment in specific medical countermeasures, including vector control measures, to protect the public.

At the same time, the frequency and severity of extreme weather events – including heatwaves, droughts, wildfires and floods – have intensified<sup>12</sup> posing both direct and indirect health risks. These events also have the potential to affect the functioning of health care facilities and public health provision, with risks of disruption of production, transport, or distribution of essential products, including medical countermeasures. This is why medical countermeasures should be fully factored in the forthcoming European Climate Adaptation Plan.

#### Antimicrobial resistance

Antimicrobial resistance (AMR) is spreading globally as one of the most pressing global health threats, intensified by misuse and overuse of antibiotics, pollution, climate change as well as conflicts. While many actions have been taken to enhance preventive measures, incentivise the access to and availability of diagnostics and antimicrobials, and stimulate the development pipeline of new products – including a new regulatory incentive proposed in the reform of the EU pharmaceutical legislation and provisions promoting the prudent use of antimicrobials – AMR continues to rise. This escalation puts at risk many of the gains made in modern medicine, undermining the effectiveness of existing treatments, including 'last resort' medicines, which makes routine medical procedures and previously easily treated infections riskier.<sup>13</sup> Availability of sensitive and specific point-of-care diagnostics in emergency care is crucial for the first-line use of targeted narrow-spectrum antimicrobials. As for most health threats, AMR has a disproportionate impact on vulnerable populations, including children, older people, pregnant women, and people with chronic illnesses.

### Armed conflict related threats and chemical, biological, radiological and nuclear (CBRN) threats

The increasingly volatile geopolitical and security environment increases the risks of security threats that would require medical countermeasures response. These include CBRN incidents, risks of state and non-state actors using biological or AI-powered capabilities to design novel molecules and bioweapons, mass casualty events or armed conflicts. In these cases, a range of medical countermeasures, such as antibiotics or antidotes, decontamination material and other protective equipment, might be needed in large quantities.

While several incidents involving biotoxins have occurred in Germany, Norway and the United Kingdom, these risks have been exacerbated by Russia's war of aggression against Ukraine, in particular with the Zaporizhzhia Nuclear Power Plant becoming a focal point of nuclear security concerns, as well as with recent developments in the Middle East. This situation requires the EU and its Member States to redouble their efforts and enhance civil-military collaboration to prepare

<sup>&</sup>lt;sup>12</sup> In the <u>Global Risks Report 2025</u>, extreme weather events were ranked as the top-risks over a 10-years horizon.

<sup>&</sup>lt;sup>13</sup> AMR is currently responsible for over 35 000 deaths every year in the EU/EEA and estimates from the UN suggest that by 2050 the number of annual deaths attributable to AMR could increase to 10 million globally and 390 000 in the EU/EEA.

for worst-case scenarios and ensure appropriate medical countermeasures are available and can be rapidly deployed.

### Examples of EU preparedness actions for CBRN incidents

In June 2018, the German police prevented a **ricin attack in Cologne**. At the time, no antidote was available to ricin toxicity, leaving possible victims without effective treatment. Through HERA Invest and COUNTERACT, the Commission supported a candidate antidote, that is now stockpiled via rescEU, ensuring protection from this threat across the EU.

In preparation for the **2024 Paris Olympic Games**, the Commission authorised the prepositioning of emergency medical intervention kits, along with PPEs and portable detectors, sourced from the rescEU stockpiles. Such stocks can serve as a temporary boost to permanent national capacities addressing the exceptional challenges posed by such events.

#### II. <u>A ROBUST INTELLIGENCE SYSTEM FOR MEDICAL</u> <u>COUNTERMEASURES INNOVATION AND RESPONSE</u>

In the face of rapidly evolving health threats, speed is of the essence and delays can cost lives. To enable a speedy response, robust surveillance and early alert systems, combined with comprehensive threat intelligence systems for medical countermeasures, are critical to detect health threats, identify the right medical countermeasures and to rapidly develop and deploy them.

## 2.1 Foresight and anticipation: enhancing collective health threats intelligence for medical countermeasures

# A robust foresight and anticipation system, that looks at threats requiring medical countermeasures in an all-hazard approach, will ensure that the EU can rapidly develop and deploy medical countermeasures to respond to health emergencies.

To upgrade the existing system, the Commission will continue to develop and operationalise its medical countermeasures intelligence system, the Advanced Technology for Health Intelligence and Action IT system – **ATHINA**. The first modules became operational in 2025 and are complementary to other intelligence systems e.g. those on epidemic intelligence run by the ECDC. ATHINA will integrate existing public health and supply chain data collected and analysed through systems operated by the EMA, the ECDC, the Commission's Joint Research Centre, the World Health Organisation Hub for Pandemic and Epidemic Intelligence<sup>14</sup> and others. By leveraging foresight and horizon scanning, future artificial intelligence (AI) functionalities, survey and modelling options, it will generate intelligence on medical countermeasures thereby enhancing the Commission's analytical capabilities and response options for specific health threats<sup>15</sup>. It will operate in synergy with the forthcoming European Crisis Management Platform (ECMP).

<sup>&</sup>lt;sup>14</sup> <u>https://pandemichub.who.int/</u>

<sup>&</sup>lt;sup>15</sup> ATHINA will allow for faster, data-driven decisions during health emergencies. It is designed to integrate diverse data sources – from within the Commission, open-source platforms, and commercial services – to enhance medical countermeasure related early detection strategic prioritization support, and response coordination. In future, it will also leverage AI-powered modelling and simulation tools to support preparedness in the field of medical countermeasures for a range of evolving threat scenarios.

The Commission in cooperation with Member States, will develop threat-specific **Medical Countermeasures Preparedness Roadmaps** by 2026. Building upon existing scientific evidence they will outline the key medical countermeasure actions needed to boost the EU's preparedness for different health emergency scenarios.

In addition, the Commission, in cooperation with Member States, will develop and publish in 2026 an **EU List of Medical Countermeasures for Priority Threats.** The list will serve as the basis for the crisis-relevant medical countermeasures list which the Commission is to draw up upon the activation of the emergency framework under the Emergency Framework Regulation<sup>16</sup>. It will also identify medical countermeasures that can be prioritised for different actions such as those fostering innovation, joint procurement or stockpiling.<sup>17</sup>

## 2.2 Strengthening detection and identification of health threats requiring medical countermeasures

Strong surveillance, rapid identification of and alerts about health threats are essential to ensure early development and deployment of appropriate medical countermeasures, minimising the impact of public health crises on the population. This is what citizens expect, and it is critical, especially for the most vulnerable and for frontline responders.

Building on the expertise and mandate of the ECDC, and in line with the ambition set out in the Preparedness Union Strategy, the EU will further strengthen its capacity to detect and assess threats taking a One Health, all-hazard, and whole-of-society approach, covering traditional health threats like disease outbreaks, the impacts of CBRN incidents<sup>18</sup>, armed conflicts and mass casualty events in the EU or its neighbourhood.

The Commission, with support from the ECDC, will also continue to assist Member States in **building their wastewater and environmental surveillance capacities**, in line with the recast Urban Wastewater Treatment Directive<sup>19</sup>.

This work will enable the Commission, in close cooperation with the ECDC, to operationalise an **EU-level Wastewater Sentinel System**, collecting data on pathogen circulation from strategic locations such as airports. In 2026, the Commission and partners will also launch a **Global Sentinel System for wastewater** as part of the **Global Consortium for Wastewater** and **Environmental Surveillance (GLOWACON)**, covering international airports and strategic locations globally, to detect and track potential outbreaks worldwide. These voluntary sentinel

<sup>&</sup>lt;sup>16</sup> <u>Council Regulation (EU) 2022/2372 of 24 October 2022</u> on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.

<sup>&</sup>lt;sup>17</sup> The EU List of medical countermeasures for priority threats will cover both marketed and medical countermeasures in development (including but not limited to medicinal products) to address specific threats with the potential of creating a public health emergency. The list complements the Union list of critical medicines which identifies human medicines whose continued supply is considered a priority in the EU.

<sup>&</sup>lt;sup>18</sup> For radiological and nuclear emergencies, the EU operates the European Community Urgent Radiological Information Exchange System (ECURIE).

<sup>&</sup>lt;sup>19</sup> Article 17 of the <u>Directive (EU) 2024/3019 of the European Parliament and of the Council of 27 November 2024 concerning</u> <u>urban wastewater treatment (recast)</u>, requires Member States to set up national systems for the surveillance in their urban wastewaters of public health relevant parameters, including AMR. In the event of a public health emergency surveillance of the relevant health parameter(s) is required.

systems will use wastewater surveillance for early detection and tracking of outbreaks, supporting timely deployment of medical countermeasures.

The Regulation (EU) 2022/2371 on serious cross-border threats to health requires the Commission to establish a network of EU Reference Laboratories (EURLs) for public health<sup>20</sup>. This work is well advanced, as nine EURLs have already been designated and are playing a vital role in strengthening the EU's health security architecture, including, for where relevant, the development of MCMs. The Commission has also established the DURABLE project composed of 19 partners from academia and public health institutes that support the Commission with high quality biological intelligence and critical research on the several categories of medical countermeasures (e.g. vaccines, therapeutics, diagnostics, PPEs, and biocides)<sup>21</sup>. The Commission considers expanding its geographical coverage, to enhance further the EU's capacity in identifying, characterising, and developing medical countermeasures and characterising pathogens of interest and concern ensuring synergies, complementarity and avoiding duplication with the work of EURLs. Overall, the Commission will continue to support Member States in strengthening their state-of-the-art laboratory capacities, harnessing innovative tools like metagenomics, bioinformatics and AI, to accelerate threat detection, enable biological characterisation and intelligence, and diagnostic development.

#### Key Actions:

#### The Commission will:

- Operationalise and expand, in collaboration with the ECDC, an EU Wastewater Sentinel System and a Global Wastewater Sentinel System [2026]
- **Consider expanding DURABLE** network geographical coverage to partners across other regions of the globe [2027]

The Commission will, in cooperation with Member States:

- Develop medical countermeasures preparedness roadmaps for specific health emergencies scenarios [2026]
- Establish an EU List of Medical Countermeasures for priority threats [2026]

#### III. <u>STRENGTHENING THE MEDICAL COUNTERMEASURES PIPELINE –</u> <u>FROM INNOVATION TO MANUFACTURING</u>

<sup>&</sup>lt;sup>20</sup> EU Reference Laboratories for public health are designated consortia of laboratories under Article. 15 of the Regulation on serious cross-border threats to health (<u>Regulation (EU) 2022/2371</u>) that provide support to national reference laboratories in the field of reference diagnostics (including testing protocols), reference materials, surveillance, notification and outbreak response, scientific advice, research, quality assurance, training and reporting uniformization. Currently, 9 EURL for public health have been nominated: <u>https://health.ec.europa.eu/health-security-and-infectious-diseases/surveillance-and-early-warning/eu-reference-laboratories-public-health en</u>

<sup>&</sup>lt;sup>21</sup> For example, <u>DURABLE</u> has been responsible for important scientific advances of the protective effect of influenza vaccines and on the transmission of H5 (avian influenza) on animals, which supports the Commission in preparing for potential outbreaks and inform on the effectiveness of existing MCMs and need for further R&D activities.

The EU is a hub for the innovation, the development and production of medical countermeasures. During the COVID-19 pandemic, almost half of global vaccine patent applications came from the EU, and the EU's strong manufacturing base was rapidly scaled up, turning the Union into the "pharmacy of the world"<sup>22</sup>.

Building upon its strong research base, robust pharmaceutical industry and talented health workforce, the EU must continue to reinforce its leadership in medical countermeasures development and production, working in close partnerships with global partners and complementing measures under the reform of the general pharmaceutical legislation, the EU Life Sciences Strategy<sup>23</sup>, the Startup and Scaleup Strategy<sup>24</sup>, the proposed Critical Medicines Act<sup>25</sup> and the planned European Innovation Act and Biotech Act.

#### 3.1 Advancing medical countermeasures innovation

Currently, EU funding tools to advance the research and development of medical countermeasures are fragmented across programmes such as Horizon Europe, EU4Health, the European Defence Fund, and Cohesion Policy funds, hindering the efficient and coherent progress of research and development efforts.

To maximise the impact of EU funding and best leverage the potential of the EU budget to accelerate the development of medical countermeasures, the Commission will develop a **Medical Countermeasures Accelerator** by 2025, an integrated and simplified framework to accelerate the development of medical countermeasures and designed to support innovators throughout the development cycle, from research to market entry. Functioning as a one-stop-shop, it will ensure a fair, transparent and competitive process through catalytic actions and support to innovation enablers. The Accelerator will draw on the range of financial instruments available in EU programmes<sup>26</sup>, in line with their specific programming and governance arrangements, ensuring synergies and avoiding duplication. These financial instruments will include grants, procurement of innovation, advance purchase agreements, loans, equity and venture capital.

The Accelerator will focus on the most needed medical countermeasures (i.e. vaccines, therapeutics, diagnostics, PPE and technologies) across the four threat categories. Building on the Commission's call to speed up the development of **next-generation influenza vaccine candidates**<sup>27</sup>, future actions will consider support for new vaccines or antivirals against vector-borne diseases, new antimicrobials to which resistance has not emerged, vaccines against Ebola and/or Marburg viruses or new point-of-care diagnostics for respiratory viruses.

<sup>&</sup>lt;sup>22</sup> In 2022, 40% of the world's vaccines against COVID-19 were exported from the EU.

 <sup>&</sup>lt;sup>23</sup> <u>Choose Europe for life sciences A strategy to position the EU as the world's most attractive place for life sciences by 2030</u>
 <sup>24</sup> <u>The EU Startup and Scaleup Strategy</u>.

<sup>&</sup>lt;sup>25</sup> Proposal for a Regulation of the European Parliament and of the Council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795.
<sup>26</sup> For the duration of the Multinannual Financial Framework 2021-2027, the Medical Countermeasures Accelerator may be

<sup>&</sup>lt;sup>26</sup> For the duration of the Multinannual Financial Framework 2021-2027, the Medical Countermeasures Accelerator may be supported by the EU programmes such as Horizon Europe and EU4Health Programme.

<sup>&</sup>lt;sup>27</sup> The Commission has pledged EUR 225 million to set up Framework contracts to speed up the development of next generation influenza vaccines.

The Commission and the European Investment Bank (EIB) have successfully rolled out a unique quasi-equity, venture loan financing instrument that stimulates innovation in medical countermeasures across Europe, with a focus on supporting EU-based SMEs. To further promote cutting-edge innovation, bridge the investment gap in this critical sector, and maintain a highly attractive environment for pharmaceutical companies and startups within the EU, the Commission, together with the EIB, will expand support for promising European startups and SMEs developing medical countermeasures and related technologies by doubling the size of HERA Invest to reach EUR 200 million by 2027.

Furthermore, together with the Member States, the Commission intends to reinforce information sharing mechanisms between EU and national funding programmes and priorities in the area of medical countermeasures. This will foster closer coordination and ensure the complementarity of actions.

#### AMR - Advancing innovation and access to antimicrobials

Building on the successful development of a new antibiotic class for resistant gonorrhoea and a new multi-resistant tuberculosis vaccine, the Commission plans to further advance innovation in antibiotics, alternative treatments, diagnostics and vaccines targeting AMR by:

- Organising **targeted calls** to speed up innovation to address high risk bacterial and fungal pathogens.
- Investing EUR 75 million in the Horizon Europe **One Health AMR Partnership** to step up EU actions to combat antimicrobial resistance taking a One Health approach.
- Incentivising the development of priority antimicrobials through the introduction of an innovative pull incentive scheme known as the Transferable Exclusivity Voucher (TEV) included in the Commission's proposal for the new pharmaceutical legislation.
- Improving access to AMR products by developing innovative economic models, including revenue guarantee or other forms of financial **pull incentives** and **joint procurement**.
- Supporting **WHO** efforts to monitor and assess the global R&D pipeline for AMR.

In addition, following the UNGA political declaration on AMR, the Commission will support the establishment of an **Independent Panel for Evidence on Action Against AMR** that is expected to support high impact interventions in the field of AMR R&D<sup>28</sup>.

### **3.2 Innovation enablers to speed-up the development of medical countermeasures addressing priority threats**

Preparedness for health threats requires the EU to support the development of a diversified portfolio of medical countermeasures leveraging the development of rapid response platforms and technological enablers, such as digital and AI technologies.

These actions will help consolidate the EU's position as a leading centre for medical countermeasures research, development, and innovation.

#### Rapid response platforms and partnerships

<sup>&</sup>lt;sup>28</sup> The Commission will continue to support Member States through the "Joint Action JAMRAI 2", to help them implement their National Action Plans and move towards achieving the 2030 targets. <u>https://eu-jamrai.eu/</u>

Since health threats can emerge unpredictably and spread quickly, rapid response platforms have become essential for ensuring timely interventions, focusing on the development of technologies that can quickly pivot to ensure rapid access to effective medical countermeasures when an emergency occurs.

Building upon projects such as the European Vaccine Hub (see box below), their early lessons learned, the Horizon Europe Pandemic Preparedness Partnership, the Clinical Research Investment Plan announced in the Life Sciences Strategy, and supported by experts' groups, such as the Clinical Trials Coordination Mechanism, the Commission will:

- Launch a pilot for a **European Diagnostics Hub** by 2026 to **invest and develop nextgeneration diagnostic tests and technologies,** that are quickly scalable, easily adaptable, and usable at point of care addressing multiple pathogens and complementing the work of DURABLE with rapid diagnostics.
- Launch a European Therapeutics Hub by 2027 to foster the development of broadspectrum monoclonal antibodies and antivirals that can be rapidly deployed against a wide range of pathogens such as coronaviruses, Ebola, Marburg, mpox, dengue, as well as unknown threats like "Pathogen X".
- Through the Research Infrastructures/ISIDORe network, the Commission will explore increased support for European researchers and projects with **facilitated or free access to infrastructure services**, such as **biobanks** or medical cohorts.

#### **Rapid Vaccine Development Platform – The European Vaccine Hub**

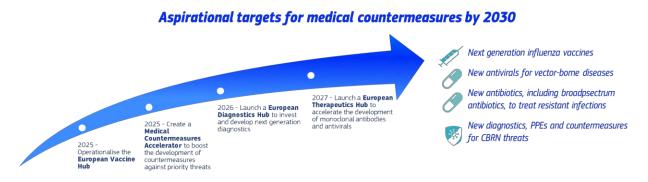
Launched in 2025, the European Vaccine Hub is a consortium of leading European actors in charge of advancing the development and manufacturing of vaccines for public health threats with EUR 102 million in funding over four years. The European Vaccine Hub will:

- Start and speed up the development of first investigational vaccines against any threat within four months from its emergence.
- Propose a prototype vaccine strategy utilizing cutting-edge platform technologies.
- Drive preclinical, phase I/II, and Controlled Human Infection Model (CHIM) vaccine trials against selected pathogens.
- Reinforce public-private partnerships for vaccine manufacturing.
- Facilitate access to vaccine production facilities, clinical trial sites, analytical laboratories, technology transfers, and expanded production via industry partnerships.

The Commission will also continue to team up with international partners, thereby enhancing synergies and alignment between EU and global initiatives for the development of medical countermeasures. Specifically, the Commission will:

• Continue to support the **Coalition for Epidemic Preparedness Innovations (CEPI)** for vaccine development against jointly agreed priorities.

- Partner with **Drugs for Neglected Diseases initiative (DNDi)** to support clinical trials for promising antivirals against dengue.
- Continue to invest in the development of new antibiotics effective against resistant bacteria, by supporting the **Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X)** and the **Global Antibiotic Research and Development Partnership (GARDP)** in innovative antibiotics and diagnostics.
- Contribute to the establishment of a **Global Therapeutics Development Coalition** under the International Pandemic Preparedness Secretariat (IPPS), aiming to increase the availability and accessibility of therapeutics against diseases with pandemic potential.



#### Technological enablers for medical countermeasures development

Digital technologies are powerful assets for the development of medical countermeasures. AIbased tools have significant potential to accelerate this process by facilitating the collection and analysis of threat intelligence guiding medical countermeasures development, identifying promising compounds for vaccines or therapeutics, or enabling faster, real-time analysis of multicountry clinical trial data. This approach can substantially accelerate the development pipeline and the discovery of new medical countermeasures. In particular, the Commission will promote AI tools to:

- **Support faster detection** and monitoring of health threats for medical countermeasures intelligence.
- Accelerate medicine discovery to quickly find potential medicine candidates including the candidates that are the most promising for repurposing.
- **Optimise clinical trials** and use AI to support clinical trials design and data analysis, thereby aiming to reduce the time to approval.

These actions would feed into the forthcoming Strategy for Artificial Intelligence in Science that the Commission plans to put forward later in 2025.

## **3.3 Building robust production capacity for medical countermeasures and reducing supply chain dependencies**

To efficiently protect citizens from health emergencies, the EU needs to maintain production readiness. Investing in **resilient, scalable manufacturing capability** that can rapidly produce

medical countermeasures at scale when a crisis strikes is essential. This involves supporting **smart**, **modular**, **and flexible manufacturing facilities**, alongside advancing production technologies and ensuring the security of production sites, including cybersecurity.

The Commission will create **RAMP UP** - the Rapid Agile Manufacturing Partnership for Union Protection - a voluntary network of EU-based pharmaceutical manufacturers, innovators, and suppliers. This partnership will create a rapid-response industrial force to protect citizens during crises. By collecting essential information on medical countermeasures manufacturing capacities during preparedness times, RAMP UP will enable the Commission to identify supply chain risks and respond swiftly in emergencies. This partnership will facilitate flexible preplanning at EU level and the rapid scale-up of production in case of health emergencies, while also helping to reduce dependencies and diversify supply chains. It will operate in line with the rules and principles of EU competition law.

In parallel to the measures set out in the proposal for a Critical Medicines Act, the Commission in cooperation with Member States, the EMA and other relevant stakeholders, will work to identify whether there are weaknesses in the supply chains of medical countermeasures that are not included in the Union list of Critical Medicines, for example personal protective equipment, diagnostics devices or medical countermeasures against CBRN threats. This assessment will inform the prioritisation of mitigating measures and enhance security of supply.

To further enhance production capacity, the Commission will also build on the **EU FAB** model, which **reserves an ever-warm production capacity** of 325 million vaccine doses that can be rapidly activated to make the required quantity of selected vaccines for the EU in case of an emergency. The Commission will explore expanding the scope of EU FAB to cover a wider range of products and include the preparedness phase, supporting both civilian and military needs and encouraging innovative manufacturing models that could boost our response to future health emergencies.

The Commission will also support a launch of **Important Projects of Common European Interest (IPCEI)** to provide financial support to R&D projects of a major innovative nature that address health threats, such as the Med4Cure project, to enhance health emergency preparedness and response to the benefit of the Union, its citizens and its competitiveness.

The COVID-19 pandemic demonstrated the risks posed by export restrictions on the availability of medical countermeasures in the EU. The revision of the EU pharmaceutical legislation and the Critical Medicines Act will provide a regulatory framework that will contribute to enhancing the availability of medicines, some of which are medical countermeasures. The revision of the EU pharmaceutical legislation also includes a new pathway to authorise medical countermeasures, such as the temporary emergency marketing authorisations. To ensure a secure supply in times of crisis the EU will further rely on the Internal Market Emergency and Resilience Act

(IMERA)<sup>29</sup> and the Regulation for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency<sup>30</sup>. The Commission will continue to work with Member States and third countries, to mitigate the risks of shortages of crisis relevant medical countermeasures by engaging in and developing international partnerships, and by facilitating the cross-border trade of necessary supplies when a crisis materialises. It will also continue to improve the EU customs crisis management capacity to detect and prevent substandard and falsified medical products and equipment from entering the EU market, to facilitate the inflow of critical medicines and products in times of crisis, and when deemed necessary, to prohibit their export from the EU.

#### Key Actions:

The Commission intends to:

- Develop a Medical Countermeasures Accelerator [2025]
- Launch a European Diagnostic Hub to support the development of next-generation diagnostics [2026]
- Launch the **European Therapeutics Hub** to accelerate the discovery and manufacturing of broad-spectrum antivirals and monoclonal antibodies [2027]
- Explore expanding the scope of EU FAB to enhance EU-based production capacity for medical countermeasures in preparedness and crisis times [2026]
- Set up **RAMP UP** to ensure rapid manufacturing of medical countermeasures in case of emergencies [2026]

### The Commission and the European Investment Bank are planning to:

• Double the size of **HERA Invest** [2027]

### IV. <u>ENSURING ACCESS, AVAILABILITY AND RAPID DEPLOYMENT OF</u> <u>MEDICAL COUNTERMEASURES</u>

The Commission will continue to work with Member States and relevant partners to ensure rapid and equitable access to medical countermeasures. It will leverage public procurement and joint purchases, expanding and sustaining EU-level strategic stockpiles, and ensure swift deployment and uptake. For the medicinal countermeasures that are on the Union list of Critical Medicines, the measures proposed in the Critical Medicines Act could be deployed.

#### 4.1 Procurement

Joint procurement of crisis-relevant medical countermeasures has proven tremendously valuable in recent years, allowing 38 countries, including candidate and potential candidate countries to

<sup>&</sup>lt;sup>29</sup> Regulation (EU) 2024/2747 of the European Parliament and of the Council of 9 October 2024 establishing a framework of measures related to an internal market emergency and to the resilience of the internal market and amending Council Regulation (EC) No 2679/98 (Internal Market Emergency and Resilience Act).

<sup>&</sup>lt;sup>30</sup> <u>Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant</u> medical countermeasures in the event of a public health emergency at Union level.

secure equitable and rapid access to essential supplies to the benefit of over 525 million Europeans. These include, for instance, COVID-19 vaccines and therapeutics, pre-pandemic and pandemic (avian) influenza vaccines, and mpox vaccines.

In 2026, the Commission will consider and, if appropriate, propose the revision of **the 2014 Joint Procurement Agreement** for medical countermeasures to align it with the revised Financial Regulation and to make it better fit for today's needs for procurement of medical countermeasures. It will also work with Member States to explore cost-effective and innovative financial and procurement models to boost product development and availability, reduce risk for companies and increase access in the EU. This will include capacity reservation contracts, based on precedents such as those for pandemic influenza vaccines.

The Commission will also develop in close cooperation with the Member States, **Guidelines for Crisis Procurement of Medical Countermeasures** in early 2026.

At the global level, the Commission will organise workshops to share experience and best practices in the field of joint procurement for medical countermeasures, responding to requests from regional and international organisations. This will enable examining where collaboration can be mutually beneficial, whether in the EU's neighbourhood and beyond.

#### 4.2 Stockpiling of medical countermeasures

Strategic stockpiles enable the EU to respond rapidly to large-scale emergencies and reduce dependency on external suppliers by having necessary medical countermeasures available for response or to ensure availability during supply chain disruptions. Building on recent experience with EU-level stockpiles, the Commission will **explore solutions to further support Member** States in maintaining strategic reserves of medical countermeasures beyond 2026.

Given the specificities of medical countermeasures stockpiling, the Commission presents alongside this strategy an **EU Strategic Plan for the Stockpiling of Medical Countermeasures** (Annex 2), complementing the wider EU Stockpiling Strategy and aiming to ensure the efficient and effective stockpiling of relevant medical countermeasures against health threats.

The plan will identify and deploy actions across the comprehensive management lifecycle of medical countermeasure stockpiles and build upon actions already implemented in this area both by Member States and the Commission when developing rescEU, taking into account the need to avoid any unintentional market effects or duplication with (inter)national stockpiles. This encompasses detailed processes for identifying essential medical countermeasures, determining necessary quantities and the potential need for replenishment, followed by effective procurement strategies, which also include EU-level joint procurement as a cost-effective tool for strengthening national stockpiles. The plan also outlines elements to strengthen the efficient management of these stocks to guarantee readiness and timely access during emergencies as well as a deployment strategy.

### Summary of the key actions foreseen under the Strategic Plan for the Stockpiling of Medical Countermeasures:

The Commission will develop a compendium of medical countermeasures suitable for stockpiling at EU level. Prepositioning and rapid deployment according to threat scenarios will be considered as will be the availability of specific medical countermeasures at national level.

In consultation with the EMA and other relevant stakeholders, the Commission will establish a list of medical countermeasure candidates for advance purchase and will carry out a pilot study on stockpiling of unfinished products.

In collaboration with Member States, the Commission will also explore the composition of EU medical countermeasures kits, which could be procured through joint procurement or by direct procurement.

To optimise the sustainability and cost effectiveness of stockpiles, the Commission will launch a pilot project to extend the shelf-life of certain medical countermeasures. Additionally, the Commission will assume, when pertinent, a more active role in coordinating at the EU level the procurement of medical countermeasures to ensure efficient and effective purchasing. The Commission will, in partnership with the Member States and the EMA, and based on lessons learnt, facilitate effective stockpiling of unauthorised medical countermeasures.

#### 4.3 Deploying medical countermeasures

Ensuring that medical countermeasures quickly reach the people who need them most is essential to safeguard lives and respond effectively to health crises.

The **Emergency Response Coordination Centre** will coordinate the deployment of medical countermeasures, in close cooperation with the HERA Board and/or the Health Crisis Board, if the Emergency Framework Regulation is activated in the event of a public health emergency at Union level<sup>31</sup>.

The Union Civil Protection Mechanism and reliefEU will provide flanking logistics support for the deployment of medical countermeasures in the European Union and where applicable to third countries.

In 2026, the Commission will facilitate swift response to health emergencies by supporting local detection of threats by easily deployable, **ready-to-use laboratories for biological and chemical hazards in emergency situations,** including for military purposes, allowing affected communities to receive the diagnostic support they need, when and where it is most needed.

In line with the Preparedness Union Strategy<sup>32</sup>, and building on the existing cooperation mechanisms, the Commission will step up coordination and cooperation between civil and military entities, notably with respect to medical countermeasures that are required for both, the civilian population and the military, to better prepare for and respond to health emergencies. The Commission also considers addressing medical countermeasures deployment in discussions with

<sup>&</sup>lt;sup>31</sup> <u>A public health emergency at Union level may be formally recognized by the Commission in situations where a serious crossborder threat to health endangers public health at Union level, in accordance with Article 23 of Regulation (EU) 2022/2371.</u>

<sup>&</sup>lt;sup>32</sup> European Preparedness Union Strategy.

armed forces, leveraging new technologies like drones and military logistics to enable rapid deployment, and secure transport.

To facilitate last-mile delivery, the Commission will promote the development of **distribution infrastructure**, such as **cold chain** infrastructure, and technologies with lower logistical constraints facilitating roll out and deployment to the most vulnerable settings.

At global level, the Commission will in 2026 develop **standardised procedures for medical countermeasures sharing agreements with global partners**, to fast-track delivery to affected countries in the event of a crisis, building on lessons learned from the recent successful response to the mpox outbreak in Africa using a Team Europe's approach. Strengthened collaboration with Gavi, the Vaccine Alliance, and UNICEF will be pursued in that respect.

#### Key actions

The Commission will:

- Consider and if appropriate propose the revision of the Joint Procurement Agreement to make it better fit for today's needs [2026].
- Support rapid response ready-to-use laboratories [2026].

The Commission will, in cooperation with Member States:

- Develop standardised procedure for medical countermeasures sharing agreements with global partners to third countries [2026]
- Establish Crisis Procurement Guidelines [2026]

#### V. <u>GLOBAL COOPERATION AND COORDINATION ON MEDICAL</u> <u>COUNTERMEASURES</u>

The global availability of medical countermeasures has been a critical issue in all major recent outbreaks of infectious diseases, and global solidarity is essential. Health threats do not stop at EU borders and require strong collaboration and diplomatic outreach across sectors at both EU and global level. The EU will continue to work with global partners to tackle challenges related to threat detection, medical countermeasures development, and supply chains strengthening, by investing more in innovation and in the security of supply.

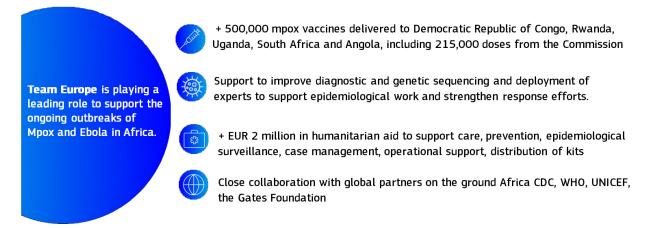
#### 5.1 EU and Global Coordination

At EU level, the Commission is developing a Union Prevention, Preparedness and Response Plan which will outline provisions on joint arrangements for governance, capacities and resources to support Member States for prevention and preparedness of as well as response to a serious crossborder threat to health.

The Commission services and the European External Action Service will enhance coordination with Member States, EU agencies, and global partners to ensure prompt detection of any emerging health threats to the EU and the world, facilitate quick and equitable access to medical

countermeasures. This reflects also the findings of the HERA review<sup>33</sup> noting that activities in the area of medical countermeasures contribute to building a robust global health security framework.

Effective worldwide warning systems for new threats requiring medical countermeasures are essential to promptly develop and distribute appropriate medical countermeasures, while medical research, pharmaceutical production, and supply chains are inherently global. This highlights the need for coordinated efforts at the global level to speed up research and development of new medical countermeasures and enhance their security of supply. Global coordination is critical to stop any new outbreak locally before it crosses borders or turns into a pandemic.



This is why the EU intends to redouble its focus on **global health security**, enhancing collaboration with the **World Health Organization (WHO)**, the **African Centre for Disease Control and Prevention (Africa CDC)**, and strengthening the role of infectious diseases' global health research partnerships such as the Global Health European and Developing Countries Clinical Trials Partnership (EDCTP3)<sup>34</sup>, which aims to advance health research and development and outcomes in sub-Saharan Africa. Additionally, the Commission will continue to collaborate with other R&D funders coordination projects, like the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R)<sup>35</sup>.

The Commission and the WHO collaborate extensively on the prevention, preparedness and response to serious cross-border health threats through technical cooperation and support, financial contributions, as well as joint initiatives. To further enhance this cooperation, in particular as regards joint priorities and activities, both parties intend to establish a framework for enhanced cooperation in line with Article 30 of Regulation 2022/2371 by 2026.

The EU will also continue developing existing or new partnerships on medical countermeasures with regional organisations or countries in the European Economic Area (EEA)/European Free Trade Association (EFTA), the Indo-Pacific region, Latin America (i.e. Pan American Health Organisation), and selected countries like Canada and the United Kingdom on global health security issues.

<sup>&</sup>lt;sup>33</sup> <u>Review of the implementation of the operations of the Health Emergency Preparedness and Response Authority (HERA)</u>.

<sup>&</sup>lt;sup>34</sup> https://www.global-health-edctp3.europa.eu/index\_en

<sup>35</sup> https://www.glopid-r.org/

Building upon initiatives under the Global Gateway Strategy such as the **Team Europe Initiative** on **Manufacturing and Access to Vaccines, Medicines, and Health Technologies** (MAV+) in Africa and the bi-regional EU-LAC initiative on local vaccine and health technology manufacturing, the Commission will continue to support the development of **regional production capacities for vaccines, medicines, and health technologies**, including medical countermeasures, in partner regions. In that regard, the EU will also take part in the **G20 Global Coalition on Regional and Local Production**<sup>36</sup>. The Commission will also explore ways to increase medical countermeasures production capacity and supply chain security in our neighbourhood, taking into account the soon-to-be-finalised study on **the Western Balkans**<sup>37</sup> and **Ukraine's medicinal products production capacity**, and globally, by continuing to engage with partners like India and China to address supply chain bottlenecks.

#### 5.2 Civil-military cooperation

Pandemics, the availability of chemical or biological substances, and antibiotic-resistant infections pose threats not only to public health but also to security, affecting the public and the military alike. The medical countermeasures needed for civilian use in hospitals or for military use on the front lines are often the same. In addition, some medical countermeasures have been developed for dual purposes, i.e. to address diseases of interest from both a civilian health perspective and a military biodefense standpoint, therefore serving civilian public health needs by controlling outbreaks and simultaneously supporting military readiness, as can be exemplified with current new-generation vaccines against smallpox and mpox. This is why enhancing civil-military cooperation on medical countermeasures is key to strengthening our societal and military readiness for emergencies and to boosting research and development, as well as production and deployment capacity.

Medical countermeasures represent one of the sectors with the most added value for civil-military cooperation. By leveraging research, (joint) purchasing, (joint) procurement or stockpiling, logistics and emergency deployment, civil-military collaboration has the potential to significantly improve preparedness and response to cross-border threats. The Commission intends to initiate an open dialogue with Ministries of Defence in Member States to explore practical ways to enhance interoperability and response capacity in the field of medical countermeasures.

Building on the objective of the White Paper for European Defence Readiness 2030<sup>38</sup>, the Commission already set up, in 2025, a **Health Security Committee<sup>39</sup> working group on civilianmilitary cooperation on health security preparedness**, to support collaboration in health security between civilian and military authorities from Member States which acts also as a platform to discuss medical countermeasures alongside wider health security cooperation issues. The PESCO COUNTERACT and RESILIENCE projects, financed through the European Defence

<sup>36</sup> Signed on 20 May 2025 in at the margins of the World Health Assembly in Geneva.

 <sup>&</sup>lt;sup>37</sup> Albania, Bosnia and Herzegovina, Kosovo\*[\*This designation is without prejudice to positions on status, and is in line with UNSC 1244 and the ICJ Opinion on the Kosovo declaration of independence], Montenegro, North Macedonia, and Serbia.
 <sup>38</sup> ReArm Europe Plan/Readiness 2030.

<sup>&</sup>lt;sup>39</sup> Article 4 of the Regulation 2022/2371 on serious cross-border threats to health

Fund, are examples of successful initiatives that have fostered civil-military cooperation for medical countermeasure development.

To enhance preparedness for CBRN and armed conflict-related threats requiring medical countermeasures the Commission will develop in 2026, a **Medifence initiative** aimed at ensuring the availability of and access to medical countermeasure relevant for those threats from detection to first response. This initiative will build on current actions under EU4Health and the European Defence Fund, the European Defence Agency's, and Member States' initiatives, and help to further strengthen civil-military R&D synergies. The initiative will comprise several actions, including:

- developing a shortlist of essential medical countermeasures for armed aggression situations and hybrid warfare; also, to help prioritise vulnerability assessments;
- supporting the development of **tools**, such as biosensors, molecular, metagenomic, and spectroscopy tools, to enhance **prompt detection**, identification and diagnosis of both known and novel CBRN agents;
- supporting the development of **pharmaceutical discovery platforms to design antitoxins**, especially for novel biological and chemical agents, and for agents without currently available effective treatment options;
- **procuring**, including via EU joint procurement and stockpiling at national or EU level, medical countermeasures with civil-military potential, including in the form of kits, to ensure quicker access;
- supporting access to advanced wound care products, pandemic-proof personal protective equipment, such as high-performing, reusable respirators and suits, and medical devices. This will improve effective response to CBRN and mass casualty events.

This initiative will build up preparedness and response capabilities for CBRN threats and armed conflicts both for civilian and military personnel. It will complement other initiatives to be developed under the umbrella of a new CBRN Preparedness and Response Action Plan and leverage synergies with possible relevant projects to be developed under the forthcoming European Defence Industrial Programme (EDIP).

In addition, in context of the EU-NATO Structured Dialogue on Resilience, the Commission, the EEAS and Member States Military Staff will promote complementarity of EU civil-military cooperation in health emergencies, including with NATO. Cooperation will also be strengthened for exercises, such as the EU-NATO Parallel and Coordinated Exercises (PACE), covering outbreak scenarios and mass casualty events. The Commission will also continue to engage with the **NATO Joint Health Group** and the **Committee of Chiefs of Military Medical Services** to strengthen operational cooperation as appropriate, focusing inter alia on preparedness for mass casualty events, and medical logistics.

#### **5.3 Public and Private collaboration**

**Private and public-sector collaboration** is essential to increase the development, availability and access to medical countermeasures both in preparedness and in times of crisis. This is key to make

optimal use of all resources, expertise, and innovation from all relevant sectors involved in the lifecycle of medical countermeasures development.

Today, the Commission builds upon a unique network of public and private stakeholders involved in the development and supply of medical countermeasures. Member States and stakeholders' engagement occurs regularly via different fora such as the HERA Board, the Joint Industrial Cooperation Forum, the Civil Society Forum, the AMR One Health network<sup>40</sup>, or events like the HERA Industry Days.

In line with the Preparedness Union Strategy, the Commission will reinforce public private-sector collaboration in existing fora to develop solutions that enhance the availability and security of supply of medical countermeasures in full compliance with EU competition law. As announced in the Preparedness Union Strategy, the Commission and stakeholders will also develop publicprivate emergency protocols to ensure the swift development and availability of medical countermeasures in case of emergencies. The Commission will furthermore leverage tools like ATHINA for secure and standardised data sharing between public and private sector to enhance transparency and accelerate the development of medical countermeasures.

#### POPULATION AWARENESS, CITIZENS' ENGAGEMENT AND SKILLS VI. **RELATED TO MEDICAL COUNTERMEASURES**

#### 6.1 Skilled workforce

Europe must be the place where today's and tomorrow's medical countermeasures are invented, developed and manufactured. To achieve this, the EU must further strengthen its pool of talented and diverse health and care professionals - from researchers and manufacturers to doctors and carers. They need to be equipped with the right skills and expertise to meet both current and future public health needs, and to reinforce our preparedness and response capacities for medical countermeasures.

As part of the Union of Skills<sup>41</sup>, the Commission will continue to invest in strengthening our domestic talents and skilled workforce and in attracting the world's top researchers and innovators. To support a global leading, future-proofed development, production and supply of medical countermeasures, the EU must invest in quality jobs in this area, including measures to improve continuing professional development standards, guidance for the workforce, and facilitate access to learning opportunities. It is equally important to build a community of medical countermeasures researchers and practitioners who can tailor health interventions to meet the diverse needs of groups and communities.

#### 6.2 Resilient health response teams

Effective deployment of medical countermeasures also requires a strong and resilient healthcare workforce to ensure the swift detection of outbreaks and the administration of countermeasures. Building on initiatives such as the ECDC's Emergency Medical Teams under rescEU which

 <sup>&</sup>lt;sup>40</sup> <u>https://health.ec.europa.eu/antimicrobial-resistance/eu-action-antimicrobial-resistance\_en#eu-amr-one-health-network</u>
 <sup>41</sup> <u>The Union of Skills.</u>

support health emergency response in affected countries, the Commission strengthens capacity building for health emergency preparedness through training and exchange of best practices including on stockpiling and joint procurement.

#### 6.3 Citizen's health preparedness, awareness and engagement

Preparedness for health threats is a collective responsibility and must have an evidence-based approach rooted in and supported by science. Understanding citizens' responses to emergencies and removing behavioural barriers that can impede responses efficiency is vital. Effective and inclusive risk and emergency communication and information is critical to building up citizens' and communities' trust by increasing awareness, engagement and access to high quality, evidence-based information. Ensuring the accessibility of emergency communications and information is essential to ensure that persons with disabilities can request and receive help in emergency situations.

To restore trust and confidence in medical countermeasures such as vaccines, the EU will develop blueprints with recommendations for their use in critical situations and rigorously fight mis- and disinformation by collaborating with online platforms, enhancing digital health literacy programmes and implement fact-checking mechanisms. In a severe health emergency, the deliberate spread of misinformation and disinformation – including the coordinated manipulation and distortion of scientific facts for political or other gains – costs lives and must be firmly prevented or countered. To support this, the Commission draws on evidence-based insights into effective risk communication and the factors that may strengthen public resilience against false or misleading information during emergencies<sup>42</sup>.

The Commission will continue to work with the WHO on immunisation and preparedness. The EU will promote the development of age- and gender-sensitive medical countermeasures, to respond effectively to different needs and better protect vulnerable groups from health threats. In particular, the Commission will map the systemic barriers that prevent women and vulnerable populations from accessing vaccines, therapeutics, and diagnostics, in close collaboration with the ECDC and the HERA Civil Society Forum. To counter foreign information manipulation and interference (FIMI), full use should be made of the EU's FIMI toolbox, the Digital Services Act, and other relevant tools and legal provisions.

<sup>&</sup>lt;sup>42</sup> Joint Research Centre - Competence Centre on Behavioural Insights

#### Key actions:

#### The Commission will:

- Build new global partnerships in the area of medical countermeasures notably with EEA EFTA countries, Canada and global and regional actors like WHO and PAHO [2025 & 2026]
- Create a **Medifence initiative** to reinforce preparedness for CBRN and security threats and strengthen civil-military collaboration. As part of it, develop **a shortlist of essential medical countermeasures for armed aggression** and facilitate the procurement and stockpiling of possible **medical countermeasures kits** [2025]
- Carry out initiatives to enhance digital health literacy, run fact-checking activities and work together with online platforms to **fight disinformation** and **promote transparency and scientific-based information** to protect citizens from public health threats.

#### **CONCLUSION**

The EU's Medical Countermeasures Strategy aims to boost collective resilience, preparedness and response to keep Europe and the world safe from health threats, irrespective and independently of the cause or origin of the health emergency.

In a rapidly changing security environment, it is pivotal for the EU and its Member States to strengthen health preparedness, resilience and response in the area of medical countermeasures, with a comprehensive end-to-end, One Health approach, from research to deployment. Treating medical countermeasures as the strategic products they are requires significant investments from both the public and private sector. These are investments in preparedness and societal resilience, and in building a safer and healthier Europe for all.