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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.