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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[1], 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,[2] 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

[1] Regulation (EU) 2022/2371 on serious cross-border threats to health

[2] 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[3]. A change of mindset is also needed, in line with the Preparedness Union Strategy's all-hazard, 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[4] and Draghi[5] reports** and is embedded in the overarching framework provided by the **Preparedness Union Strategy[6] and the Competitiveness Compass[7]**.

[3] In particular, attention should be paid to the needs of persons with disabilities, younger and older persons, and racial or ethnic minorities. The Union of Equality framework promotes equal access to health for all.
[4] Safer Together Strengthening Europe's Civilian and Military Preparedness and Readiness.
[5] The future of European competitiveness - A competitiveness strategy for Europe.
[6] The European Preparedness Union Strategy.
[z] A Competitiveness Compass for the EU.

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[8].

## I. PRIORITY HEALTH THREATS REQUIRING MEDICAL COUNTERMEASURES

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[9], 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[10] in regions that were considered low-risk, this includes the EU[11]. The establishment and spread of mosquitoes and ticks across the EU is facilitating the transmission of tropical diseases like dengue, West Nile virus, chikungunya.

[8] EU Stockpiling Strategy COM(2025)528
[9] Consultations with Member States have been carried out via the HERA Board
[10] 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).
[11] The first European Climate Risk Assessment, 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[12] 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.[13] 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

[12] In the Global Risks Report 2025, extreme weather events were ranked as the top-risks over a 10-years horizon.

[13] 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. A ROBUST INTELLIGENCE SYSTEM FOR MEDICAL COUNTERMEASURES INNOVATION AND RESPONSE

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[14] 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[15]. It will operate in synergy with the forthcoming European Crisis Management Platform (ECMP).

[14] https://pandemichub.who.int/

[15] 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[16]. It will also identify medical countermeasures that can be prioritised for different actions such as those fostering innovation, joint procurement or stockpiling.[17]

### 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[18], 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[19].

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

[16] Council Regulation (EU) 2022/2372 of 24 October 2022 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.

[17] 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.

[18] For radiological and nuclear emergencies, the EU operates the European Community Urgent Radiological Information Exchange System (ECURIE).

[19] Article 17 of the Directive (EU) 2024/3019 of the European Parliament and of the Council of 27 November 2024 concerning urban wastewater treatment (recast), 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[20]. 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)[21]. 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. STRENGTHENING THE MEDICAL COUNTERMEASURES PIPELINE – FROM INNOVATION TO MANUFACTURING

**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

[20] EU Reference Laboratories for public health are designated consortia of laboratories under Article. 15 of the Regulation on serious cross-border threats to health (Regulation (EU) 2022/2371) 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: https://health.ec.europa.eu/health-security-and-infectious-diseases/surveillance-and-early-warning/eu-reference-laboratories-public-health_en

[21] For example, DURABLE 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.

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"[22].

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[23], the Startup and Scaleup Strategy[24], the proposed Critical Medicines Act[25] 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[26], 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**[27], 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.

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

[22] In 2022, 40% of the world's vaccines against COVID-19 were exported from the EU.
[23] Choose Europe for life sciences A strategy to position the EU as the world's most attractive place for life sciences by 2030
[24] The EU Startup and Scaleup Strategy.
[25] 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.
[26] 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.
[27] The Commission has pledged EUR 225 million to set up Framework contracts to speed up the development of next generation influenza vaccines.

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[28].

### 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***

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

[28] 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. https://eu-jamrai.eu/

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 next-generation 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 broad-spectrum 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**

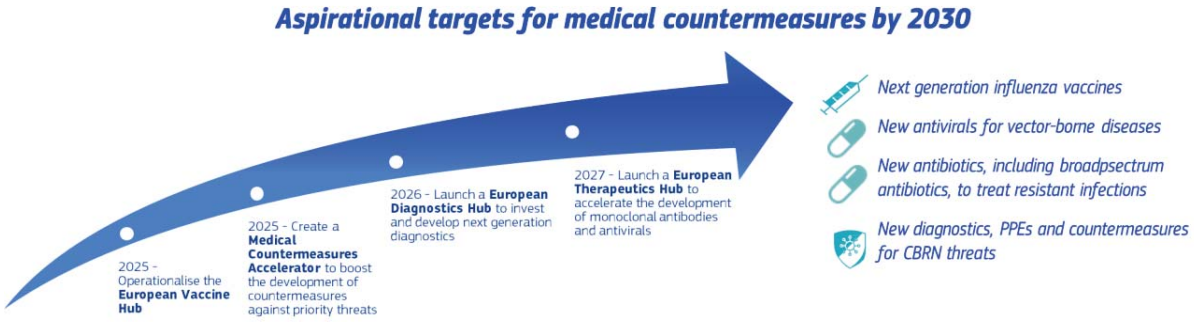
Launched in 2025, the European Vaccine Hub is a consortium of leading European actors in charge of advancing the development and manufacturing of vaccines for public health threats with EUR 102 million in funding over four years. The European Vaccine Hub will:

- 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. AI-based 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 multi-country 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 pre-planning 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)[29] and the Regulation for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency[30]. The Commission will continue to work with Member States and third countries, to mitigate the risks of shortages of crisis relevant medical

[29] 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).
[30] Council Regulation (EU) 2022/2372 of 24 October 2022 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.

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. ENSURING ACCESS, AVAILABILITY AND RAPID DEPLOYMENT OF MEDICAL COUNTERMEASURES

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 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[31].

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[32], 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 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

[31] A public health emergency at Union level may be formally recognized by the Commission in situations where a serious cross-border threat to health endangers public health at Union level, in accordance with Article 23 of Regulation (EU) 2022/2371.
[32] European Preparedness Union Strategy.

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. GLOBAL COOPERATION AND COORDINATION ON MEDICAL COUNTERMEASURES

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

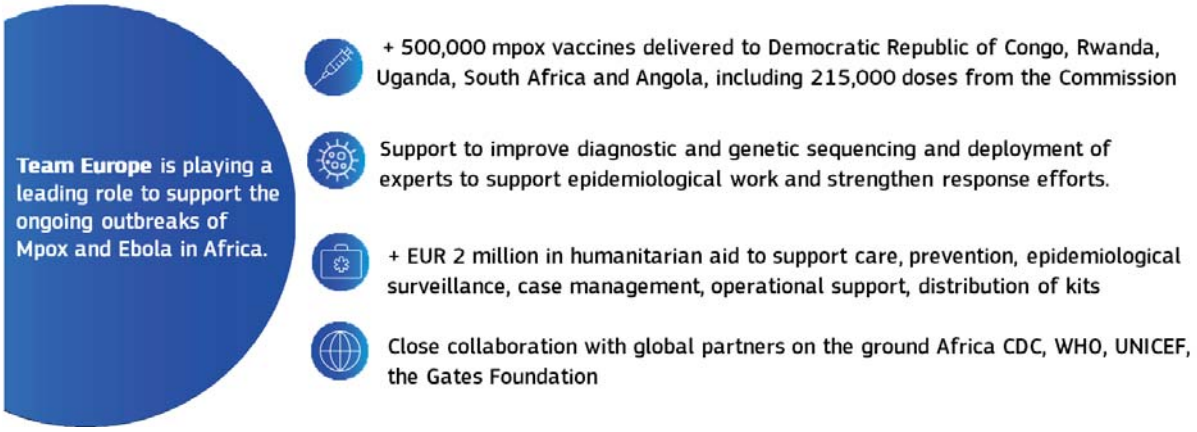
At EU level, the Commission is developing a Union Prevention, Preparedness and Response Plan which will outline provisions on joint arrangements for governance, capacities and resources to support Member States for prevention and preparedness of as well as response to a serious cross-border threat to 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[33] 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

[33] Review of the implementation of the operations of the Health Emergency Preparedness and Response Authority (HERA).

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)[34], 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)[35].

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.

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**

[34] https://www.global-health-edctp3.europa.eu/index_en
[35] https://www.glopid-r.org/

**Coalition on Regional and Local Production**[36]. 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** [37] **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[38], the Commission already set up, in 2025, a **Health Security Committee**[39] **working group on civilian-military 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 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

36 Signed on 20 May 2025 in at the margins of the World Health Assembly in Geneva.
37 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.
38 ReArm Europe Plan/Readiness 2030.
39 Article 4 of the Regulation 2022/2371 on serious cross-border threats to health

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[40], 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 **public-private 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.

## VI. POPULATION AWARENESS, CITIZENS' ENGAGEMENT AND SKILLS 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[41], 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 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

[40] https://health.ec.europa.eu/antimicrobial-resistance/eu-action-antimicrobial-resistance_en#eu-amr-one-health-network
[41] The Union of Skills.

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[42].

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.

***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.

[42] Joint Research Centre - Competence Centre on Behavioural Insights

## 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.

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COM(2025) 529 final

ANNEXES 1 to 2

**ANNEXES**

***to the***

**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**

# ANNEX 1: 2025 Health Threat Prioritisation assessment for medical countermeasures

The purpose of the Commission's 2025 Health Threat Prioritisation assessment for medical countermeasures (MCMs) is to identify serious cross-border health threats that necessitate targeted action at EU level to support access to and availability of MCMs, including research and development, procurement, stockpiling and distribution.

The process of prioritising threats, once consolidated and taking into account stakeholder feedback, will play a pivotal role in prioritising future EU action on medical countermeasures. The 2025 Health Threat Prioritisation assessment gives an overview of the most relevant health threats and the related MCMs, drawing on current knowledge and expertise. Building on previous assessments, which were developed in close collaboration with the Health Emergency Preparedness and Response Authority's (HERA) Board, HERA Advisory Forum, Commission services and EU agencies, this assessment provides a foundation for understanding public health threats and identify needs for MCMs.

Threat prioritisation is a dynamic, consultative, and iterative process that continuously evolves. This assessment serves as a foundation for outreach and engagement with key stakeholders, including Member States, other EU institutions and the professional and scientific medical countermeasures community. It will facilitate a coordinated and effective response to emerging threats. Building on this input, the Commission plans to publish it in late 2025 as a Staff Working Document, and to update it by 2027 at the latest.

The 2025 Health Threat Prioritisation assessment identifies four major threat categories that can be addressed by means of MCMs:

- **Respiratory or contact-based viruses with pandemic potential –** highly transmissible viruses with a history or likelihood of causing large-scale outbreaks and influenced by e.g. biodiversity loss;
- **Vector-borne or animal-reservoir viruses with epidemic potential –** viruses whose spread is accelerated because of climate change and other environmental factors, which are qualified as a specific threat category due to its growing relevance for the EU, the fastest warming continent;
- **Antimicrobial resistance (AMR);** a rising global concern that threatens the efficacy of existing treatments and increases the burden of infectious diseases;
- **Armed conflict related threats and chemical, biological, radiological and nuclear (CBRN) threats**.

Informed by European and global activities, including work carried out by the World Health Organization (WHO), the European Centre for Disease Prevention and Control (ECDC) and other global health institutions, the assessment prioritises 12 families of viruses with pandemic and epidemic potential. It also examines the latest developments in antimicrobial resistance trends, analyses emerging CBRN threats, and examines the impact of climate change on the spread of infectious diseases.

## 1. VIRAL FAMILIES OF EPIDEMIC AND PANDEMIC CONCERN

HERA's prioritisation process took into account existing scientific and epidemiological assessments, integrating global and EU-level frameworks, including from WHO and the ECDC. The methodology used assesses the pandemic potential, the likelihood of an EU-wide public health emergency, the availability of MCMs, and the impact of climate change on the spread and severity of viral threats.

The assessment identifies two groups of viral families of epidemic and pandemic concern that can be addressed by means of MCMs:

- Group 1: *viral families of highest priority*, which pose the most immediate and severe risk to the EU and global health security;
- Group 2: *viral families of high priority*, which present serious but slightly lower levels of immediate threat.

### 1.1. Respiratory or contact-based viruses with pandemic potential[1]

#### 1.1.1. *Group 1: Viral families of highest priority*

***Coronaviridae***, including SARS-CoV, MERS-CoV and SARS-CoV-2, remain a concern due to their airborne transmissibility, their ability to cause severe disease outcomes, their capacity for human-to-human transmission, relatively rapid mutation rate, and potential for immune escape, including reduced effectiveness of vaccines and some therapeutics against emerging variants. There are no licensed vaccines or treatments for SARS-CoV-1 or MERS-CoV, and overall availability of medical countermeasures remains variable.

***Orthomyxoviridae***, including Influenza A subtypes such as H1, H2, H3, H5, H6, H7 and H10, comprise both seasonal and potentially pandemic influenza viruses. These viruses are a concern as they mutate frequently (antigenic drift), reassort rapidly (antigenic shift), and have historically caused global pandemics. Although vaccines against seasonal influenza and certain strains of zoonotic influenza are available, their efficacy is limited by antigenic variability, and may not provide protection against novel pandemic strains.

***Filoviridae***, including the Ebola and Marburg viruses, are a concern due to their association with severe haemorrhagic fevers, high case fatality rates, and their potential to cause large-scale outbreaks, particularly in sub-Saharan Africa. Sporadic imported cases remain a concern, and while vaccines and monoclonal antibody-based therapeutics targeting Zaire ebolavirus are licensed – none for Sudan ebolavirus or Marburg virus –, challenges remain in terms of equitable access, production scalability and swift deployment, particularly in outbreak settings.

***Poxviridae***, including the monkeypox (causing mpox) and variola virus (causing smallpox), remain a concern in the context of bioterrorism and accidental release, but also in view of the possible emergence of new, more virulent mpox strains. Existing vaccines provide partial cross-protection, and limited availability of effective therapeutic options remain as important challenges.

#### 1.1.2. *Group 2: Viral families of high priority*

***Paramyxoviridae***, including the Nipah virus, pose a concern due to high fatality rate and zoonotic potential. Although not currently a threat within the EU, climate change and

[1] While the Corona- and Orthomyxoviridae families mark this category with their well documented pandemic potential, the other viral families in this category typically exhibit epidemic rather than pandemic potential, largely owing to differences in transmission dynamics.

habitat disruption are altering bat migration and habitat patterns, increasing the likelihood of spillover events. No authorised vaccines or specific treatments are currently available.

***Picornaviridae***, including poliovirus and enteroviruses D68 and A71, remain a concern due to the risk of wild-type or vaccine-derived polio outbreaks. While effective polio vaccines are available, no authorised treatments exist for non-polio enteroviruses.

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

Viral families in this category are of increasing concern for Europe because climate and environmental changes are highly dynamic drivers of their spread, divided according to the same criteria, into group of highest and high priority in relation to MCMs.

#### 1.2.1. *Group 1: Viral families of highest priority*

***Flaviviridae***, including the dengue, West Nile, tick-borne encephalitis, Yellow Fever, Zika, and Japanese encephalitis viruses, are a growing concern due to vector-borne transmission and the expanding range of mosquitoes and ticks, driven by climate change. While vaccines exist for some flaviviruses, treatment options are limited, and the number of cases originating locally is increasing in parts of Europe.

#### 1.2.2. *Group 2: Viral families of high priority*

***Togaviridae***, including the chikungunya and Venezuelan equine encephalitis viruses, pose a threat due to severe disease outcomes and their potential for rapid geographic spread. While newly authorised vaccines for chikungunya represent major progress in treating these viruses, most viruses of this viral family, like Venezuelan or Eastern equine encephalitis viruses, currently lack medical countermeasures.

***Arenaviridae***, including the Lassa, Junin and Lujo mammarenaviruses, as well as ***Hantaviridae***, including Hantaan and Sin Nombre viruses, are zoonotic pathogens maintained in rodent-reservoir hosts, and are associated with viral haemorrhagic fevers and significant epidemic potential. No vaccines or specific treatments are currently authorised in the EU.

***Phenuiviridae***, including severe fever with thrombocytopenia syndrome (SFTSV) and Rift Valley fever viruses (RVFV), pose a threat due to their capacity to cause severe disease and large-scale outbreaks. SFTSV is primarily transmitted by ticks, while RVFV is transmitted by mosquitoes, particularly *Aedes* and *Culex* species. No vaccines or specific antiviral treatments are currently authorized in the EU.

***Nairoviridae***, including Crimean-Congo haemorrhagic fever virus (CCHFV), are of growing public health concern, and are already endemic in parts of southern and eastern Europe. CCHFV is primarily transmitted by *Hyalomma* ticks, whose range is expanding due to climate change. Currently, there are no authorised vaccines or specific antiviral treatments available in the EU.

Figure 1. Overview of prioritised viral families, including a partially semi-quantitative mapping of relevant attributes. The information is primarily based on publicly available sources;. *(Disclaimer: This figure is intended for general informational purposes only and does not constitute legal, medical, or professional advice.)*

| HERA Prioritisation | Viral family | PHEIC potential | EU cross-border threat potential, likelihood to require Union response | Availability of vaccines | Availability of therapeutics |
|---|---|---|---|---|---|
| highest priority | *Coronaviridae* | high | **Very high** (highly transmissible, novel strains, airborne; epi- and pandemic emergence) | **Available** (updated vaccines widely deployed; no universal coronavirus vaccine yet) | **Available** (e.g., Paxlovid, remdesivir); no broad-spectrum coronavirus antiviral yet available |
| | *Orthomyxoviridae* | high | **Very high** (airborne, seasonal variants, antigenic shifts maintain pandemic risk) | **Available** (Seasonal flu vaccines, pandemic preparedness) | **Available** (Antivirals like oseltamivir, baloxavir) |
| | *Flaviviridae* | high | **High** (vector-borne with expanding range; climate and travel increase risk of EU-wide transmission) | **Available** (Yellow Fever vaccines, Qdenga and Dengvaxia for Dengue; TBEV vaccine used in endemic EU regions) | **Limited** (antivirals in trials, supportive care) |
| | *Filoviridae* | high | **High** (importation risk through travel and lab exposure; high fatality risk and potential for severe outbreaks) | **Limited** (Ebola vaccines authorised with limited deployment; no vaccines for other strains, no pan-filovirus vaccine) | **Limited** (Monoclonals for Ebola, no broad-spectrum treatments; supportive care) |
| | *Poxviridae* | high | **Moderate to high** (MPXV outbreak, historical smallpox risk) | **Available** (Smallpox vaccine, MPXV vaccines) | **Available** (Cidofovir, tecovirimat for smallpox and MPXV) |
| high priority | *Paramyxoviridae* * | high | **Moderate** (Nipah virus: zoonotic, high-fatality risk; potential for importation or spillover) | **Not available** | **Limited** (supportive care only; no approved antivirals for Nipah or Hendra) |
| | *Togaviridae* | high | **Moderate** (Chikungunya autochthonous cases in southern Europe; EEEV/VEEV monitored, no EU cases to date) | **Available** (Chikungunya vaccine authorised in EU; no licensed vaccine for EEEV/VEEV) | **Limited** (supportive care only; no approved antivirals) |
| | *Arenaviridae* | high | **Moderate** (Lassa: imported cases show risk via travel, lab exposure; requires high-level containment readiness | **Not available** | **Limited** (ribavirin used for Lassa; no broadly approved antivirals for other arenaviruses) |
| | *Phenuiviridae* | high | **Moderate** (RVF importation risk; climate-driven vector spread raise potential for EU transmission) | **Not available** | **Limited** (supportive care; no approved antivirals) |
| | *Hantaviridae* | high | **Moderate** (endemic in rural EU; potential outbreaks require coordinated awareness and rodent exposure prevention) | **Not available** | **Limited** (supportive care; no approved antivirals) |
| | *Nairoviridae* | high | **Moderate** (CCHF virus detected in southern Europe; travel-related cases and vector presence increasing) | **Not available** | **Limited** (supportive care; no approved antivirals (ribavirin use remains inconclusive, not broadly approved)) |
| | *Picornaviridae* | medium | **Low to moderate** (poliovirus eradicated in EU; non-polio enteroviruses cause localised outbreaks, limited cross-border relevance) | **Available** (polio vaccines widely used; no vaccines for non-polio enteroviruses) | **Limited** (supportive care; no broad-spectrum antivirals for enteroviruses) |

**Measles were excluded, as outbreaks within the EU/EEA result from reduced vaccination uptake, not intrinsic cross-border threat from viral evolution or emergence.*

## 2. ANTIMICROBIAL RESISTANCE

Antimicrobial resistance (AMR) continues to grow as one of the most pressing global health threats, undermining the effectiveness of existing treatments and increasing the burden of infectious diseases through higher morbidity, mortality and healthcare costs. Without urgent action, AMR is projected to become a leading cause of death worldwide by 2050, with annual fatalities potentially reaching 10 million people.

In 2021, AMR contributed to 4.71 million deaths globally, with 1.14 million directly attributed to resistant infections. In the EU/EEA, over 35 000 deaths occur every year due to AMR infections, disproportionately affecting infants, older people and immunocompromised people. The COVID-19 pandemic exacerbated antimicrobial resistance, as the increased use of last-resort antibiotics led to a rise in multidrug-resistant bacterial and fungal infections.

The WHO, with support of HERA, updated the AMR pathogen prioritisation at global level, including the (i) *WHO Bacterial Priority Pathogens List 2024* and (ii) *WHO Fungal Priority Pathogens List 2022*.

The assessment highlights key bacterial priority pathogens, including **rifampicin-resistant *Mycobacterium tuberculosis***. It also emphasizes that **rifampicin-resistant (RR), multi-resistant (MDR)** and **extensively-resistant (XDR) tuberculosis**, continue to remain a critical challenge especially in high-burden regions. It also identifies ***Enterobacterales* resistant to third-generation cephalosporins,** as top priorities. In addition, ECDC surveillance data further underline increasing and concerning resistance trends in **carbapenem-resistant *Enterobacterales*** and **vancomycin-resistant *Enterococcus faecium***. Lastly, the increasing rates of AMR in *N. gonorrhoeae* in the EU, and the emergence of **extensively drug-resistant *N. gonorrhoeae,*** are a major global public health concern.

The **antibiotics** pipeline analysis notably shows that while the number of antibacterial agents in clinical development increased in 2023, it is not sufficient to address serious infections and to complement antibiotics that are becoming ineffective due to AMR. The current pipeline continues to show a **major gap in antibacterials with activity against metallo-β-lactamase (MBL) producers,** while the prevalence of those enzymes in resistant pathogens is increasing. Alternative to antibiotics such as the use of **bacteriophages** and **monoclonal antibodies** may serve as alternative treatment options in the near future.

Finally, **fungal priority pathogens**, including *Cryptococcus neoformans, Candida auris, Aspergillus fumigatus*, and *Candida albicans* require attention as they pose a growing threat due to their multidrug resistance, particularly to immunocompromised patients.

The 2023 WHO antibacterial pipeline highlights a shift towards the development of narrow-spectrum antibacterials which will likely require an increased use of **rapid diagnostics** to ensure these narrow-spectrum products are used in the correct patients.

Both **vaccines** against viral and bacterial infections can contribute to reducing the spread of infections and AMR by preventing the need for a treatment with antimicrobials. Although, new vaccines are under development, vaccines against high priority bacterial pathogens are still **missing.**

Beyond the insufficient innovation, the **lack of availability of certain antibiotics in the EU** has the potential to worsen the AMR threat, either by causing a direct risk for the patients, or by hindering the proper use of antibiotics and consequently promoting AMR emergence and spread.

Against this multifaceted and complex threat, a wide arsenal of MCM is necessary, which currently suffers from both lack of innovation and access, requiring a multifaceted approach, combining push and pull interventions to ensure both the development of novel antibacterials, as well as the availability and access of both new and old antibacterials, and other MCM. This is complemented by work of the ECDC and other ongoing Commission work strengthening surveillance and promoting AMR stewardship and responsible use.

## 3. ARMED CONFLICT-RELATED THREATS AND CHEMICAL, BIOLOGICAL, RADIOLOGICAL AND NUCLEAR (CBRN) THREATS

Assessing preparedness for chemical, biological, radiological and nuclear (CBRN) incidents is a key component of the work to boost the EU's health security. Russia's war of aggression against Ukraine and the overall more volatile geopolitical situation have heightened the need for preparedness in this area.

The assessment provides an overview of current CBRN threats and also covers emerging threats and the medical countermeasures that can be used against these threats. The assessment covers the availability of medical countermeasures for all priority CBRN agents, as well as gaps and medical countermeasures under development It is developed in close consultation with civil authorities in Member States through an iterative process. This assessment contains classified information, due to its sensitive nature, and is not publicly available. Identified threat include:

**Biological agents**, including anthrax, smallpox, haemorrhagic fevers and plague. These pathogens, known for their high case fatality rates, potential for weaponisation and social disruption, remain the primary focus for biodefense initiatives.

**Chemical warfare agents,** including nerve agents, blister agents, pharmaceutical-based agents and vesicants. They were used during the civil war in Syria and in targeted attacks in Europe and Asia over the past decade.

**Biotoxins**, covered by both the Chemical and Biological Weapons Conventions, and at the intersection of biological and chemical agents. There have been several incidents involving biotoxins in Europe since 2018, including in Germany, Norway and the UK, underscoring the need for more medical countermeasures to protect from and treat biotoxin exposure and injury.

**Emerging biological and chemical threats**. Biotechnology and computational chemistry are progressing rapidly, presenting promising advancements in the development of medicines but also bringing potential threats.

**Radiological and nuclear threats.** These threats are an increasing concern in Ukraine and the EU. The situation is especially concerning around the Zaporizhzhya nuclear power plant.

By setting up rescEU, a strategic reserve of disaster response capabilities, the Commission has made substantial progress in stockpiling personal protective equipment, detection and decontamination tools, vaccines and therapeutics needed in the event of a CBRN incident. Additional efforts are ongoing to quantify potential needs for medical countermeasures for selected threats in the event of an incident involving each agent.

## ANNEX 2: EU strategic plan for stockpiling of medical countermeasures

### Introduction

The EU Strategic Plan for Stockpiling Medical Countermeasures ("the strategic plan") is a **pillar of the EU's Medical Countermeasures Strategy's** end-to-end approach. It establishes a comprehensive and proactive framework to strengthen preparedness and rapid response to health emergencies via stockpiles of medical countermeasures (MCMs).

Building upon the Niinistö report[1], the Preparedness Union Strategy[2] and the EU Stockpiling Strategy[3], the strategic plan will contribute to **strengthening access** to critical resources across the EU, in the area of medical countermeasures. The strategic plan builds upon the lessons of response to COVID-19 and of the current medical and chemical, biological, radiological, and nuclear (CBRN) rescEU stockpiles. The strategic plan proposes actions to enhance the current framework and will be used as a tool to guide future decisions.

Establishing stockpiles of medical countermeasures at EU level means creating and managing a strategic capability with a **specific focus on global or Europe-wide public health emergencies** to protect EU citizens. Strategic stockpiles of medical countermeasures **act as an insurance** and allow gaining time in the event of a health crisis, mitigating its economic and social costs. This work aims at complementing Member States' national stockpiles and global efforts in order to ensure a cost-effective approach that enhances solidarity in the European Union in the event of a health crisis[4].

Although the EU and national stockpiles are established to address local and regional risks, on occasions, they have also been deployed to **show global solidarity** to mitigate threats in third countries (and to prevent further spread beyond these). Despite the regional focus, complementarity with globally held stockpiles is equally relevant. This layered approach is not only important to ensure complementarity, but also to avoid market disruptions.

Over the past few years, the European Commission has significantly enhanced its ability to anticipate, prepare and respond to disasters and crises, notably through the **establishment of rescEU**, a pioneering strategic reserve of European disaster response capabilities and stockpiles, fully funded by the EU. This initiative has provided a critical safety net, enabling the EU to respond swiftly and effectively in times of crisis. To date, the Commission has invested €1.65 billion and created 22 specialised medical and CBRN countermeasures stockpiles, strategically located across different Member States.

These stockpiles bolster the EU's collective response capacity and have helped to address critical gaps in national response capabilities, particularly in situations across different Member States or where national response capabilities are insufficient, inadequate, or unavailable. The value of this investment has been demonstrated by the successful deployment of these stockpiles in response to high-pressure situations, such as the mpox outbreaks and the geopolitical tensions triggered by Russia's invasion of Ukraine, underscoring the EU's commitment to protecting its citizens' health and well-being in the face of emerging threats.

The lessons from this investment show that **stockpiling medical countermeasures is significantly more complex** than storing non-perishable items. This complexity stems also

[1] Safer together: A path towards a fully prepared Union - European Commission

[2] Joint Communication to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions on the European Preparedness Union Strategy, JOIN(2025) 130 final of 26.03.2025

[3] EU Stockpiling Strategy COM(2025)528

[4] In line with Art 222 TFEU.

from strict regulatory requirements for medical countermeasures and market viability challenges. These are further compounded by the **unique characteristics** of medical countermeasures - their high value, need for technical expertise, stringent security measures, demanding logistical needs, such as storage conditions and shelf-life constraints, and deployment constraints, such as specific customs rules. This distinguishes stockpiling of medical countermeasures, in many instances, from non-medical stockpiles such as emergency shelters or generators.

Strategic stockpiling is done both by the **military and civilian** sectors, with a need to align preparedness strategies. Military expertise is also required as stockpiles may be subject to external physical and digital disruption or destruction, being considered dual-use assets and therefore potential targets.

The **key objective under this strategic plan** is to ensure the efficient and effective stockpiling of relevant medical countermeasures that can address the threats identified in Annex 1 of the EU's Medical Countermeasures Strategy (viruses with pandemic or epidemic potential and chemical, biological, radiological and nuclear threats) so as to secure their timely availability and access in time of emergency as a concrete example of European solidarity in the event of health crisis.

Building on lessons learnt from **rescEU** implementation, the plan seeks to identify and implement actions to ensure a comprehensive management of the stockpiling of medical countermeasures. It encompasses detailed processes for **identifying** essential medical countermeasures, **determining necessary quantities** and the potential need for replenishment (section 1), followed by **effective procurement** strategies, which also include the use of joint procurement as a cost-effective tool for strengthening national stockpiles (section 2). The plan also outlines elements to strengthen the **efficient management** (section 3) of these stocks to guarantee readiness and timely access during emergencies as well as a **deployment** strategy (section 4), which includes streamlined request processes, efficient transportation, and clear procedures for receiving States.


The strategic plan feeds into the discussion on future funding, considering that there is no further budget allocated to expand or maintain the established EU stockpiles under the current multiannual financial framework (MFF). Building-up a strategic stockpile takes a **long-term commitment** and requires sustainable funding to be prepared for future crises[5]. In this respect, factoring stockpiling considerations in the EU budget programmes from the start, may help reduce vulnerabilities and exposure to risks, reducing the cost of potential remedial action.

[5] As a reference, the US has invested between 2014 and 2024 on a yearly basis between $534 million and $995 million for their strategic national stockpile of medical countermeasures, and additionally between $225 million and $830 million annually for their Bioshield project, which also allows them to purchase countermeasures which are not yet on the commercial market, but under development (The Strategic National Stockpile: Overview and Issues for Congress | Congress.gov | Library of Congress)

# 1. STRATEGIC STOCKPILE ASSESSMENT – DETERMINING THE NEEDS FOR EU STOCKPILES OF MEDICAL COUNTERMEASURES

**To ensure the availability and rapid deployment of relevant medical countermeasures during health crises, it is essential to establish a coordinated EU-level system for the identification and quantification of medical countermeasures to be stockpiled.**

Until now, the items stockpiled in rescEU have been proposed by the Member States based on a priority list established by the Commission. In the future, to ensure alignment with the HERA threat assessment and facilitate effective planning, the Commission, in close collaboration with Member States, **intends to propose items and quantities** for stockpiling based on the methodology described below.

Indeed, Annex 1 of the **EU's Medical Countermeasures Strategy identifies the pathogens or agents** that have the potential to cause public health emergencies and require EU interventions in the area of medical countermeasures. Beyond the likelihood of these threats materialising and their potential impact on health, it assesses the adequacy of the current medical countermeasures arsenal to respond to these threats, focusing on the availability of vaccines and therapeutics.

Since 2020, the Commission **has worked with Member States** to identify priority items for the rescEU stockpiles. A common and layered strategic approach to stockpiling was presented[6], to ensure adequate emergency reserves managed at sub-national, national, and regional levels, complemented with EU level reserves. Different practices were exchanged during workshops and training that took place over time. These inputs were compared with international practice concerning the creation of strategic stockpiles for health crises.

Building upon that experience and the existing stocks, a **new approach** was developed leading to the process and criteria outlined in the section below.

## 1.1. A methodology to identify the medical countermeasures for EU stockpiling

The Commission will develop **a methodology by 2025** to assess which threats and medical countermeasures would be suitable for EU stockpiling as a relevant and cost-effective intervention to enhance EU preparedness and response, while ensuring that the quality, efficacy and safety standards meet the requirements of the EU regulatory framework.

The Commission will conduct an assessment that will result in a **compendium** of selected medical countermeasures, using a set of predefined **criteria to identify and prioritise** those to be stockpiled at EU level. The main criteria could be:

- **Potential impact**: this criterion assesses the likely impact of the medical countermeasures on the response to serious cross-border health threats, if made accessible rapidly. This criterion considers the characteristics, existing evidence of the considered product (e.g. safety, efficacy, etc.) or the availability or absence of potential alternative products. Where a product has received approval from a stringent regulatory authority and is deemed essential for an effective response, the absence of EU authorization alone should not prevent its consideration for stockpiling.
- **Time-Critical Effectiveness:** this criterion assesses whether the considered medical countermeasures effectiveness will be conditioned to a quick deployment.

[6] Register of Commission expert groups and other similar entities - Background paper for the HERA Board -common strategic approach to stockpiling - final version

- **Redundancy**: this criterion assesses whether other instruments or systems already exist to ensure access to the considered medical countermeasures, such as national stockpiles or other EU instruments then stockpiling, such as joint procurement.
- **Market failure/limitations:** this criterion assesses whether the existing (commercial) market ensures access to the concerned medical countermeasures outside and during emergencies, or whether public intervention is necessary.
- **Production capacity:** this criterion will identify products that have limited production capacity or scalability, or other vulnerabilities in the supply chain that could lead to unacceptable delays in time of crisis.

In cases where multiple medical countermeasures are available to address the same cross-border health-threat or indication, the identification process could include additional criteria such as:

- **EU strategic autonomy**: this criterion will assess whether the supply chain for the considered medical countermeasures presents vulnerabilities, notably whether the EU is highly dependent on supply chains outside the EU. The EU strategic autonomy in crisis response is crucial even more so in the light of the current geopolitical tensions, i.e. medical countermeasures with EU-controlled manufacturing capacities and supply chain will be prioritised to strengthen strategic preparedness and reduce reliance on third countries during global health emergencies.
- **Operational considerations:** medical countermeasures of similar quality, safety and efficacy could be prioritised, for instance according to how they fit international guidelines on national healthcare capabilities, national preparedness plans and emergency response logistics. In addition, factors such as storage conditions, like temperature control, special handling conditions and shelf-life could be considered. For instance, among similar medical countermeasures with different shelf-life those with longer shelf-life should be preferred, as they reduce the need for frequent stock rotation and minimise waste.

The same methodology will be applied to inform strategic decisions about **re-procurement**. The approach should be tailored to the specificity of the medical countermeasure. While some therapeutics may need to be restocked immediately, it may be different for others in case the cross-border health threats situation has changed. For high impact - low probability threats, the replenishing can increase production and ensure continuity of supply.

The Commission will propose to Member States a compendium of medical countermeasures suitable for EU stockpiling, in Q3 2025.

Among the medical countermeasures identified for potential EU stockpiling, certain ones, particularly those comprising antidotes against chemical agents, require administration as soon as possible after exposure, and must be available close to the intervention site. In such cases, there is the need for these medical countermeasures to be **available at local, regional or national level**. Furthermore, medical kits can provide added value in scenarios such as mass casualty events, where multiple medical countermeasures for wound management, burn treatment or trauma care are simultaneously required.

However, under rescEU, the pre-positioning of stocks can only be requested in exceptional situations of increased risk, as it was the case during the 2024 Olympic games in Paris or the 2023 Rugby World Cup. With the current geopolitical tensions, the **need for pre-positioning** certain medical countermeasures **might increase** to ensure immediate treatment.

In the future, the Commission could propose the procurement and pre-positioning of **"*EU medical countermeasures kits*"** in each Member State, including overseas departments, to ensure rapid initial responses to serious health threats at both national and EU levels, in accordance with the EU solidarity. These kits would contain a range of medical countermeasures, which would be stored in a manner that allows for a swift deployment, either as a complete kit or as individual components to meet the needs of a rapidly evolving health crisis.

The Commission will conduct meetings as of 2025 with Member States to discuss the **relevance, the composition and location** of such kits[7]. This discussion is crucial, as the kits will need to be useful for different national context. Additionally, the Commission will explore with the receiving Member States if the management of the kits is feasible in terms of labelling, transportation, regulatory considerations, security, and ensuring compatibility with regional healthcare systems and infrastructures.

The Commission will explore different **possibilities to procure such kits**. The kits could be centrally procured, after which the recipient Member States would determine where best to store and manage them. Additionally, to improve national preparedness and complement the EU stockpile, the pertinence of organising joint procurement for EU emergency kits will be considered together with Member States, as national preparedness is in the first place a national responsibility

The Commission, together with Member States will explore possibilities of the composition, location, and procurement of EU medical countermeasures kits.

### 1.2. Identification of potential stockpiling advance purchase commitments

Since threats and response capacities develop over time, the compendium needs to be reviewed regularly, including when health threat specific plans are published or revised. The Commission is building on its work of the **medical countermeasures preparedness roadmaps** for specific health emergency scenarios[8]. These operational plans will identify what steps are needed at EU-level to ensure availability of medical countermeasures for priority threats and function as adaptable blueprints for crises. The first set of plans is expected to be completed by 2026. Therefore, it should be assessed in 2026 if (future) strategic stockpiling would be a suitable instrument for the pipeline candidates, considering alternatives like capacity reservation contracts.

The Commission will establish a list of medical countermeasures candidates suitable for advance purchase commitments in the EU strategic stocks, with consultation of the European Medicines Agency (EMA), in 2026.

### 1.3. Quantification and information exchange

Upon establishment of the compendium of medical countermeasures suitable for potential EU stockpiling, the Commission will use specific criteria to determine the **optimal quantities** for stockpiling. In doing so, the Commission will engage closely with Member States, without prejudging future budget decisions.

[7] This includes the consideration for preparedness for armed conflict, as highlighted in section 5.2 of the EU's Medical Countermeasures Strategy
[8] As highlighted in section 2.1 of the Medical Countermeasures Strategy

The **quantification of medical countermeasures** will be on priority scenarios such as pandemics, industrial/laboratory accidents, transportation incidents, climate-related events, food/water contamination, intentional events, terrorist threats, state-sponsored events or hybrid attacks, and conflicts. It will consider the existing national, EU and global preparedness plans or other strategies that Member States aim to implement in response to these scenarios.

Where necessary, modelling capacities will be mobilised to determine the quantity of medical countermeasures that could significantly decrease the health burden in such scenario, if stockpiled at EU level. In addition, the estimation of quantities will consider:

- The type of threat (i.e. spread likelihood, severity, duration),
- The estimation of affected population including vulnerable population (i.e. elderly, children, pregnant women, etc.)
- The use of medical countermeasures (e.g. dosage, duration of treatment).

To be able to determine the appropriate quantities for an EU-level reserve, a critical element is the **collaboration with Member States and the exchange of classified information** on national needs and capabilities. When defining quantities, it is important to consider in the exchange of information with Member States their contingency stockpiling obligations.

To overcome these challenges and make informed decisions, the Commission facilitates discussions, with Member States in a classified format. IT tools supporting this exchange will be enhanced, which will also support forward planning for stockpiles.

The Commission will present in a classified format draft quantification for EU stockpiling of medical countermeasures to Member States for their input, in Q1 2026.

To further strengthen the information exchange, the Commission will need to tackle several challenges, including **sensitivity of information** and the lack of **comprehensive data-sharing mechanisms**. Member States are cautious about sharing sensitive data due to security concerns, while private companies hesitate to disclose inventory levels or supply-chain data for competitive reasons. Additionally, the disparity in preparedness among Member States might create fragmentation, making it difficult to establish a stockpiling at EU level.

The Regulation on serious cross border threats to health[9] requires Member States to report on the capacity that Member States have in place to be ready for a public health emergency, including arrangements aimed at ensuring the continuous delivery of critical services and products, such as stockpiles of medical products. The Commission could consider options to strengthen reporting requirements.

## 2. PROCURING FOR THE FUTURE: A FLEXIBLE AND RESILIENT APPROACH TO THE ESTABLISHMENT OF STOCKPILING

**EU preparedness and response to health emergencies can also be enhanced by refining procurement strategies for medical countermeasures stockpiles, prioritising centralised purchases, stockpiling of unfinished products, non-EU authorised and investigational medicinal products to ensure flexibility, resilience, and strategic autonomy.**

Budget implementation methods directly influence the effectiveness, efficiency, and sustainability of the stockpiling of medical countermeasures, making it a critical component in

[9] Regulation (EU) 2022/2371 of 22 December 2022 on serious cross-border threats to health.

preparedness and response strategies. Looking ahead, the Commission is committed to **refining and advancing the procurement strategies** for EU medical countermeasures stockpiles to maximize their impact.

### 2.1. Stronger coordinating role for the Commission

Thus far, the Commission has established EU medical countermeasures stockpiles through **grants**, where the Member States become grant holders and are responsible for the purchase, management and deployment of the stocks as owner of the stocks. The **advantage of using this forms of grants** is that they enable a comprehensive arrangement whereby all aspects of the process, from purchase to deployment, are managed under a single agreement

At the same time, with several grants holders in charge of the purchase, there is the risk that different buyers reach out to the same company, **causing a surge in demand** that the company may struggle to meet, resulting in **delayed deliveries, higher prices, or stockouts**.

By better coordinating medical countermeasures purchase plans and providing visibility into demand, the stockpiles holders can optimize the purchase of medical countermeasures, reduce inefficiencies, and ensure a more reliable supply chain.

The Commission will take a stronger coordinating role in future stockpiling procurements, which will be based on the compendium.

### 2.2. Procurement of unfinished products

Stockpiling unfinished products would ensure that the stockpiled medicines are suitable for **long-term storage and customised** to the specific emergency use. It would provide for a more flexible response as more final products can be manufactured when required. Additionally, if all the processes within the supply chain take place in the EU, it could strengthen the EU's resilience and strategic autonomy. For a production capacity to ramp up it is essential to have advanced pharmaceutical ingredients, excipients, packaging and manufacturing facilities.

Exploring different options along the different production stages may help also to extend shelf-life as certain "pre"-products are often more stable compared to the finalised product. Examples of different unfinished products include:

- **Stockpiling of raw materials, excipients, active pharmaceutical ingredients (APIs) and their intermediates**, suitable if the emergency lasts for a longer period.
- **Stockpiling in bulk**, for instance for vaccines, with vials quickly filled once there is a need.
- **Lyophilisation,** i.e., freeze-drying of a product, often suitable for vaccines.

However, the management of these stockpiles **requires specific arrangements** such as transport, manufacturing capacities, access to additional ingredients, etc. It is therefore important to establish the intended use of such stockpiles of ingredients.

Currently, is not possible to stockpile unfinished products under rescEU, given the need for swift deployment.

An innovative approach to stockpiling is emerging, one that **combines the long-term storage of** APIs with flexible, continuous manufacturing processes to produce finished dose forms. This new concept has the potential to transform the EU's stockpiling system, making it more cost-effective, less wasteful, and more responsive to health emergencies.

By storing APIs under optimal conditions, it is possible to maintain their physical and chemical stability for up to 20 years, depending on the ingredient. When paired with a compact, modular, and flexible continuous manufacturing platform, this approach enables the **rapid production of medical countermeasures** in response to emerging health threats. This decentralised network can be established across EU, providing a resilient and adaptable manufacturing capacity that can be quickly scaled up or down as needed. The benefits of this approach are numerous such as cost savings, increased flexibility, improved sustainability and enhanced resilience.

This action could be aligned with:

- EU FAB to provide EU with a manufacturing capacity reservation beyond vaccines and provide the infrastructure with an activation system under the Emergency Framework Regulation.
- Civil-military interactions to provide an infrastructure able to respond to a range of threats.

The Commission, in collaboration with Member States, will conduct a pilot study on the benefits and added value of stockpiling unfinished products at EU level in 2026.

### 2.3. Procurement of non-EU authorised and investigational medicinal products

The current rescEU legislation does not address the stockpiling of **investigational medicinal products**[10] and of medical countermeasures that **lack marketing authorisation** or a recommendation for compassionate or emergency use from EMA or a Member State[11].

In the absence of such stocks, there is a risk that the relevant products will not be available when a public health crisis emerges, or in case of high-risk events relating to chemical, biological, radiological and nuclear threats.

Despite the potential strategic value of such medical countermeasures, the lack of authorisation in the EU may stem from factors such as **a limited or unpredictable market, high production costs, or burdensome post-marketing obligations**.

This also prevents the quick deployment of non-authorised products that are often under clinical investigation, to outbreaks, where they could also facilitate clinical trials and ultimately support the future authorisation of much-needed medical countermeasures, such as those for haemorrhagic fevers.

Although from a health security and reputational point of view, it is strongly recommended to stockpile medicines authorised in the EU (and therefore it is important to incentivise developers to obtain marketing authorisation for the countermeasures before they are stockpiled), for some health threats this may not be possible.

To address this gap, the Commission has proposed in the revision of the pharmaceutical legislation new tools, like the temporary emergency marketing authorisation to further faciliate authorisation of medical countermeasures in the EU, and **will facilitate the implementation of flexibilities stemming from the current and future legislations.**.

For investigational products, the Commission will also consider how it could be possible to secure stocks of medical countermeasures that present a strategic interest as regards emerging threats, through **funding for their research and development**.

[10] A pharmaceutical form of an active ingredient being tested or used as a reference in a clinical trial
[11] Annex vi of https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX%3A32020D0414

The Commission, in collaboration with the Member States and the European Medicines Agency, will assess how purchase of unauthorised or investigational medicinal products can be further faciliated.

## 3. BUILDING RESILIENCE THROUGH SUSTAINABLE AND PROACTIVE STOCKPILE MANAGEMENT

**Enhancing EU emergency preparedness and response can be further achieved by establishing a centralised, sustainable, and cost-effective management framework for medical countermeasure stockpiles, which integrates IT tools for real-time tracking, implements shelf-life extension programmes, and fosters collaboration among stakeholders to ensure operational efficiency and proactive crisis readiness**.

Good stockpile management **strengthens the sustainability and cost-effectiveness** of the stockpiled items. A common set of principles and clear governance for the management of medical countermeasures stockpiles across the EU should be established to ensure consistency and increase the efficiency, safety and security of the stocks.

Indeed, stocks of medical countermeasures must be operated and managed under strict **regulatory controls**, necessitating a high level of oversight to ensure full compliance with pharmaceutical legislation and good management practices. Additionally, attention must be paid to the specific management of the stocks, such as the management of the shelf-life, the special storage conditions, the interoperability of the items, the labelling, the packaging, the rotation and the waste management, without forgetting the management of the security of the stocks. This makes the medical countermeasures stock management a **different expertise from non-medical stockpiles**.

The current management of the stockpiles, with different grant holders acting independently, results in different approaches which may affect both the composition, the management and the deployment of the stocks. For instance, while the grant holders are fully responsible for the warehouses, they have different approaches as regards the management of the stockpiles, with different stakeholders involved, such as public/private partnerships, partnerships with different national authorities and agencies, partnerships with military, civil protection and other actors.

### 3.1. Exchange of information

To manage the rescEU stockpiles, the Commission needs a comprehensive overview of all items, at every stage of the process. This encompasses items that are yet to be procured as well as those currently in the procurement process. The overview of all the items should be kept in a secure database. This starts with **effective IT tools** for stockpile management. They are crucial for ensuring accuracy and real-time tracking of the stocks to avoid waste and overstocking. Access to precise data and analytics improves decision-making especially in time of deployment. Overall, IT tools for stockpile management are essential for maintaining operational efficiency, reducing costs, and enhancing the ability to the demand effectively. The stockpile manager should ensure interoperability with the Common Emergency Communication and Information System[12] (CECIS 2.0), which integrates stocks, shelf-life, early flagging of end of shelf-life and procurement planning to ensure a centralised vision of the stock developments. This allows stockholders to move from reactive to proactive stock management.

[12] CECIS is web-based alert and notification application enabling a real-time exchange of information.

Exchange of information and best practices amongst the stockpiles managers is also essential. The Commission intends to facilitate a network of warehouses to share experiences, guidelines, the use of IT-tools for management, and to train on specific good management practices, such as sustainability tools, deployment, and use the network to create synergies and improvements where desirable.

The Commission will facilitate a continuous exchange with the network of grant holders of stockpiles on best practices, organise trainings, and create synergies.

### 3.2. Shelf-life extension programme

Because a stockpile functions much like an insurance policy—you invest in it for protection, hoping you will never need to use it—**some items will inevitably expire and require disposal**. This is an expected part of stockpile management, and the associated costs must be factored into planning.

For those medical countermeasures that cannot be used outside of an emergency, such as antidotes and certain vaccines, the Commission will work together with the Member States and the European Medicines Agency, to pilot a **shelf-life extension** programme of medical countermeasures which are currently in the rescEU stockpiles, and which are reaching the end of their shelf-life**.** Shelf-life extension of selected medical countermeasures is a strategic measure to enhance sustainability, reduce waste, and optimize stockpile management, while also ensuring that the medical countermeasures still meet the regulatory standards. With structured shelf-life extension programme, medical countermeasures could remain usable beyond their initial expiration date, provided they undergo rigorous scientific testing and regulatory oversight. This initiative, conducted in non-crisis periods, ensures that cost-effective stockpiling practices support continuous emergency preparedness. The Commission has already started such a collaboration for the current rescEU grants.

The Commission, European Medicines Agency (EMA) and grant holders have started to implement a pilot on shelf-life extension programme for certain medical countermeasures, with full roll-out in Q3 2026.

### 3.3. Other sustainable approaches to stockpiles management

Given the unique requirements of medical countermeasures, including shelf-life and storage conditions, sustainability is a crucial aspect. When a medical countermeasure approaches one year from expiry and its shelf life cannot be extended, **different sustainability approaches must be considered by the stockpile manager**.

The most sustainable way would be **stock rotation** – meaning when the end of shelf-life approaches of a regularly used product it is replenished via normal supply chain, with products with a longer shelf-life. This sustainability tool is possible in the current practice, and procedures are predefined and pre-agreed in the grants preventing waste and maintaining stock freshness. Implementation of this tool depends on legal elements such as national marketing authorisation for the specific stocked formulation, and how the national procurement of the specific good is arranged. Furthermore, it also depends on the size of the EU stockpile, this might be larger than annual national usage of the routine product. As a result, it is crucial to consider sustainability not only in stock management, but also **throughout all aspects of the process, including procurement**.

For routine products with a short shelf-life, or personal protective equipment that is both bulky to store and dispose of, a viable option is to procure these medical countermeasures

through contracts with a specific manufacturer and have them stored by the manufacturer at the manufacturer's premises. This arrangement, known as **Vendor Managed Inventory** is a strategic reserve of a predefined quantity of selected medical countermeasures. Vendor Managed Inventory can achieve several key objectives:

- Guaranteed rapid access and availability of specific medical countermeasures when required, 24/7 access.
- The product is stored at the manufacturers warehouse in full compliance with regulatory requirements and rotated through the manufacturer's normal sales / distribution processes, hence the product never goes out of date and no need to replace.
- No replacement costs and no destruction costs.
- It simplifies rotation for the routine products which serve as a safety net.

However, the manufacturer would have to have premises in the EU, and there are limited manufacturers able to facilitate warehouse capacities. Within the grant agreements there is the possibility for the grant holder to set-up a Vendor Managed Inventory, as long as the grant holder remains the owner of the product.

If national rotation is not possible, asking consent for a **donation** (without an activation of the Union Civil Protection Mechanism) is a possibility under Article 36 of the Union Civil Protection Mechanism Implementing Decision[13]. In such a case, the logistics costs remain a factor to be determined.

Ensuring the **security** of the stocks at their location and during transport is another crucial element. When designing their stocks, stockpile managers will have to consider issues such as access control, surveillance and monitoring, inventory management, physical security measures, cybersecurity, fire and safety protocols, scenario planning and emergency response planning.

## 4. STOCKPILING FOR SUCCESS: ENSURING TIMELY DEPLOYMENT AND EU MINIMUM BUFFER FOR MEDICAL COUNTERMEASURES

**Finally, effective response can only be achieved by ensuring timely deployment of the medical countermeasures via resilient logistics services and compliance with the regulatory requirements and by securing minimum buffer stocks at EU level.**

### 4.1. Deployment tools

**Timely and safe deployment** is a critical objective for effective emergency response and patient care.

For the deployment of rescEU medical countermeasures stocks, the Union Civil Protection Mechanism needs to be activated. This ensures that EU resources are utilized efficiently, and only when necessary, complementing national capabilities. Upon receiving a request for assistance, the Commission's European Response Coordination Centre (ERCC) assesses whether existing capacities offered by Member States are sufficient to ensure an effective response to that request. Where an effective response cannot be ensured, the Commission through the ERCC decides on the deployment of rescEU capacities[14] in accordance with the

[13] Commission Implementing Decision 2025/704 of 10 April 2025 laying down rules for the implementation of Decision N°1213/2013/EU of the European Parliament and of the Council on the Union Civil Protection Mechanism
[14] In accordance with the procedure laid down in Article 12(6) of Decision No 1313/2013/EU

criteria laid down in Commission Implementing Decision (EU) 2025/704, such as the operational situation across Member States and potential disaster risks, as well as additional criteria in the event of conflicting requests for assistance, such as **allocation keys based on different scenarios**. Based on the lessons from previous deployments, the Commission will analyse the pertinence of the current deployment criteria.

To support the deployment of medical countermeasures stocks, it is essential to ensure a resilient distribution scheme with **expedited logistics providers** through multimodal distribution capabilities (road, air, sea, and rail), including temperature control. This includes overseas regions and the EU's outermost regions. Several options exist for the optimal deployment of stocks such as the rescEU or reliefEU capacities, or through agreement with the company supplying the medical countermeasures. It also requires the development of deployment, distribution, and dispensing plans at national level. The plans should be developed, exercised and reviewed, to ensure their effectiveness during serious cross-border outbreaks or high-impact events.

The deployment of medical countermeasures across Europe is subject to **several regulatory requirements** aimed at ensuring safety, efficacy, and quality. Navigating these regulatory requirements necessitates careful planning and coordination among manufacturers, regulatory bodies, and health authorities to ensure the timely and efficient deployment of medical countermeasures while adhering to legal requirements. In addition, the donation of the EU stockpiles to beneficiary countries involves additional challenges such as regulatory compliance, customs regulations, liability issues, traceability, etc. which have to be agreed between the stakeholders to ensure regulatory compliance and effectiveness of the donations.

To address these challenges, in 2025 the Commission will build on existing tools and resources, such as template contracts outlining considerations for donations. These challenges also apply for the donations of national stockpiles, therefore the Commission played a strong coordination role in the donation of mpox vaccines, to support the EU's solidarity in times of global health threats. The lessons learned from this valuable experience will be included in the tools.

The Commission will also continue to support Member States to integrate medical countermeasures deployment into comprehensive emergency response trainings.

The Commission together with Member States will build on existing **deployment tools** in the second half of 2026, including on the experience from the mpox donations.

### 4.2. EU minimum buffer

The Union Civil Protection Mechanism has a broad reach, and covers the 27 EU Member States, and ten participating states (Albania, Bosnia and Herzegovina, Iceland, Moldova, Montenegro, North-Macedonia, Norway, Serbia, Türkiye, and Ukraine). The rescEU stocks can be requested in times of crisis, including for humanitarian aid reasons, which may mean stocks are deployed beyond these countries.

Medical countermeasures are often much **more costly than non-medical goods** and the lead-time for restocking a medical product can be much longer than for a non-medical product. This makes **replenishment** of medical countermeasures under rescEU more challenging, and the problem is exacerbated by the limitations of the current funding streams for replenishment. Having medical countermeasures available for deployment at any time, is only feasible when there is stock maintained in the warehouses to use for pandemic preparedness and response as well as CBRN threats within the EU. The **possibility of replenishment** after deployment will be explored in the preparation for the next multi-annual financial framework.

To be able to find a balance between the optimal use of EU stockpiles and the level of EU preparedness, safety margins are envisaged to be established in the form of an **EU minimum buffer under future procurements.** This buffer is envisaged to ensure that a part of the stockpiles remains available at EU level in case of an emergency. The optimal use of EU stockpiles in this context cannot be seen in isolation from national stockpiles, their availability and use and is dependent on strengthened secured information exchange and transparency on national stocks, including in real-time.

The Commission will explore possible options to always maintain sufficient stocks at EU level and establish safety margins.