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EU-WIDE STOCKPILING:

BETTER PREPAREDNESS FOR SERIOUS CROSS-BORDER HEALTH THREATS

A White Paper *prepared by EUCOPE's HERA Steering Group*

EUCOPE
European Confederation of Pharmaceutical Entrepreneurs AISBL

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WHITE PAPER

EU-wide stockpiling: *Better preparedness for serious cross-border health threats*

INTRODUCTION

Stockpiling of critical biomedical countermeasures is crucial for an effective EU preparedness against priority cross-border health threats with a potential large health and societal impact. In our view, stockpiling of biomedical countermeasures is important especially for products against known health threats that are needed more quickly than they can be produced or imported during an outbreak. An EU-wide coordinated approach and significant additional investments (including vaccines) at EU and national level are necessary to reach adequate preparedness.[1]

HOLISTIC APPROACH TO HEALTH EMERGENCY PREPAREDNESS

As serious health emergencies and threats may not limit themselves to one Member State, cross-border preparedness can only be effective if an adequate preparation at EU-level is matched by the necessary measures within the Member States. Highly pathogenic diseases pose a significant risk to patients in a Member State and across borders. Especially for dangerous infectious diseases or highly disruptive threats that spread easily, it is important to contain an epidemic as quickly as possible. For these types of diseases, a minimum local and regional stockpile is needed not only to treat people, but also to prevent the disease from further spreading. In case of a chemical attack, the time to treat is much shorter, making a local or regional stockpile for priority threats a prerequisite.

KEY CONSIDERATIONS WHEN DESIGNING A STOCKPILE STRATEGY

Many aspects need to be taken into consideration before deciding upon the necessity and prioritization of medical stocks. For instance, the nature of the disease or threat is crucial:

- Are the disease burden and lethality high enough to warrant investing in strong preparedness?
- Is the disease so severe that we need to protect the whole population?
- Is it necessary to be prepared for a chemical attack where we must treat as soon as possible?

[1] HERA's priority list of top 3 health threats that require coordination of measures at EU level are: 1) *Pathogens with high pandemic potential*, (2) *Chemical, biological, radiological and nuclear threats (CBRN)* and (3) *Antimicrobial resistance (AMR).* Effective responses should also be based on internationally recognised threat prioritisation lists such as the US Centers for Disease Control and Prevention (CDC).

- Is the disease burden more severe in certain subgroups that are – for example – immunocompromised or have had a certain medical treatment?
- How many people are still protected or partially protected by earlier vaccinations?

The nature of the disease or threat does not only influence the potential effects of the disease but also the speed of spreading and easiness of identification. Certain diseases can be more dangerous as they spread more widely, easier, and quickly than others. The incubation period of a disease or the time before it shows symptoms and becomes recognized are other criteria to consider. Additionally, a disease from a natural origin usually has a different spreading pattern than a disease from a deliberate attack. A deliberate attack with a disease that is not easily or quickly detectable can result in a wider and more undetected spreading in a shorter period.

The type of threat or disease also influences the feasibility of countermeasures like antivirals, protective clothing, isolation, immediate treatment, and ring vaccination. Ring vaccination can be an option in certain cases but only when we are looking at a low-impact disease that can be detected when infection levels are still limited. Therefore, factors like a quick disease spread, highly populated areas or high travel areas may limit the feasibility of ring vaccination. In these situations, other approaches or other types of countermeasures may be needed to reduce morbidity and mortality in the population or within the group of at-risk persons.

A relevant question concerns the parts of society that we need to protect in case of an outbreak or an attack with biological or chemical means. In addition to the protection needed for the general population, we have to consider how many people we do need to protect to keep our critical infrastructure active. Please see the attachments for additional information.

Other factors to consider when designing a stockpiling strategy include the need of countermeasures like vaccines, antivirals, face masks or protective clothing for first responders, emergency services, parts of or the whole healthcare sector, as well as protecting the police, the military, lab people and people crucial for government services.

Support and social trust within the civilian population will also have to be considered in the decisions on the necessary stockpiles. There will have to be enough medical countermeasure available to counter a threat that may be perceived higher than it is because of rumors getting out of control and fueled by social media or terrorist campaigns.

EUCOPE RECOMMENDATIONS

Effective countermeasures

The choice of countermeasures will have to be determined on factors like efficacy and safety of the products (population and subgroups) in relation to the price, cost, and time it takes to access the product. As an example, vaccine campaigns usually take time and may have to be done preventively when a certain threat level has been reached. Other countermeasures may also be necessary to enhance the full complement of medical protection for persons. Additional relevant topics are time to treat, shelf life,

storage temperature, storage conditions and transport limitations as determined by the marketing authorization of the product.

Immediate need versus mid- and long-term need

Stockpiling of biomedical countermeasures is most important for those products against known priority health threats that are needed more quickly than they can be produced or imported after an incident or during a cross-border outbreak. This way we can ensure:

- A rapid response mechanism.
- The protection of first responders, healthcare practitioners and patients.
- Mitigate the spread or impact of a disease or incident in the early stages of a health event. When the time to treat is short, such as after a CBRN attack, a local or regional stockpile is needed.

For an outbreak of a natural priority disease, national and EU stockpiles should be both available for immediate and short-term use. For mid-term use, stockpiles of finished products, stockpiles of bulk products and contracts with industry are possible options. For example, advance purchase agreements (APAs) can be considered for less known pathogens and products that are close to market. Manufacturing contracts like EU FAB are another option to consider. The development of new critical medical countermeasures is a longer-term option for new diseases, variants of diseases or in case effective countermeasures are not available.

Choosing optimal and safe locations for stockpiles

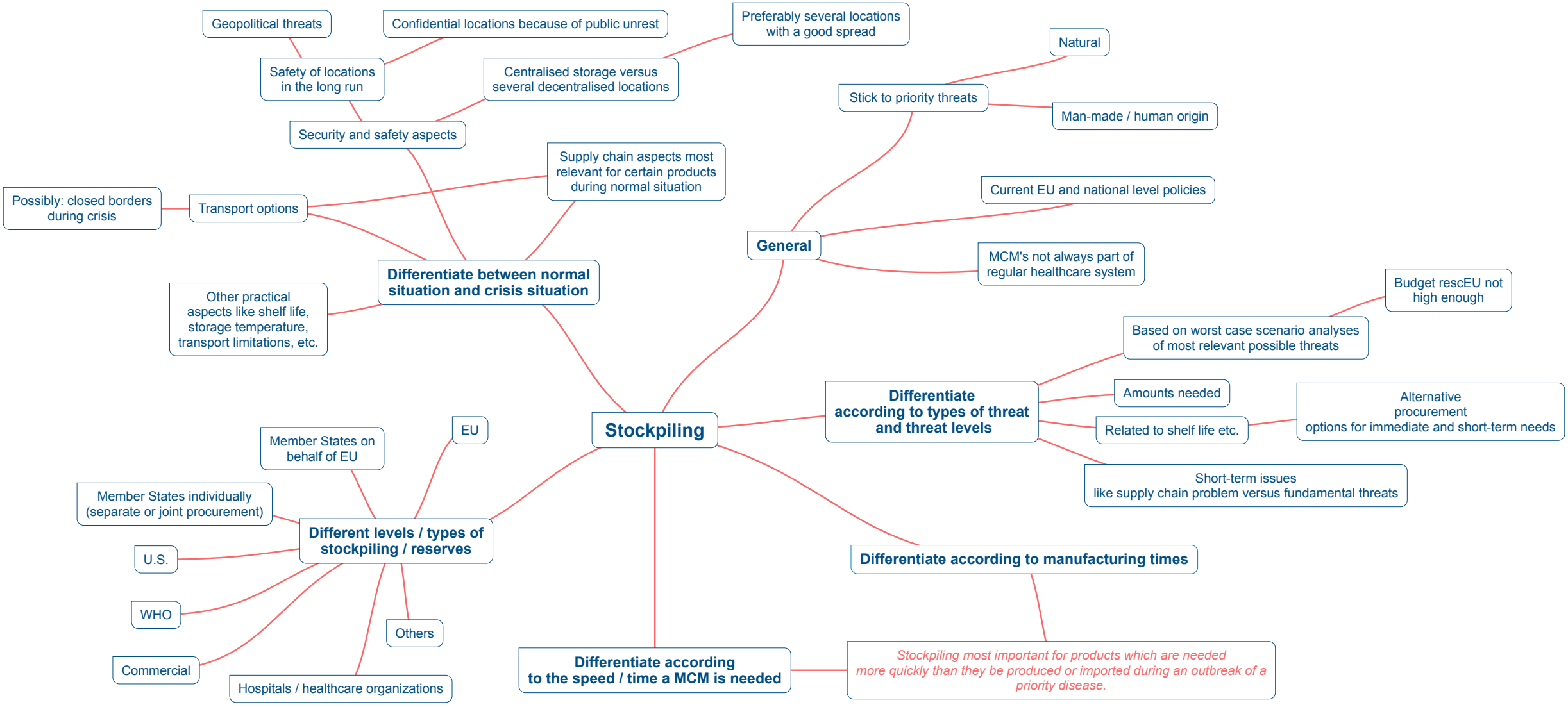
Several practical aspects are very important for any stockpiling strategy. Environmental circumstances, distance to potential deployment areas and long-term geopolitical threats are some of the aspects influencing what is the right location for an EU stockpile. The products should be close enough to where they are needed in case of an emergency, but not too close to potential external threats for the stockpile. Transport options are worth considering too. If borders are closed during a major multi-country incident or pandemic, the armed forces may be needed to transport stockpiles.

Depending on the type of threat, the threat level and other security and safety aspects, it could be preferable to have several locations with a good spread over the EU instead of one central location. Security measures for stockpile locations will need to be effective in normal times and during major crises including at times societal unrest and riots. If locations for stockpiles cannot be protected enough, storage in secret locations can be an alternative.

Clear priorities and additional funding

As government budgets are limited, the available financial means need to be used effectively and efficiently. This can be accomplished by an EU-wide agreement on the selection of priority threats and the right level of preparedness.

Regardless of the current financial limitations, significant additional investments at both EU and Member State level are necessary to reach adequate preparedness. International examples show that vaccines should play a more important role in EU preparedness to cross-border health crisis in order to protect the health of its citizens.


Stockpiling
General
Stick to priority threats
Natural
Man-made / human origin
Current EU and national level policies
MCM's not always part of regular healthcare system
Differentiate between normal situation and crisis situation
Security and safety aspects
Safety of locations in the long run
Geopolitical threats
Confidential locations because of public unrest
Centralised storage versus several decentralised locations
Preferably several locations with a good spread
Supply chain aspects most relevant for certain products during normal situation
Transport options
Possibly: closed borders during crisis
Other practical aspects like shelf life, storage temperature, transport limitations, etc.
Differentiate according to types of threat and threat levels
Based on worst case scenario analyses of most relevant possible threats
Budget rescEU not high enough
Amounts needed
Related to shelf life etc.
Alternative procurement options for immediate and short-term needs
Short-term issues like supply chain problem versus fundamental threats
Differentiate according to manufacturing times
Stockpiling most important for products which are needed more quickly than they be produced or imported during an outbreak of a priority disease.
Differentiate according to the speed / time a MCM is needed
Different levels / types of stockpiling / reserves
EU
Member States on behalf of EU
Member States individually (separate or joint procurement)
U.S.
WHO
Commercial
Hospitals / healthcare organizations
Others

Threat Levels and Possible Stockpiling Scenarios - General Example to Indicate Topics to Consider

Which perspective(s) to use?
- *Preparedness*
- *Minimum national protection needed*
- *Disease aspects (e.g. incubation time, speed of spreading and ease of detection)*
- *Vaccine or vaccines available and their characteristics, including safety, shelf-life, manufacturing times and storage conditions*
- *Efficacy of (other) countermeasures / strategies like isolation or ring vaccination*
- *Effects actual and perceived threat and preparedness on civil trust*
- *Communication aspects*

Assumptions for all levels:
- Potential health and societal impact of the disease threat is considered high.
- Threat level is actual or can be reached within 5 years.
- Level of pre-vaccinated people is estimated as a example at 50 % for the next 5 years. For this group alternative vaccination strategies can be applicable (different vaccine or booster shot only).
- It is assumed that the risk of transmission of the disease is high for this example.
- The number of people contra-indicated for a vaccine has to be assessed, if applicable.
- It is assumed that certain groups and / or locations may have to be vaccinated with a certain vaccine only (for practical and / or other reasons) even if this not necessary for the whole group / location. Check per threat level if all household contacts have to be vaccinated at the same time.
- It is assumed that deployable troops are younger and mostly not pre-vaccinated (later vaccinations or revaccinations not taken into account).
- Check to what extent an alternative vaccine can be used under certain conditions.

No Threat

Vaccine A available for:
- Selected research staff - X people

Threat level 1
Very low
Potential threat

Vaccine A available for:
- 10 % of personnel in key positions government - X people
- 10 % of personnel in key positions critical infrastructure - X people
- 10 % of core group medical staff - X people
- 10 % of other first responders - X people
- 25 % of CBRN units, MP and special forces MOD - X people
- 15 % of contra-indicated people - X people
- Selected research staff - X people

Total without contra-indicated: X people
Total with contra-indicated: X people

Threat level 2
Low
Probable threat

Vaccine A available for:
- 10 % of personnel in key positions government - X people
- 10 % of personnel in key positions critical infrastructure - X people
- 15 % of core group medical staff - X people
- 15 % of first responders - X people
- 25 % of CBRN units, MP and special forces MOD - X people
- 15 % of other deployable troops - X people
- 15% of other people in healthcare - X people
- 30 % of contra-indicated people - X people
- Selected research staff - X people

Total without contra-indicated: X people
Total with contra-indicated: X people

Threat level 3
Medium
Likely threat

Vaccine A available for:
- 25 % of personnel in key positions government - X people
- 25 % of personnel in key positions critical infrastructure - X people
- 50 % of core group medical staff - X people
- 50 % of first responders - X people
- 50 % of CBRN units, MP and special forces MOD - X people
- 25 % of other deployable troops - X people
- 25 % of other people in healthcare - X people
- 30 % of contra-indicated people - X people
- Selected research staff - X people

Total without contra-indicated: X people
Total with contra-indicated: X people

Threat level 4
High
Actual threat

Vaccine A available for:
- 50 % of personnel in key positions government - X people
- 50 % of personnel in key positions critical infrastructure - X people
- 50 % of core group medical staff - X people
- 50 % of first responders - X people
- 50 % of CBRN units, MP and special forces MOD - X people
- 50 % of other deployable troops - X people
- 50 % of other people in healthcare - X people
- 100 % of contra-indicated people - X people
- Selected research staff - X people

Total without contra-indicated: X people
Total with contra-indicated: X people

Threat Levels and Possible Stockpiling Scenarios - General Example Spreadsheet

See the graphic for the topics, underlying assumptions, estimates and other information.

Groups and Numbers

Group of people	Number of People	Subgroup	Percentage to Protect	Number of People Subgroup
Government		Key positions	20	0
Critical infrastructure		Key positions	25	0
First responders				
MOD (CBRN, MP and special forces)				
MOD (others)				
Medical staff		Core group	10	0
Research staff (labs)				
Contra-indicated		Absolutely and relatively contra-indicated	100	0

Threat Levels and Scenarios

No Threat

Group of people	Percentage to Protect with Vaccine	Number of People to Protec with Vaccine A
Research staff (labs)		0

Very Low (Potential threat)

Group of people	Percentage to Protect with Vaccine	Number of People to Protec with Vaccine A
Key positions government	10	0
Key positions critical infrastructure	10	0
Core group medical staff	10	0
First responders	10	0
MOD (CBRN, MP and special forces)	25	0
Research staff (labs)	100	0
Contra-indicated	15	0
Total without contra-indicated		0
Total with contra-indicated		0

Low (Probable threat)

Group of people	Percentage to Protect with Vaccine	Number of People to Protec with Vaccine A
Key positions government	10	0
Key positions critical infrastructure	10	0
Core group medical staff	15	0
First responders	15	0
MOD (CBRN, MP and special forces)	25	0
(MOD (other deployable troops)	15	0
Other people in healthcare	15	0
Research staff (labs)	100	0
Contra-indicated	30	0
Total without contra-indicated		0
Total with contra-indicated		0

Medium (Likely threat)

Group of people	Percentage to Protect with Vaccine	Number of People to Protec with Vaccine A
Key positions government	25	0
Key positions critical infrastructure	25	0
Core group medical staff	50	0
First responders	50	0

Threat Levels and Possible Stockpiling Scenarios - General Example

MOD (CBRN, MP and special forces)	50	0
(MOD (other deployable troops)	25	0
Other people in healthcare	25	0
Research staff (labs)	100	0
Contra-indicated	30	0
Total without contra-indicated		0
Total with contra-indicated		0

High (Actual threat)

Group of people	Percentage to Protect with Vaccine	Number of People to Protec with Vaccine A
Key positions government	50	0
Key positions critical infrastructure	50	0
Core group medical staff	50	0
First responders	50	0
MOD (CBRN, MP and special forces)	50	0
MOD (other deployable troops)	50	0
Other people in healthcare	50	0
Research staff (labs)	100	0
Contra-indicated	100	0
Total without contra-indicated		0
Total with contra-indicated		0