COMMON STRATEGIC APPROACH TO STOCKPILING OF MEDICAL COUNTER-MEASURES FOR CRISIS PREPAREDNESS AND MEDICINES ON THE UNION LIST OF CRITICAL MEDICINES

BACKGROUND PAPER FOR THE HERA BOARD – SEPTEMBER 2024

This document presents the building blocks for a HERA and Member States Common Strategic Approach to stockpiling for crisis preparedness. It addresses ongoing challenges related to stockpiling as the starting point for coordinated medical stockpiling efforts in the EU. It defines a common vision and strategic purpose and priorities for stockpiling of medical countermeasures, as well as the resulting actions. The scope of this strategic approach focuses on preparedness for cross-border health emergencies, which result in an acute spike in demand for medical countermeasures.

As regards shortages of critical medicines, stockpiling by public entities can be one of the solutions to reduce the risks of shortages, while at the same time it could also exacerbate shortages if not managed properly as it can worsen the supply availability gap between Member States in case production is not adapted to meet increased demand while building the stockpiles. Contingency stocks that companies may be required to hold are not within the scope of this Common Strategic Approach. Building on existing experience in the Member States, on current challenges and on the potential synergies, a separate chapter is dedicated to considerations regarding stockpiling to mitigate shortages of critical medicines. The Commission proposal for the Pharmaceutical Regulation[1], which is under negotiation with the co-legislators, provides a possible future legislative framework for strengthening security of supply of critical medicines, including through potential contingency stock requirements, therefore this is not in the scope of this document.

While the definition of health policy, organisation and delivery of health services and medical care is the competence of individual Member States, recent health crises have highlighted the importance of collaboration and coordination between Member States, including with respect to stockpiling of medical countermeasures.

The Common Strategic Approach to stockpiling should be seen as one of the starting points of increased coordinated efforts and solidarity across the EU towards better preparedness against cross-border health threats. To that end, the document proposes different actions to be taken by HERA and the Member States.

1 COM(2023) 193 final

The following box clarifies the overall definition of a stockpile in this strategic approach:

In this strategic approach, a **stockpile** is defined as the stock of a medical countermeasure kept by public entities for future use in case there is a sudden increased demand or lack of availability during a crisis. The concept of stockpiling includes the identification, purchase and storage options, management and distribution of the medical items or products.

Contents

1. Scene setter

The stockpiling of medical countermeasures [2] is one of the core approaches to strengthen preparedness for cross-border health threats. It aims to ensure that there are appropriate medical products accessible during emergencies, enabling Member States and the EU to protect Europeans from the first moment.

Stockpiles can be constituted for situations where medical countermeasures must be mobilised or deployed more quickly than they can be obtained, to respond to sudden and unexpected events, or to facilitate an effective response to outbreaks. They might also help mitigating the risks linked to supply chain disruptions due to transport or trade interruptions, or geo-political tensions. The latter calls for an increased production capacities at EU level in case of global crisis.

Medical countermeasures could also be stockpiled when it is anticipated that the availability of a product would not be sufficient to respond to the demand that would occur during a crisis situation, for instance for health threat specific medical countermeasures for which production is limited, or when production is not sufficient to meet increased demand in times of crisis, or when the production time is too long. Stockpiling can bridge a gap between an initial demand surge and ramped-up production, procurement or import of the necessary medical countermeasures.

The EU has been gradually strengthening its medical countermeasures capabilities taking into account the lessons drawn from different health crises up to the COVID-19 pandemic. During those crises, the EU's limited medical stockpiles proved to be insufficient to meet the demand, and limited coordination on management and distribution of national stocks as well as EU level stocks under rescEU further undermined timely access to medical countermeasures where most needed.

The continued risk of pandemics and other threats to public health, including chemical, biological, radiological and nuclear (CBRN) incidents, as well as vulnerable supply chain dependencies stress the need to further improve the resilience of European health systems.

In response to these risks and in anticipation of future events, the EU created more robust tools for coordination at EU level and enhanced its legal basis to secure easier access to medical countermeasures and critical medicines. Notably, the most important aspects include the following: adoption of the Regulation on serious cross-border threats to health[3] as well as of the Emergency Framework Regulation[4], the establishment of the Health Emergency Preparedness and Response Authority (HERA)[5], the reinforcement of the roles of the European Medicines Agency (EMA)[6] and the European Centre for Disease Control (ECDC)[7], and more recently the adoption of the Communication addressing medicines shortages in the EU[8]. In addition, in 2020 the scope of the Union Civil Protection Mechanism was extended to include the stockpiling of medical countermeasures aimed at combating serious cross-border threats to health[9], through the EU level stocks under rescEU.The Commission also proposed a reform of the EU pharmaceutical legislation in April 2023[10] to further reinforce the role of EMA with respect to shortage management and to ensure the security of supply of critical medicines.

[2] See definition in Annex 1
[3] Regulation (EU) 2022/2371
[4] Regulation (EU) 2022/2372
[5] Commission Decision C(2021)6712
[6] Regulation (EU) 2022/123.
[7] Regulation (EU) 2022/2370
[8] COM(2023)672
[9] Article 5(3)(a) of Regulation (EU) 2022/2371
[10] COM(2023) 193 final

This set of measures aims at increasing public health preparedness by improving access to and availability of medical countermeasures, including through actions on stockpiling at Union and national levels by:

- The obligation for Member States to report on the basic 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[11].
- Several obligations for Member States in the area of risk management[12].
- Ensuring coordination and information exchange between the entities organising and participating in any action under the different mechanisms related to procurement and stockpiling of medical countermeasures[13].
- Establishing measures that can be activated to ensure the availability and supply of crisis-relevant medical countermeasures through stockpiles of crisis-relevant medical countermeasures in the event of a public health emergency at Union level[14].
- Assessing existing stockpiling capacities in the EU and developing a strategy to ensure effective geographical coverage and timely deployment across the EU including stockpiling of CBRN relevant medical countermeasures and other medical items and increasing stockpiling capacity of medical countermeasures[15].
- Developing a Common Strategic Approach to stockpiling with the Member States in the first half of 2024, building on the experience under the Union Civil Protection Mechanism (UCPM) and the existing EU level stocks under rescEU[16].

Actions on **contingency stocks to be held by private entities** are also foreseen in the **Commission proposal for the Pharmaceutical Regulation**[17] where, based on recommendations or information from the MSSG, the Commission may decide, through an implementing act, to impose contingency stock requirements of active pharmaceutical ingredients or finished dosage forms, or other relevant measures required to improve security of supply of critical medicines, on marketing authorisation holders, wholesale distributors or other relevant entities.

It should be noted that national measures on contingency stocks to be held by private entities are outside of the scope of this common strategic approach to stockpiling. The scope of this strategic approach is explained below.

2. An EU coordinated stockpile system – vision and scope of the Strategic Approach

As a contribution to a stronger European Health Union, the **Commission and Member States envision** a future where the EU has a strengthened stockpiling capability to accelerate the equitable deployment of medical countermeasures in times of emergencies.

Stockpiling is a complex component of public health preparedness and emergency response. Several governments across the world, including some EU Member States, have established and are maintaining effective stockpiles aiming at safeguarding public health and minimising societal

[11] Article 7 of Regulation (EU) 2022/2371 and Commission Implementing Regulation (EU) 2023/1808

[12] Article 6 of Decision No 1313/2013/EU and COM(2023) 400 final
[13] Article 12 (4) of Regulation (EU) 2022/2371 on serious cross-border threats to health
[14] Article 12 of Regulation (EU)2022/2372 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
[15] Communication Introducing HERA COM(2021)576 and Commission Decision C(2021)6712 establishing HERA
[16] COM(2023)672
[17] COM(2023)193

disruption during health emergencies. Their expertise and experience will contribute to the implementation of the Common Strategic Approach to stockpiling in the EU.

The **purpose of the strategic approach** is to co-design and co-implement effective, appropriate, complementary and sustainable stockpiling systems at EU, regional[18] and Member States levels.

Together with the Member States, HERA has identified **three priorities** as the main pillars of this Strategic Approach:

- **Priority 1** - To establish a coordinated mechanism for the identification and quantification of the medical countermeasures to be stockpiled based on threat and risk assessments.
- **Priority 2** – To identify and establish a complementary, coordinated, layered stockpiling system to meet the needs of Member States.
- **Priority 3** – To develop principles and best practices for safe, and sustainable stockpile management and deployment.

Definition and scope

The term stockpiling is commonly used to describe different types of interventions regarding medical countermeasures at different stage of their supply chain. Therefore, the establishment of common understanding and definitions ensures that all stakeholders involved (governments, healthcare providers, the public) understand the purpose of a stockpiling intervention in the context of the strategic approach. Annex 1 of this document provides a set of definitions in relation to stockpiling. The following box clarifies the overall definition of a stockpile in this strategic approach (as also referenced in the introduction):

In this strategic approach, a **stockpile** is defined as the stock of a medical countermeasure kept by public entities for future use in case there is a sudden increased demand or lack of availability during a crisis. The concept of stockpiling includes the identification, purchase and storage options, management and distribution of the medical items or products.

The scope of this strategic approach focuses on preparedness for cross-border health emergencies, which result in an acute spike in demand for medical countermeasures. As mentioned in the scene setter, national measures on contingency reserves are outside of the scope of this strategic approach.

The general considerations on stockpiling in **Sections 3 to 5** focus on preparedness for cross-border health emergencies, i.e., **focus on medical countermeasures**, and refer to critical medicines only as far as they are relevant for preparedness to cross-border health emergencies. **Section 6** then refers specifically to stockpiling considerations for medicines on the Union list of critical medicines[19].

Considering the numerous reasons that can lead to shortages, **physical stockpiling of critical medicines** at EU level is not considered as an appropriate solution and **therefore will not be organised**, unless specifically recommended by the Medicines Shortage Steering Group (MSSG) in exceptional circumstances, in which case the Commission could consider it under rescEU. This is further explained in Section 6. The strategic approach is envisaged to complement the efforts under the Critical Medicines Alliance and the vulnerability assessment of the supply chains of critical medicines, to support the work of the EU and Member States in addressing shortages.

[18] As defined in section 4.
[19] Cf. the Union list of critical medicines, published in December 2023: First version of the Union list of critical medicines agreed to help avoid potential shortages in the EU | European Medicines Agency (europa.eu)

The Common Strategic Approach is expected to benefit Member States and those countries which benefit from the funding and activities that support stockpiling:

- For the Union Civil Protection Mechanism, it concerns the 27 Member States and 10 participating states (Albania, Bosnia and Herzegovina, Iceland, Moldova, Montenegro, North-Macedonia, Norway, Serbia, Türkiye, and Ukraine).
- Activities funded under the EU4Health programme are open the 27 Member States and 5 eligible countries (Iceland, Moldova, Montenegro, Norway, and Ukraine).
- The Joint procurement, also mentioned in this document is open to the 27 Member States and 9 other countries (Albania, Bosnia and Herzegovina, Iceland, Kosovo, Liechtenstein, Montenegro, North Macedonia, Norway and Serbia.)

All EU candidate countries – and Kosovo*[20] as a potential candidate and a signatory of the Joint Procurement Agreement - working towards alignment with the EU acquis, are expected to benefit from the lessons and best practices drawn from the Joint Action mentioned in this document. The results of the Joint Action might also benefit other regions in the world carrying on similar initiatives.

3. Coordinated mechanism for the identification and quantification of the medical countermeasures to be stockpiled

One of the core mandates of HERA is to identify and assess cross-border health threats relevant to medical countermeasures, taking into account also the work of the European Centre for Disease Control (ECDC). HERA has identified three priority categories of threats: 1/ pathogens with pandemic potential, 2/ Chemical, Biological, Radiological and Nuclear (CBRN) threats and 3/ antimicrobial resistance (AMR).

This threat prioritisation is the basis for the development of different HERA lists of medical countermeasures that will inform preparedness for and response to those threats.

A list of countermeasures to address CBRN threats and a list of priority medical countermeasures for stockpiling under the 2023 call were defined as a support for the further establishment of the EU level stocks under rescEU.

A fit-for-purpose layered stockpiling system at EU, regional and national levels requires that HERA and the Member States continue to identify and quantify the most relevant medical countermeasures to be stockpiled to address priority threats. It also requires a joint analysis of the medical countermeasures' gaps in preparedness at each response level, carried out with the necessary care due the sensitiveness of the data analysed. It is important to note that additional factors may need to be considered in the selection of medical countermeasures to be purchased such as legal, financial or intelligence considerations.

Determining which medical countermeasures need to be stockpiled based on **prioritisation of the pathogens and agents** that could threaten the health of Europeans, and additionally the potential difficulty of securing those countermeasures in case of emergency, is the first step to consider when establishing stockpiles. HERA and DG ECHO have already been working closely with Member States to establish a shortlist of medical countermeasures for the calls for the EU level stocks under rescEU. The shortlists were developed relying on three key criteria: supply chains and their vulnerabilities,

[20] * This designation is without prejudice to positions on status, and in line with UNSCR 1244 and the ICJ Opinion on the Kosovo Declaration of Independence

benefit of EU stocks, and storage conditions. In addition, it accounted for the agent's impact, and how easily applicable and effective the available medical countermeasures are.

The identification of threats and medical countermeasures is therefore supported by different actions implemented by HERA, the European Medicines Agency[21] and other relevant Commission services. HERA intends to assess the optimal **composition of stockpiles** across the EU, through a collaborative process including with other Commission services, that takes into account the sensitivity of the topic. The results of this work will be captured in a compendium organised according to threat agents. For the compendium, HERA also intends to factor in additional criteria to the ones, above-mentioned such as the need to reinforce the EU strategic autonomy, or alternative medicines available for the identified threat (as outlined in EMA's guidance for chemical and biological agents), as well as proven efficacy and safety, shelf life, health threat specific medical countermeasures, and waste management.

The quantification exercise will start from scenarios and could rely also on Member States' assessments of their needs in emergency situations. This quantification will be done through scenario modelling, quantification exercises, and/or through a review of national processes to select the medical countermeasures to be stockpiled. This quantification exercise can be used for decisions on future EU level stockpiling and serves as an information tool for Member States to decide nationally on stockpiling approaches. Revisiting the scenarios and corresponding quantification as necessary or in the case of specific high-profile events (e.g., Olympic games, EURO 2024, etc.) would help ensuring readiness across the EU.

It should be noted that certain goods falling within the definition of medical countermeasures such as Personal Protective Equipment (PPE) falling within the scope of Regulation (EU) 2016/425[22] are also used for non-medical purposes, such as to ensure protection of workers in industrial settings. With respect to such goods, these additional use cases need to be considered when determining which medical countermeasures need to be stockpiled, to ensure that any stockpiling of such medical countermeasures does not provoke shortages[23].

This work would be complemented with secure exchange of information on existing stockpile measures at national, regional and EU-levels, e.g. coming from the regular follow-up with Member States and from national mitigation plans to address the changing risk landscape and resulting needs. In addition, the regulation on serious cross border threats to health requires Member States to report on the basic 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. This reporting gives HERA a better overview of national stockpiling efforts. The Joint Action on stockpiling could be another tool to share further information on existing stockpiling capabilities in a confidential setting organised by Member States.

21 For example, the European Medicines Agency has developed in July 2022 a list of the main therapeutic groups of medicinal products that are necessary for emergency care, surgery and intensive care. (Article 6(1) Reg 2022/123), and in August 2024 the EMA published a guidance on the use of medicinal products for treatment and prophylaxis in case of exposure to chemical and biological agents.

22 Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.

[23] To this end, it is necessary to ensure the coordination with the mechanism laid down by the Internal Market Resilience and Emergency Act with respect to medical countermeasures which are also widely used for non-medical purposes such as PPE.

Key actions

1. HERA and the Member States intends to develop, by the end of 2024, the methodology to define the optimal composition of stockpiles across the EU.
2. HERA and the Member States intend to collaborate on the drafting of a compendium on the optimal composition of stockpiles across the EU by mid-2025.
3. HERA and the Member States are invited to develop an ongoing process of exchange of best practices and information about quantification methodologies and stock composition.

4. Coordinated layered stockpiling system

Structure of the stockpiling systems

Adequate reserves managed at sub-national, national, and regional levels, complementary with EU level reserves and strategically located in different geographic zones, will enhance supply security, and ensure access to critical countermeasures in an emergency. Definitions of the different layers are following.

The spread of stockpiling assets allows for a distribution of medical countermeasures according to the threat assessment, but also, if one stockpile is compromised, the complementarity and coordination mechanism established with the others would still guarantee access. The smaller the geographical area covered by a reserve, the more it can be tailored to local risks, such as specific industrial risks, population characteristics, and the faster the medical countermeasures can be distributed (e.g. several antidotes are only useful within few hours).

Several layers already co-exist within the EU; stocks managed at EU level under rescEU, regional stocks, national stocks and finally subnational stocks (in country regions, in cities, in hospitals, in private structures). The physical locations of the stocks are determined according to accessibility, sustainability, and security factors.

EU level stockpiles means creating and managing a strategic capability with a specific focus on global or Europe-wide public health emergencies. Such a capability complements national and regionally established capacities to provide an additional, complementary response capacity when required. The current EU level stocks under rescEU offer a safety net in cases Member States are overwhelmed in a health emergency and until the national response capacity is ramped up. There is consensus among Member States that the focus for EU level stockpiling should be on health threats with **high impact and low probability**, or on very specific/rare health threats requiring, amongst others, **health threat specific** medical countermeasures.

The EU has already shown how it can bring added value to stockpiling. In 2022[24] and 2023[25], HERA invested €1.2 billion in EU level stockpiles of medical countermeasures under RescEU[26]. The purpose of these stockpiles, co-managed with DG ECHO, is supporting access to medical countermeasures to respond to three categories of health threats: pathogens with high pandemic potential, antimicrobial

[24] Results of the rescEU 2022 call- Croatia, France and Poland join EU's strategic reserves for chemical, biological and radiological emergencies - European Commission (europa.eu) and rescEU: Commission creates first ever chemical, biological, radiological and nuclear strategic reserve in Finland
[25] Results of the rescEU 2023 call- EU funds further strategic reserves for medical, chemical, biological and radio-nuclear emergencies worth €690 million - European Commission (europa.eu)
[26] More information about rescEU - European Commission (europa.eu)

resistance (AMR) and CBRN threats. These stockpiles are being implemented through grants and are intended to complement existing national and regional stockpiling initiatives. This work has increased medical stockpile awareness by leading several discussions with Member States as well as industries.

EU level stockpiles should be governed by rules allowing efficient and equitable deployment in case of needs. HERA will reflect on the principles that should govern both the establishment and deployment of EU stockpiles for medical countermeasures[27] taking into consideration in particular factors contributing to the availability of the countermeasures (e.g. guaranteeing minimum production of health threat specific medical countermeasures and support to EU industry).

Regional Stockpiles means establishing coalitions of neighbouring Member States sharing similar risks with the aim to increase the resilience at regional level. Such regional cooperation already exists in some regions where the Member States involved cooperate closely to produce a regionally focused threat determination, to share the financial burden of creating and managing a regional strategic stockpile of medical countermeasures.

National Stockpiles are stockpiles created and managed by individual Member States. Such stockpiles should include medical countermeasures for specific national threats and based on national risk assessments, designed to provide an initial response to a public health emergency and protect a defined target population. Each country defines its stockpiles based on their national assessment of risks and threats.

Several Member States have areas of their territory that are not located on the European continent. These **outermost regions** count 4.8 million citizens and are an integral part of the EU. Their remote location poses **logistical challenges**, especially for medical countermeasures that need to be available rapidly. For outermost regions, stockpiling at regional level is essential, within the national preparedness frameworks. It is also an advantage that the EU's outermost regions are located around the world, as they could act as logistical hubs for Member States during global health emergencies as a support to international cooperation.

Sub-national stockpiles are managed by regional or local authorities, such as provincial governments, municipal health departments, or healthcare facilities. They aim at preparing for high probability threats and threats that require action in the first hours of an event, and usually coordinate and are complementary with national stockpiles.

International or interregional organisations, such as the World Health Organization, public structures, non-governmental organisations are also stockpiling to rapidly deploy essential medical countermeasures to countries facing public health emergencies, diseases outbreaks, natural disasters, or humanitarian crisis. These stockpiles are not considered within the scope of the Common Strategic Approach, but enhanced information and best practices exchange is considered beneficial, including with structures such as the PAHO Revolving Fund for the LAC region, the PAHM (formerly PAVM) procurement platform, and the Global Fund mechanism.

While there might not be a full overview of all existing stockpiles, it is important to note that a variety of stocks co-exist as illustrated in the table below.

[27] For rescEU such principles are set out Commission implementing decisions 2019/570 and 2019/1310 [*note: to be aligned to consolidated implementing act if adopted before this HERA Board paper*].

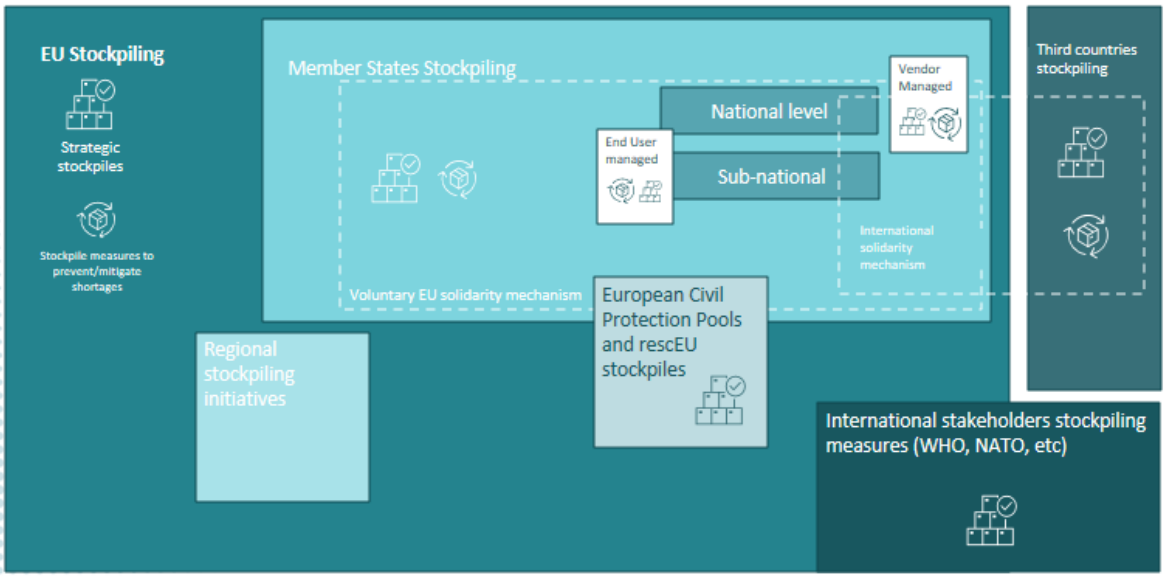

Figure 3 - Source: HERA

Military actors hold stockpiles for their own personnel, but not in quantities to support the civilian health care systems in case of a large cross border emergency. However, there is merit in civil-military collaboration to exchange information on stockpiling best practices. In addition, research and development by the defence sector of new specific or health threat specific medical countermeasures (e.g. CBRN antidotes) is of interest to civil actors and could be an additional topic of collaboration[28]. Nevertheless, it should be noted that civil and military stockpiling is done under different legal bases for different purposes, which in certain cases can limit cooperation both at EU and national level.

Coordination amongst stockpile owners

As shown in figure 3, stocks exist at different levels. **Increased coordination** at these different levels within the EU could facilitate the response to short term needs through re-allocation of stocks where they are most needed and ensure that the stockpiles measures are adequate and complementary.

The **voluntary solidarity mechanism** developed by the Commission and the European Medicines Agency[29] is a concrete example of such coordination by enabling any Member State facing a critical shortage to request assistance from other Member States in obtaining medicines stocks as a last resort measure.

Similarly, fostering **collaboration** among EU Member States is an essential component for the success of the common approach to stockpiling. For instance, pooling efforts through joint procurements will offer better prices and gain greater bargaining power to build stockpiling reserves. In addition, careful coordination and collaboration across the EU is important to allow for proper planning of purchases for stockpiles at different levels, to avoid supply chain disruptions.

Specific stockpiling challenges may require equally the pooled expertise of the EU and its Member States, including EMA and national competent authorities, such as for projects relating to shelf-life extension, market authorisation, donations, etc.

[28] Such collaboration is already taking place, e.g. for project COUNTERACT: EDF21_Outcome_Template (edrin.org)
[29] As announced in COM(2023) 672 final.

In addition, next to coordination among stockpile owners, cross-sectoral coordination is crucial, e.g. between health, civil protection, internal security as well as military stakeholders.

Public-private partnerships, including through innovative initiatives and contracts, can encourage collaboration between public health authorities, private manufacturers, and distributors to create shared stockpiles that can be used to address emergency needs but can also address many of the technical challenges requiring coordinated action.

Finally, it is important to establish closer connections and information exchange with **international organisations** such as WHO on e.g., the contents and modalities of their stockpiles.

Different stockpiling formats

Stockpiles may be organised in different forms to better respond to their intended objective. Some examples are **physical stockpiling**[30] and **virtual stockpiling**[31]. Other stockpiling solutions could also be relevant according to the specificities of the medical countermeasures to be stockpiled, such as **vendor managed inventories**[32]**.**

When developing stockpiling strategies, actors should consider whether stockpiling is the best intervention, and which other interventions are possible to achieve the intended results or even complementary interventions to ensure successful stockpiling interventions. Activities such as "production capacity reservation[33]" or "forthlooking procurement and supply reservation, including advanced purchase"[34] could be considered as valuable alternative to stockpile and highly useful tools for public health preparedness complementary to stockpiling efforts. An example of production capacity reservation is EU-FAB[35], which reserves manufacturing capacities for the EU to produce vaccines.

The Figure 4 below is an attempt to design a model listing criteria that could be used to define the structure and nature of stockpiles. It would be for HERA, other relevant Commission services and the Member States to further develop those criteria to design the most effective and appropriate stockpiling systems, for example as part of the Joint Action, in particular as regards the complementarity and added value of each level.

Criteria	Vendor Managed Inventory or other reservation contracts	End user managed inventory	Sub-national stockpiles	National stockpiles	EU stockpiles
Shelf Life	Depending on the products	Depending on the products	Depending on the products	Depending on the products	Depending on the products
Administration to patient		Immediate >>>>>>>>>>>>>>>>>>>>>>>>>>>>>> Less time sensitive			
Product specificity (examples)	Very specific storage conditions Routine products with large turnovers	Products to be administrated quickly		Nationally decided	MCMs for low probably - high impact threats
Probability		Very likely	Very likely	Likely	Low
Risks		Recurrent	Moderate	High	Extreme
Impact		Moderate	Major	Catastrophic	Overwhelming

[30] See definition in Annex 1
[31] See definition in Annex 1
[32] See definition in Annex 1
[33] See definition in Annex 1
[34] See definition in Annex 1
[35] For more information, please see here: Framework contract signed under EU4Health to guarantee a fast response to future health crises - European Commission (europa.eu)

Figure 4 – Source: HERA

When creating stockpiles of medical countermeasures, it is useful to consider:

- the lead time required by manufacturers/ marketing authorisation holders to increase production in order to meet the volumes required for the stockpiles, so that the impact on the normal supply for other Member States is minimalised.
- making the stocks available to other Member States when in need, e.g. if the Voluntary Solidarity Mechanism is launched for that medicine in the MSSG.

In addition, it could be helpful to take into account the various stages of production for medicines and to develop specific formulations for stockpiling, in addition to the usual formulations used for regular purposes. It needs to be assessed if such specific formulations are needed and can be manufactured, and they would need to be assessed against the same criteria as the initial ones (quality, safety, efficacy) in line with regulatory and legislative requirements.

This approach would ensure that the stockpiled medicines are suitable for long-term storage and emergency use. 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 from other jurisdictions include:

- **Stockpiling of raw materials, excipients, active pharmaceutical ingredients (APIs) and their intermediates**, suitable for shortages rather than in case of emergency needs, unless 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.

Finally, stockpiling can also be seen as a demand mechanism for new or innovative medical countermeasures under development, e.g., through advanced market commitments or purchase agreements. This is particularly relevant for health threat specific medical countermeasures suffering market failures such as medical countermeasures for putative pandemic-prone viral families or CBRN antidotes. Commitments by the public sector to procure and stockpile medical countermeasures in the pipeline ensure a commercial market for the product once authorised, incentivising, and financing the development of new or innovative medical countermeasures. Rather than buying already existing products, such mechanisms could be pre-investigated within authorisation procedures of medicinal products and would allow governments to leverage stockpiling demand to spur innovation and bolster an innovative EU medical countermeasures industry while respecting regulatory process. HERA is, therefore, closely collaborating with the European Medicine Agency on medical countermeasures candidates. The need to ensure access to new or innovative medical countermeasures for the purpose of research should be anticipated in the case of stockpiling through advanced market commitments or purchase agreements. HERA is also supporting research and development of new or innovative medical countermeasures through the EU4Health and Horizon Europe programmes. The use of such mechanisms integrating R&D funding and procurement of medical countermeasures should be further explored, by HERA or at Member States level.

Purchase of the stocks

The procurement of medical countermeasures is a key element of stockpile constitution. Procurement practices vary in the EU. In 2020 the Commission adopted a **Pharmaceutical Strategy for**

Europe[36] that recognises the potential of using enhanced procurement of medicines in the EU to improve accessibility, affordability, and sustainability of healthcare systems. The strategy encourages the design of smarter procurement procedures that prioritise security and continuity of supply. In addition, the Commission published a study on best practices in the public procurement of medicines[37] which assessed the impact of the procurement practices on different indicators like availability of medicines, affordability, competition, security of supply and environmental aspects. Following the Commission Communication on Addressing Shortages in the EU, the Commission is preparing an EU guidance on best practices for public procurement of medicines. The focus will be on procurement practices that can make a direct contribution to security of supply and availability of medicines throughout the product lifecycle, by effectively integrating supply security as an award criterion.

In addition, in line with the **European Economic Security Strategy**[38], the Commission advises Member States, to factor in their procurement procedures overarching criteria, such as **EU competitiveness and supply chain resilience**. Work on procurement guidelines, such as the ongoing work of HERA on "crisis procurement guidelines", would also contribute to a better preparedness.

Elements that may be considered in the procurement, depending also on the stockpiling format, are shelf life, environmental impact, storage conditions, regulatory compliance, waste management policies and pharmaceutical forms. Multi-source supplier selection can help prevent further supply chain consolidation.

In addition to procurements organised at national level, HERA and the Member States are also considering how **joint procurement** could better support stockpiling efforts. Joint procurement could allow Member States to obtain better prices or to have timely access to innovative medical countermeasures, and it also serves as a demand signal to industry.

When purchasing medical countermeasures, depending also on the stockpiling format, the purchasing authorities should consider the **replenishment of stockpiles** to replace the medical countermeasures in the stocks as they are rotated, expired, or deployed. This approach should be tailored to the medical countermeasure and need —while therapeutics may need to be restocked immediately in some scenarios, it may be different for vaccines in case of high vaccination coverage in the population. In the case of medical countermeasures for low probably - high impact threats, and to promote manufacturing in the EU, the replenishing of stockpiles leads to an increase in production to ensure continuity and security of supply, and financing stockpiles thus provides positive, sometimes vital, side-effects.

For several reasons, it may be necessary to consider stockpiling of certain products at more than one layer.

Sustainable financing[39]

While stockpiling may be expensive initially (big upfront investment), it can be significantly more cost-effective than responding to a large-scale health crisis without readily available medical countermeasures. Investing in stockpiles mitigates the high costs associated with the economic and societal impact of emergencies, but also it can prevent panic buying, inflated prices, and potential shortages during a crisis. Most importantly, stockpiles should be seen as a population-wide public

[36] COM(2020) 761 final.
[37] Study on best practices in the public procurement of medicines - Publications Office of the EU (europa.eu)
[38] JOIN(2023) 20 final
[39] It is important to recall that all national and EU financial supports should be compatible with the State aid framework.

health insurance policy and could be communicated as such. The communication aspect is particularly important for the stockpiling of medical countermeasures for low-probability, high-impact threats, as products are more likely not to be used at all. At the same time, a robust process is needed to identify which medical countermeasures to stockpile at what quantities, as explained in Section 1. Such policies have a pre-defined duration (related with the timeframe of the stockpile), intend to cover the needs of a certain population regarding specific threats (if these ever materialise), and ultimately will be used in certain scenarios (such as an emergency) that may never materialise. If stockpiles are never deployed, it may give the impression that stockpiling interventions are not cost-effective, but as for any insurance policy, the investment should be assessed on credible scenarios, on the impact cost of the event materialising and of the cost of its mitigation. Some medical countermeasures are stockpiled hoping they will never be used, while others are stockpiled to ensure availability in case of demand surge of supply disruptions, depending on their criticality to the delivery of healthcare. In both cases, stockpiling creates the necessary redundancy, as health services without buffer capacity are more exposed and vulnerable.

Securing a robust and sustainable financial foundation is crucial for stockpiling of medical countermeasures to secure long-term readiness. Sustainable financing allows for continuous upgrading and replenishment of stockpiles according to the evolving needs, maintenance of storage facilities, training of personnel. The financing should ideally take into account the shelf life of the stockpiled products (e.g. from 1 year for some medicines to 10 years for some personal protective equipment).

A long-term EU medical stockpiling system should consider a multi-pronged financing approach, encompassing contributions from the EU, Member States, and possible innovative co-financing mechanisms. Planned procurement, early dialogue and a longer-term vision are important elements to give demand visibility to the industry. This helps to ensure that when an organisation is looking to purchase medical countermeasures to stockpile, the medical countermeasures are available without unnecessary delays.

Member States have a primary responsibility for ensuring preparedness within their borders. National budgetary allocations for medical countermeasures stockpiles are essential. Budget allocations can rely on previous stockpiling initiatives, but also investments based on population size, risk assessments, and historical data on health emergencies.

In complementarity, the EU has dedicated funding programs under rescEU for medical countermeasures stockpiles. To preserve this investment, the Commission intends to extend the current grants and is considering the funding of ongoing maintenance of the stocks.

Depending on the needs and nature of stockpiles, HERA and other relevant Commission services will continue to assess how it could further support the acquisition, storage, rotation and maintenance of strategic stockpiles through mechanisms that do not necessarily require a physical stock in a warehouse. In the upcoming Joint Action on stockpiling, the piloting of innovative stockpiling methods could be considered.

The real power of addressing stockpiling at the EU level lies in harnessing synergies between EU and national funding. Co-funding mechanisms offer several advantages, such as fostering a sense of shared responsibility between the EU and Member States, securing long-term commitments and sustained investment; unlocking financial capacity for stockpile development; and aligning priorities between the EU and Member States among others.

Key actions

4. HERA and the Member States will work together to further develop criteria to design the most effective and appropriate stockpiling systems for health crises (e.g. at EU, regional or national levels) and incentivise the Member States to pilot the most effective and innovative approaches.
5. HERA, with the Member States, intends to develop a package of different solutions for different types of medical countermeasures, based on criteria such as their shelf life, administration time and product specificities.
6. HERA will continue to support Member States in reinforcing their national stocks, notably via the organisation of (joint) procurements or via potential other support to pooled purchases, potentially also for innovative medical countermeasures still under development.

5. Sustainable stockpile management and deployment

When establishing a stockpile, several factors will influence its organisation, management and deployment. Good stockpile management and deployment measures could indeed help to mitigate shortages or unavailability of a specific medicinal product.

Maximum and safest use of medical countermeasures

A challenge when managing stockpiles is monitoring and managing the shelf life, i.e. period of safe use. Stockpiling medical countermeasures with a short **shelf life** can have adverse ecological impact if they can only be used in a scenario that is less likely to happen. At the same time, stockpiling medical countermeasures in such a way that shelf life is maximised may also have cost implications (e.g. if special facilities are required). When establishing or replenishing stockpiles, shelf life should be considered. It may then form part of a tendering process.

For medical countermeasures that cannot be used outside of an emergency, such as many antidotes and vaccines, HERA proposes to work together with the Member States and regulators, especially the European Medicines Agency and national equivalents, to better determine the issues around shelf life of stockpiled medical countermeasures. After the expiry of the shelf life of a medical countermeasure, its full effectiveness is no longer guaranteed. However, in certain cases, an initial shorter shelf life may be extended, once additional stability data is available. It is therefore important to explore the feasibility and challenges of a shelf-life extension programme balancing the desirability of maximising shelf life in specific cases, and the need to ensuring safety and efficacy standards while taking into account the requirements of the pharmaceutical legislation. HERA and DG ECHO have already started such a collaboration for the current rescEU grants.

Alternative solutions exist to ensure a maximum use of the products. For medical countermeasures in regular use, **rotation** or recycling through donations could be a solution. Other methods such as **progressive deliveries** of products with different expiry dates should also be part of any stockpile purchase agreements, facilitating rotation while also acting as replenishment.

To maximise the use of stockpiles, aspects relating to the **interoperability** of the different medical countermeasures composing the stocks should be considered to secure that they can be combined and used in conjunction with others. It is also important to ensure that medical countermeasures are stockpiled with the ancillary items that are needed for their administration or use, e.g. for medical devices. Interoperability is paramount to protect citizens by ensuring that there is a level of coherence amongst the different stockpiles of medical countermeasures that reduces problems related to the use of the medical countermeasures.

Faster and easier use of the medical countermeasures will also benefit from more **harmonised packaging and labelling** across the EU, as well as the use of e-leaflets. The proposal for a pharmaceutical regulation proposes a set of updated rules to simplify labelling across the EU.

Availability and regulation

Medical countermeasures are stockpiled to support availability in case of demand surge or supply issues. Stockpiling purchases, for example through joint procurements, could also reinforce the EU's strategic autonomy. Indeed, if a medical countermeasure is available but produced outside the EU, signalling larger volumes may justify the establishment of manufacturing operations in the EU.

Next to existing adapted regulatory approaches, some Member States have signalled interest in developing a **specific legal status** for strategic stockpiles, in line with examples of such a status already existing for defence/security assets, and for continuing to explore existing possibilities for flexibility on regulatory issues such as packaging requirements. Another example concerns PPE, for which in the context of a Single Market Emergency Mode activated in accordance with the Internal Market Resilience and Emergency Act, certain emergency procedures for the conformity assessment and placing on the market of crisis-relevant PPE can be applied. The **Commission proposal for the Pharmaceutical Regulation** includes rules on temporary emergency marketing authorisation (TEMA)[40] which introduces for the first time an EU level emergency marketing authorisation in times of health emergency although it does not apply to preparedness scenarios such as the one that underpins stockpiling. Specific flexibilities could be also useful for shelf life, selected pharmaceutical obligations and for procurement procedures or donations possibilities. These aspects could be considered as part of the upcoming Joint Action on stockpiling, noting that it is important to ensure consistency with current pharmaceutical legislation, the existing provisions for marketing authorisation in the case of medicinal products, and the proposed reform of the EU pharmaceutical legislation. Without prejudice to regulatory flexibilities afforded, the quality, safety and efficacy requirements foreseen in the marketing authorisation should be complied with for medicinal products (and medical countermeasures) marketed in the EU,

Additional constraints have been identified concerning the **dual use Regulation[41],** under which certain medical countermeasures fall (such as specific personal protective equipment, especially for Biosafety level 4). This regulation requires that, **special permits** are in place for the transport and use of certain medical countermeasures, for example, controlled substances.

Waste, environmental and security considerations

When establishing a stockpile, it is essential to consider the environmental impact of the medical countermeasures stored and to reduce such impact. Effective management of the purchase, the storage and inventory practices will greatly contribute to reducing waste. For medical equipment or

40 Article 30 of COM(2023) 193 final
41 Regulation (EU) 2021/821

for personal protective equipment, **reusability** can contribute to a more sustainable management. Reusable items are also less vulnerable to supply disruptions than single-use items, as they do not need to be replaced daily and therefore rely less on a continuously operating supply chain. In addition, reusable products require less storage space than disposable products covering the same period and produce less biohazardous waste. However, these items will require additional standardised procedures to ensure safe use as well as increased operational capacity at healthcare facilities to apply these procedures.

To improve the sustainability of stockpiles and limit waste, Member States are encouraged to develop or expand links between national stockpiles and national/regional health systems to allow an optimal use of the items, in case of specific event requiring the use of the stockpiled medical countermeasures.

HERA intends to share best practices among Member States to encourage innovative and efficient ways of managing stocks, taking into considerations waste and environmental considerations.

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

Deployment and distribution

The rapid deployment and equitable distribution of medical countermeasures during public health emergencies relies **on a robust EU framework that tackles legal, logistical, and ethical challenges, ensuring that life-saving medical products reach those in need faster,** in line with Good Distribution Practice[42].

The Commission already collaborates with the European Medicines Agency and Member States on the authorisation status of stockpiled medical countermeasures under rescEU, and the identification of pathways that can better facilitate efficient deployment and use.

At the time of deployment of any stockpile, **activation and allocation criteria** should be predictable and transparent, considering the threat's severity and potential dissemination across European borders and global reach. Determining who has **decision-making authority** and establishing a **transparent process** (such as a decision tree based on a factual assessment) will strengthen trust and facilitate timely deployment.

For EU level stocks under rescEU, there is a stepwise process to decide on deployment. 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 capacities43 in accordance with the criteria laid down in Commission Implementing Decision 2019/1310, 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.

Assessing the most suitable allocation keys should be at the core of a stockpiling strategy, considering equitable distribution. While deployment remains a prerogative of the ERCC, HERA will make operational recommendations to establish allocation strategies for EU level stocks of medical

[42] Good distribution practice | European Medicines Agency (EMA) (europa.eu)
[43] In accordance with the procedure laid down in Article 12(6) of Decision No 1313/2013/EU

countermeasures under rescEU for different scenarios in preparedness times by the second half of 2024. The need for such allocation strategies has been widely confirmed by Member States. Addressing populations or at-risk groups disproportionately affected by public health emergencies requires specific considerations and therefore a one-size-fits-all approach is not optimal. Determining when a pro-rata allocation system (based on population size) may be appropriate versus alternative methods that prioritise vulnerability and disease prevalence is crucial.

Transfers, such as donations of medical countermeasures can be challenging. The Commission will work with Member States and European Medicines Agency to ensure clear procedures for deployment as well as donations.

Where a Member State has triggered the **voluntary solidarity mechanism**, the Member State that has available stocks (e.g. in a national stockpile) can work with the requesting Member State to arrange delivery of those medicines.

Information exchange

To manage efficiently the stockpiles, authorities need to always have a clear overview of the stockpiled medical countermeasures. This requires well-designed, user-friendly, and secured **information technology (IT) tools**. This is essential to ensure a rapid response, to limit waste and to ensure a proper rotation and replenishment of the stocks.

While recognising that information related to stockpiled medical countermeasures is **highly sensitive**, exchange of information across national and EU levels is important to maximise stockpile utility in case of need and to manage critical shortages.

New initiatives could be considered by the Commission, such as an **EU virtual stockpiling warehouse:** a data warehouse on EU-level stocks and national stocks that are made available, and a mechanism for rapid exchange of those stocks between EU Member States in case of need.

Member States have noted that it is important to have secure means of exchanging information, to be better able to share information on stockpiles and assist each other. Several Member States have noted that transparency around national stocks is important, also in light of solidarity efforts. Therefore, HERA will work closely with Member States and EMA to ensure **safe information exchange and cooperation for EU and national stockpiles** in synergy with EU HIP[44] and HERA's IT tool ATHINA[45]. This will include agreeing on which data can be collected and shared between national authorities, as well as other relevant players, and the Commission. HERA encourages Member States to adopt similar approaches for regional and sub-national stockpiles, and stockpiles managed by third parties.

[44] The project EU-HIP supports participating countries to enhance and improve national IT systems in an efficient and coordinated manner, with the objective to obtain the needed interoperability with HERA's IT platform EU-HIP (ssi.dk)
[45] HERA IT System 'ATHINA' to collect intelligence and assess threats: call for tender published - European Commission (europa.eu)

Key actions

7. HERA and European Medicines Agency, with support of the Member States, intends explore the feasibility and challenges of a shelf-life extension programme.
8. HERA intends to develop allocation keys for rescEU, based on different scenarios and information from the Member States by the end of 2024.
9. HERA intends to work with Member States and European Medicines Agency to ensure clear procedures and a toolbox (including processes and templates) for deployment within and outside of the EU, by 2025.

6. Stockpiling considerations for medicines on the Union list of critical medicines

In anticipation of the proposed pharmaceutical legislation, a first version of the Union list of critical medicines[46] was published by EMA, HMA and the Commission in December 2023, identifying medicines which are considered as the most critical for EU health systems for which it is essential to secure sufficient supply.

HERA has conducted supply chain vulnerability assessments for a first set of 11 critical medicines[47]. The recently launched Critical Medicines Alliance will support this work by proposing industrial policy solutions to strengthen the supply of critical medicines in the EU, ultimately enhancing efforts to prevent and address shortages effectively. The MSSG may also make recommendations on measures which can be taken to strengthen security of supply of these critical medicines. Both MSSG and the Critical Medicines Alliance may propose measures to support appropriate stockpiling of these medicines by public authorities (not to be confused with national measures on contingency reserves, as explained in the scene setter).

As highlighted in the Communication on addressing medicines shortage in the EU, when stockpiles are already built up before shortages occur, they can help to bridge the supply gap before production increases or provide the input materials in shortage, needed to boost the quantities that can be manufactured.

However, national stockpiling can impact availability of medicines in other Member States, be costly and potentially wasteful, particularly if not used in tandem with mitigation measures to address the shortage itself. It is up to Member States to assess the impact of such stockpiles of critical medicines on other Member States.

In addition, and focused on anti-microbial resistance specifically, in 2022, HERA conducted a study on stockpiling in the context of anti-microbial resistance. It found that "the most effective and feasible model for HERA to consider for how to reduce the burden from shortages caused by supply chain disruptions is the increase of inventories of final medicinal product or active pharmaceutical ingredients in existing commercial supply chains. This might be combined with virtual stockpiling in

[46] The Union list of critical medicines is an element of the proposed Pharmaceutical legislation. First version of the Union list of critical medicines was agreed by the MSSG to strengthen the security of supply of these medicines in the EU | European Medicines Agency (europa.eu). https://www.ema.europa.eu/en/news/first-version-union-list-critical-medicines-agreed-help-avoid-potential-shortages-eu
[47] Critical Medicines Alliance - European Commission (europa.eu)

the form of a transparency system on the availability of critical antibiotics across different EU MS"[48]. The study also finds that "the alternative model of public sector physically stockpiling for final product or active pharmaceutical ingredients may be regarded as less feasible for a number of reasons".

Considering the numerous reasons that can lead to shortages, **physical stockpiling of critical medicines** at EU level is not considered as an appropriate solution and **therefore will not be organised**, unless specifically recommended by the Medicines Shortage Steering Group (MSSG) in exceptional circumstances, in which case the Commission could consider it under rescEU.

At EU level, other initiatives could be envisaged such as support to production capacities increase, maintenance or reshoring, in which case national and EU financial support should be compatible with the State aid framework.

The Critical Medicines Alliance is an example of coordinated actions between governments and industry. Such coordinated action may prevent further **EU inequities** regarding the availability of medicines and medical countermeasures, while respecting the proper functioning of EU's single market. This interaction with industry stakeholders will also be essential to ensure equity, harmonisation, and negotiation power between Member States.

Managing strategic stockpiles of medical countermeasures and stockpiles for critical medicines involve different actors and may require **different measures to ensure continuity of care**, **complementary stockpiling management**, partnerships, expertise, and capabilities. Nevertheless, stakeholders are invited to identify and build on synergies, in particular within the Critical Medicines Alliance.

The discussions within the Critical Alliance could in particular reflect on non-regulatory interventions, such as:

- **early identification of vulnerabilities and data-driven insights** (monitoring and analysing data on critical medicines can help identify vulnerabilities in the supply chain of medical countermeasures so that possible stockpiling measures can be taken in a timely manner),
- **economies of scale** (combining procurement and purchasing power for both critical medicines and medical countermeasures stockpiling),
- **response capacity in sudden demand surge** (buffer stocks of medicines can improve the system's response to sudden surges in demand, whether for regular use or during a health emergency)
- **shared infrastructures and expertise** (e.g., secure storage facilities, transport logistics, and inventory management systems),
- **flexible stockpile management** (items can be easily put in rotation if strategic stockpiles are connected to the regular use items supply chain),
  and **response capacities** (through the re-allocation of stocks where they are needed or through the donations of medical countermeasures or medicines available through the existing solidarity mechanism, i.e., Union Civil Protection Mechanism or the Voluntary Solidarity Mechanism).

7. Conclusions

[48] European Commission, European Health and Digital Executive Agency, *HERA AMR feasibility study on stockpiling – D6/D7 – Final report*, Publications Office of the European Union, 2022, https://data.europa.eu/doi/10.2925/208305

This Common Strategic Approach to Stockpiling is the starting point for more coordinated stockpiling efforts in the EU.

The HERA Board is invited to use this Common Strategic Approach to Stockpiling as a reference background document for cooperation and future actions on stockpiling, and to consider the use of the EU4Health 2024 Joint Action on stockpiling as a vehicle to implement some of the recommendations of the document.

Annex 1 – Definitions

EMA's Medicines Shortages Single Point of Contact (SPOC) Working Party

EMA's Medicines Shortages Single Point of Contact (SPOC) Working Party is responsible for monitoring and reporting events that could affect the supply of medicines in the European Union (EU). The SPOC Working Party also provides recommendations to the European Medicines Agency's (EMA) Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) on all matters related to the monitoring and management of medicines shortages and other medicine availability issues affecting human and veterinary medicines.

EMA's Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)

The role of the MSSG is to ensure a robust response to medicine supply issues caused by major events or public-health emergencies. It coordinates urgent actions within the European Union EU to manage medicine supply issues and issues related to the quality, safety and efficacy of medicines. In addition, the Executive Steering Group on Shortages of Medical Devices (MDSSG) and supporting Working Party has been established to ensure a robust response to supply issues with medical devices during public health emergencies in the EU/EEA.

Medical countermeasures

Medical countermeasures are products, including substances that can be used to diagnose, prevent, protect from or treat medical conditions associated with any kind of serious health threat, including medical devices and other goods or services that are necessary for the purpose of preparedness for and response to serious cross-border threats to health. Examples are vaccines, antibiotics, medical equipment, chemical antidotes, therapeutics, diagnostic tests and personal protective equipment (PPE), such as gloves and masks (reference: definition Article 3, point (10), point (12), of Regulation (EU) 2022/2371, and Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use).

Critical medicinal product

Critical medicinal product means a medicinal product for which insufficient supply results in serious harm or risk of serious harm to patients and identified using the [agreed] methodology (ref proposed pharmaceutical legislation).

Note: Some critical medicines/ medicinal products may also be identified as medical countermeasures. Some but not all medical countermeasures may also appear on the Union list of critical medicines.

Physical stockpiling

Physical stockpile is a tangible collection of pharmaceutical goods in the form of final medical products and/or active pharmaceutical ingredients (APIs), hold privately or publicly, stored, in a designated centralised or decentralised location for future use.

Strategic stockpile:

A physical or virtual stockpile, typically managed by governments, containing essential medical countermeasures intended for use in public health emergencies.

Virtual stockpile

Reserve of medical countermeasures based on availability and location of medical reserves held by various entities (manufacturers, distributors, private stockpiles). Virtual stockpiles notions can range from purely conceptual, if relying solely on non-formal agreements and intelligence from suppliers (e.g., buffer stocks policies and market allocation) to empirical if based on contractual arrangements with entities and definite information on allocated supplies. Virtual stockpiles can take the form of contractual arrangements with e.g. manufacturers and distributers that medical countermeasures will be delivered in a set timeframe in case of need. Virtual stockpiles are also sometimes understood to refer to intelligence from suppliers (e.g., buffer stocks policies and market allocation).

Buffer stocks:

A reserve of medical countermeasures intended to address short-term disruptions in the supply chain or unexpected increases in demand. Buffer stocks are typically held by individual players across the supply chain, from hospitals or other healthcare facilities to economic operators (e.g., wholesalers to manufacturers and suppliers of materials).

Reserve allocation:

Governments or other coordinating bodies may secure agreements with manufacturers or distributors to reserve a portion of their production or stock for emergency use.

Vendor Managed Inventory (VMI)

VMI is a supply chain management practice in which the supplier or vendor takes responsibility for managing the inventory levels of their products at the customer's location. In a VMI arrangement, the vendor monitors the customer's inventory levels, initiates replenishment orders, and manages the delivery of products to ensure that the customer has an adequate supply on hand.

Production capacity reservation

An agreement between public entities or healthcare organizations and manufacturers to reserve a portion of their production capacity for specific medical countermeasures in case of an emergency. Contracts are established outlining the types and quantities of medical countermeasures that manufacturers will prioritize during a crisis, guaranteeing some level of production is allocated to a specific market in a given timeframe.

Forthlooking procurement and supply reservation, including advanced purchase

Pre-purchase of specific quantities of medical countermeasures from manufacturers at a pre-determined price, which needs to be available within a specific timeframe. While the actual purchase agreement is not concluded, such medical countermeasures do not belong to the buyer.

End users

In the context of stockpiling, end users refer to the individuals or entities who ultimately utilize or consume the stockpiled medical countermeasures. These end users could be consumers, businesses, or organizations that rely on the stockpiled medical countermeasures for various purposes, such as production, distribution, or consumption. (source: Investopedia.com)

Voluntary Solidarity Mechanism

The Voluntary Solidarity Mechanism has been developed by the EMA Medicines Shortages Steering Group (MSSG), with the involvement of the Commission, Member States and the EMA. This voluntary mechanism allows Member States to support each other in the face of a critical medicine shortage. The solidarity mechanism, which is based on an informal setup in the medicines regulatory network, enables any Member State facing a critical shortage that has been escalated to the MSSG for coordination at European level to request assistance from other Member States in obtaining medicine stocks. This mechanism can only be used under very limited conditions and was developed as a last resort tool for Member States after they have exhausted all other possibilities. More information at: EMA takes further steps to address critical shortages of medicines in the EU | European Medicines Agency (europa.eu)