Stockpiling as an instrument to strengthen public health emergency preparedness and healthcare systems' resilience

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Summary – Key principles for effective and sustainable stockpiling

Emergency preparedness is a public health imperative and stockpiles are a cornerstone of a holistic approach to strengthen preparedness strategies. The COVID-19 pandemic has proven that Member States' capabilities to purchase, stock and distribute healthcare products are limited.

Strengthening stockpiles at national and EU level will prove essential for any future public health emergency, like a pandemic. Effective and sustainable stockpiling of medical technologies should focus on ensuring availability of needed devices and services all along the continuum of care where needed for patients and at any (unforeseeable) place and point in time.

The following principles should be considered:

- The medical technology industry has well-established processes when it comes to storage and distribution of medical goods and therefore can be a strong partner to ensure future effective stockpiling.
- A comprehensive stockpiling system in Europe should be based on stockpiling at national level and be complemented at EU level.
- Stockpiling would be based on Member States' needs and capacities and the EU can play a crucial role in coordination and alignment on the scope and quantities, at all phases (from production to deployment, including period reviews).
- Different disciplines, such as procurers and epidemiologists, should be involved in the definition of the scope of equipment to be stockpiled.
- Periodic reviews and dynamic use of stockpiles are conditions to ensure the equipment stored are not thrown away when expired and are always ready-to-use.
- Member States and the EU need to set clear rules on the establishment, maintenance, updates as well as on the deployment and use of the stockpiles.
- Based on the lessons learnt from JPA, new purchasing models are to be explored through new partnership agreements that can reflect the need for continuous stock flow.
- As stockpiling means increased costs, separate budget lines for stockpiling should be secured, on the long run.
- An optimum system should combine a mix of physical and virtual stockpiling.

Establishing an effective and sustainable stockpiling system in Europe: Elements to consider at national and EU levels

I. Role of the industry as a partner

Medical technology manufacturers can play a constructive role in the following way:

- **Supply the stocks** for the stockpile
- **Design the stockpiles by:**
  - **Defining the nature (physical vs virtual**): the industry has experience in developing innovative concepts for (physical and virtual) stockpiles. The digitisation of healthcare has accelerated the development of such innovative solutions. The design of these solutions that focus on having availability when needed, rather than stockpiles in warehouses, requires dialogue and co-creation with the industry and procurement processes that allow for "out of the box" solutions to qualify.
  - **Defining potentially needed equipment**
  - **Explaining variations and defining specifications** of equipment
  - **Sharing information on supply capacities and logistics.**
- **Manage and maintain effective stockpiles**: stockpiling as a managed equipment service would ensure dynamic stockpiles where proper service contracts allow for the rotation and maintenance of devices.

Clear **visibility on Member States' needs** is essential for the industry to meet the actual needs across the EU and contribute to responding to future health crisis.

Member States and the EC are therefore encouraged to establish a close and regular dialogue with the medical technology industry in the development of an effective and sustainable stockpiling system.

II. Complementary national and EU stockpiles

- **A comprehensive stockpiling system in Europe would comprise of both stockpiling at national as well as EU level stockpiles.**
  - The national stockpiling would provide a baseline of equipment needed in a country.
  - The EU strategic stockpiling would come in when national stockpiles cannot keep up with the demand: e.g. as the peak of a pandemic or any other public health emergency differs in time and extend per member state, the EU stockpiles could soften the demands during these peaks.
- **Stockpiling should be based on Member States' needs and capacities.**

In a Communication on 15 July 2020[1], the European Commission recommends Member States "*to urgently establish a clear overview on their needs for medical supplies, national production capacities and stockpiles of essential equipment*". The development of such an overview (and its regular update) is a necessary step to base future stockpile on actual Member States' needs and capacities in terms of equipment and quantities.

- **The EU should ensure strong coordination and alignment amongst Member States at all phases of stockpiling to maximise the value of stockpiles in times of crisis and to avoid disrupting well-established processes in logistics and warehouse management:**

    - **Production of devices to be stockpiled**. Ramping up of idle machinery and capacities is as important as stockpiling to be able to provide products during a crisis. Member States and the EU can have a role to support in building-up capacities.

    - **Establishment of national stockpiles:** Member States and the EC should consider aligning to define he product categories needed as well as the appropriate quantity of national stockpiles per product category. This would ensure that each Member State secures similar minima of stockpiles per population. Stockpiles could exceed the minimum stockpile but should not fall below that level. Alignment is key to ensure optimal quantities are available per product category and to avoid shortages and surplus.

    - **Deployment/use of stockpiles**: Clarity, coordination and, if possible, alignment on the deployment of stockpiles amongst Member States are desirable as the use defines the needed amounts of (minimum) stockpiles. E.g. it could include defining risk populations or population prioritisation criteria (e.g. healthcare workers first). The EU would have a strong role to play in coordinating requests of deployment to ensure the right products in enough quantity get quickly to where they are needed.

    - **EU guidelines and exchange of best practices**: Stockpiling can be done based on very different criteria depending on the country and region. The EU could share guidelines and best practices, to assist Member States identifying their own needs.

    - **Technical compatibility and specifications**. Cross-border provision should account for technical diversity of the devices and the associated consumables and accessories (hardware and electrical differences across Europe): e.g. a UK ventilator will not work in France or vice-versa as the pneumatic input hardware is different.

[1] European Commission, *Communication from the Commission to the European Parliament, the council, the European Economic and Social Committee and the Committee of the Regions - Short-term EU health preparedness for COVID-19 outbreaks*, COM(2020) 318 final, 15 July 2020

III. Composition and maintenance of stockpiles

A. Scope of equipment

Different disciplines (e.g. procurement, epidemiology etc.) should be involved in the definition of the equipment needed. There are different approaches for identifying the equipment potentially needed, they have all validity:

- **Epidemiologic approach based on how the equipment will be used, for example:**
  - **PPE** for protection of workers
  - **ICU treatment and care**, e.g. haemorrhagic (like Ebola) and respiratory (like COVID19) pandemics: eg. ICU beds, patient monitors, respiratory support systems (e.g. ventilators, ECMO, etc.), infusion pumps and acute dialysis machines, in addition to critical pharmaceuticals
  - **Diagnostics systems** (machines on which the tests will be run) **and appropriate equipment of laboratories**
  - **Needles and syringes** (for vaccination phase)
  - **Emergency beds** to help augment surge capacity through the various stages of triage, transportation, treatment points of care.

- **Procurement approach based on what types and quantifies are needed:**
  - **High-volume mass equipment**, such as protective gear, masks and gloves, infusion sets, syringes, needles, sampling systems (e.g. swabs), emergency beds
  - **Low-volume complex equipment** that consists of hundreds of different parts, such as infusion pumps, ventilators, dialysis machines, patient monitors, ICU beds, diagnostics systems[2]
  - **Certain product groups that cannot be predicted** before the exact cause of a pandemic is known, such as tests that need to be developed for each new virus or bacteria or support systems specific to the symptoms of a pandemic. Likewise, it is important to map and prepare for multiple possible scenarios, including a new pandemic but also serious natural catastrophes (like an earthquake), or major accidents (like Chernobyl) which would generate needs for an entirely different portfolio of products.

    As those products cannot be stockpiled, governments might need to consider which kind of framework can facilitate a fast ramp up in the development and production when needed:
    - **Accelerated approval of these devices**, *e.g., through acceptance of existing regulatory approvals the device may have already received in recognised third countries*
    - **Financial support**, e.g. for second or third tier suppliers and SMEs
    - **Guidance:** e.g. which laboratories will be allowed to run tests (public or private)

- **Approach based on the shelf life of supplies**: Some products need more regular maintenance than others such as sterile equipment whose lifetime typically span 3-5 years.

[2] Testing platforms and lab equipment need to allow for running x tests per million population and day (not a percentage)

B. Criteria for quantities and quality of stockpiles per product group

Quantities can be defined as absolute figures or in relative terms**. A relative approach** would help get a more realistic estimate of the needs, especially if the figure is above normal usage: e.g. 20% additional ICU capacity or three months of PPE usage. The number might be different for different products. Data from the actual use during COVID-19 can be a baseline.

Production of equipment for storage purposes only (with no immediate use) should be avoided as it could potentially lead to the late detection of a quality issue, making the entire stock unusable

C. Appropriate information sharing systems

Appropriate information sharing systems about national stockpiles should be established to allow for a high level of **transparency for all actors** in the healthcare system. Member States would gain an aggregated overview on available stockpiles across Europe and could consider a flexible use of stockpiles depending on the changing needs, e.g. for hotspots, during the different phases of a pandemic.

Data sharing should also include information on existing machines that are in use in each Member State to ensure full compatibility.

D. Periodic reviews

Periodic reviews should be foreseen to stress-test various elements:

- **Content of stockpiles:** Is the choice of products and the amount still appropriate?
- **Maintenance and validity of the products**:
    - Stocks that are expired should be replaced.
    - Rolling inventory systems must ensure products are used before their expiry dates and therefore are not thrown away unused: e.g. automatic placing on a pre-defined market at X-time prior to expiry. This might be challenging in some markets where the demand is small or if the supplier has a small market share and is supplying against only a % of a contract.
    - Certain equipment, in particular complex ones, need regular maintenance (e.g. complex invasive ventilation machines or ECMO systems).

  One way to address this and ensure dynamic stockpiles is to set up a collaborative approach between authorities and industries where proper service contracts (perhaps against a fee) allow for the rotation and maintenance of devices.
- **Evolution of needs:** Are there external factors that could influence the needs?
- **Innovation:** Medical equipment is characterised by continuous innovation, which makes the equipment more efficient, user-friendly or personalised (e.g. smart or reusable face masks). Stockpiling concepts should consider how these innovations could be taken into account, e.g. to ensure that previous versions of products are used before stockpiling the newest versions.

IV. Governance

Clear rules on decision making among members states vis-à-vis the EU are important elements to consider:

- Rules for the **establishment, maintenance, and updates** of stockpiles.
- Clear definition and prioritisation of **disease areas as well as products** to be stockpiled.
- Decision-making power for the **deployment and use** of stockpiles as from the moment a crisis arrives, which also embrace access to a (centralised) stockpile when borders are closed.
    - Predictive disease monitoring and early warning system play a crucial role at this stage
    - Clear governance on what metrics trigger the use of the stockpile is needed to ensure the full use of local systems before drawing on EU stockpile
    - Clarity and transparency on the role (leading, coordinating, supporting…) of every actor involved – be it at EU level or national level. For example, the Clearing House set up by the Commission could be officialised as a critical platform to centralise the information on available supplies in all Member States and enable a common planning and allocation of needs across the EU. This would help avoid duplications and would speed up the overall response.
- Development of **international standards on package labelling and languages** in which the device/consumables are available in times of crisis.
- Strong EU leadership that will **safeguard the internal market**, keep the borders open as well as provide tangible and efficient support to the **transportation** of medical equipment from out of the EU to the EU (as well as distribution within the EU).
- Careful **coordination at international level by the EU** to avoid shortages in other regions of the world, which may have more pressing and immediate needs for equipment at a given moment in time.
- The **industry's role** in assisting in the discussion of all these points (see *Section VI Role of the industry as a partner*).

V. Purchasing instruments

A. Key observations from EU JPAs

The EU JPA is a traditional 'supply of goods' model[3]. There are important lessons learned from the EU JPAs used to address the COVID-19 pandemic:

1. **Definition of the content of the JPA upfront**

[3] Member States pool their demand, the Commission sets up a framework agreement for the needed equipment, including amounts and specifications, manufacturers can supply offers to that framework agreement, and then Member States would contract and purchase the amounts they demanded.

- **Need for clarity about 'net demands' of Member States**: it is important for potential suppliers of medical equipment to understand if the demand of a Member State placed in EU JPAs happens on top of or in parallel to national procurement procedures. The potential suppliers need to have the net amount of demand without duplication to be able to provide reliable offers. This is especially important regarding production planning: e.g. will production take place with the equipment already existing on top of the "normal" production? will companies have to establish new production facilities? etc.

- **Vice-versa: Need for a pre-tender market consultation on specifications of the EU JPA:** Setting up efficient EU JPAs will need a good understanding of the supply side to set realistic criteria on volume and technical specification. Pre-tender market consultation with potential manufacturers can ensure a high level of information on the supply side, thus ensure feasible and optimal tender formulations.

2. Implementation of the JPA

- **Need for a certain security on the final purchasing by Member States:** Whilst manufacturers committed to the delivery of a certain quantity of supply set in the EU framework agreement, Member States did not fully purchase the demand asked in the EU agreement, but made it dependent on the development of their national needs. As a result, manufacturers were unilaterally bound to the contract and could not supply these amounts to other countries that might have real needs. That is why it is important to have the total net demand as legally binding quantities, as eventually net demands by individual Member States may vary.

- **Need for addressing surplus due to change in demand:** In some EU JPAs where manufacturers committed a defined amount of equipment in a framework agreement, the demand during the pandemic development remained below the demand stated in the JPA. Reasons included a peak of demand lower than expected (like for ventilators) and protocols changes in the course of the pandemic management (like for serology tests). As a consequence, unnecessary surplus was produced at the cost of manufacturers.

B. Future purchasing models to explore

Around 70% of medical equipment is purchased through procurement instruments. It can therefore be considered as the most likely tool for setting up and maintaining stockpiles.

- In general, the EU should apply the **European Public Procurement Directive** and use the appropriate procurement procedure to award the contract on the product or solution. Unlike the negotiated procedure which was used for JPA during the COVID-19 pandemic, an **open procedure or a competitive dialogue** would maximise market competition, transparency, and a maximum number of participating suppliers.

- The **types of purchasing or procurement contracts** differ significantly:
  - 'traditional' contracts safeguarding a (re-) supply of products; and

- more innovative procurement contracts that can ensure the availability of needed products and solutions that are yet unknown. As the concrete needs of a future pandemic are not completely definable, these contracts could require inventory levels with viable auditing mechanisms.

- Purchasing contracts for EU stockpiling (complementary to national stockpiling) should reflect a needed flexibility level. These are best achieved through **new partnership agreements** that reflect the need for continuous stock flow and through multiple providers contracts. To anticipate potential dependency issues and respond to treatment needs, it is important to maintain a sufficiently large pool of available suppliers to ensure the best available prices and optimal quantities.

- Looking ahead, there are clear benefits in **advancing from a 'supplier of goods' model to a model of continuous 'stock management' as a key service.** For example, stockpiling can be complemented with services contract where a stock is rotated before it expires or for the logistic and transportation from the stockpile location to the EU Member State that expressed needs. The medical technology industry and its partners can offer their expertise on this.

VI. Funding

- **Stockpiling means additional costs, on top of purchasing devices and components**: eg storage, maintenance and transport.

- **Separate budget lines for stockpiling vs 'general' health care expenditures:** The COVID-19 pandemic showed that existing stockpiles were not sufficient nor kept up-to-date: e.g. there were cases where protective equipment was expired and needed to be disposed. One reason is tight healthcare budgets in the past years paired with the increase in demand for healthcare due to demographic changes, yet investment in health care has not been increasing accordingly. Stockpiles were eventually considered as a 'nice to have' and were cut in several countries. It is essential to keep the budget for stockpiling investments for public health preparedness totally separated from the budget of ongoing healthcare services to preserve stockpiling budgets on the long run.

- **EU funding complementing national funding for stockpiles:** A combination of Member States' and EU investments, such as rescEU, could represent a robust model.

- **Longevity of funding instruments:** It is crucial for any funding instrument for stockpiling to be set up and preserved long-term, ie. decades, as the pandemic preparedness needs long-term thinking.

VII. Physical and virtual stockpiling

A. Options for virtual stockpiling

There are already multiple interpretations of what constitutes 'virtual stockpiling' and further clarity on the Commission's starting point would be useful.

- The Commission's roadmap foresees a **virtual stockpiling for vaccines** as follows: "*Consider developing a virtual European data warehouse on vaccine needs and, if applicable, offerable stocks, to facilitate the voluntary exchange of information on available supplies, possible surpluses and global shortages of essential vaccines.*"

- **Fully decentralised stockpile:** the stockpile does not sit in a central warehouse but is distributed along the distribution network: e.g. each hospital has a portion of equipment and materials; this option might be challenging for some hospitals, like urban hospitals, who have limited sorting capacity.

- **Option-based stockpile:** suppliers would offer options on equipment which governments can 'purchase' when needed and the production and delivery of equipment would only unfold in times of a real demand, for example, once a crisis appears. This option would have limitations:

    - Stock would not necessarily be where it is most needed in a crisis and it could be hard to repatriate to a central point if needed;
    - It would be difficult to maintain oversight of expiry dates and to arrange stock rotation if split among different sites;
    - Unless suppliers have spare capacity, this would require suppliers to make significant capital investment in storing unsold equipment.

B. An optimum system would combine different models

Without a longer-term strategy, national healthcare systems could go for the creation of a traditional route of procuring a stockpile via a classic CAPEX (capital expenditure) model – meaning volume and stock focused. A solution could be a **mix between real and virtual stock** (Stockpiling as a Managed Equipment Service).[4]

In this case, the equipment manufacturer would commit a **minimal stock** and be paid as a **service to ensure the availability and maintenance of this stock**. For each unit taken out of the stockpile, the national healthcare system pays the difference between pre-agreed price and already paid subscription and a new unit will be added to the stockpile.

[4] See WHO complementation of physical stockpiling with virtual stockpiling**:** Based on a set of commonly established triggering alarms, a certain percentage of the production of pre-assigned companies/products would be mobilised and prioritised to reach the stockpiling warehouses. This pre-assignment would apply to key suppliers along the supply chain.

On top, a **retainer fee** would give healthcare systems the right to a pre-determined number of units that could be delivered within a pre-determined timeline.

This combination of a **real minimal stock and a virtual, convertible stock** would create a financially viable medical equipment subscription model.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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ANNEX - External Reference Points

1. The White Paper from 6 governments of 09 June 2020 to the EC President on pandemics preparedness

2. NATO: stockpiling for a second wave (18 June 2020): https://www.nato.int/cps/en/natohq/news_176558.htm

3. Dutch political parties wonder what is the division of responsibilities between RescEU and EU4health – link (in Dutch)

4. EURIPHI Blog Hans Bax, 16 June 2020 (Cross-border public procurement: how far do we go?) https://www.euriphi.eu/news/cross-border-public-procurement-how-far-do-we-go/