

Lessons Learnt from the COVID-19 Pandemic and Recommendations on Purchasing Models

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Executive Summary

Appropriate and well-coordinated procurement mechanisms are crucial for crisis preparedness and management

- Public procurement is the main channel for purchasing medical equipment. Procurement mechanisms during the COVID-19 pandemic have been substantially stressed at all levels.
- Coordination of procurement actions is needed, to anticipate actual demand and better adapt supply chain, production, and logistics requirements.

Joint Procurement Agreement (JPA) can support crisis preparedness to build effective stocks, rather than be a tool for crisis management

- An EU JPA has been applied to procure medical equipment to manage COVID-19. However, several limitations in its implementation have become apparent for the following main reasons:
 1. The main issue experienced throughout the pandemic is the so-called 'echo-effect': ie. the same demands for medical equipment made throughout multiple procurement channels. This echo-effect has been particularly detrimental in the case of EU procurement procedures on capital equipment (i.e. ventilators, ECMO devices). To mitigate surplus, the JPA could be adapted for the EU to also be one of the beneficiaries in the contract in support of subsequent stockpiling.
 2. The JPA procedure has not been designed to focus on addressing timely supply issues.
 3. The closed negotiated tender procedure led to a lack of transparency and a limitation of the potential number of suppliers engaged on the European market, in particular from local SMEs.
- The EU JPA could be an adequate tool to support crisis preparedness in building stockpiles. Improvements should be considered to ensure effective and sustainable stockpiling: allowing for a transparent procedure; introducing coordinated forecast (for a more accurate planning on the supply needs).¹

¹ See MedTech Europe Reflection on Effective and Sustainable Stockpiling for Emergency Preparedness: <https://www.medtecheurope.org/resource-library/reflection-paper-on-sustainable-and-effective-stockpiling-for-emergency-preparedness/>

rescEU can also support crisis preparedness and management

- rescEU seems to be a promising mechanism to purchase medical equipment both for crisis preparedness (stockpiling) and management.
- rescEU would benefit from ensuring further process transparency, selecting the most appropriate procurement procedure and contracting as well as providing support for the operationalisation (eg. transportation) when needed.

New cross-border collaborative models of procurement should be explored for crisis preparedness and management

- Under EU leadership, more advanced cross-border collaborative models of procurement that are specific to health crisis should be applied. Models of cross-border collaborative innovation procurement with supportive legal guidance have recently been developed to support the transformation of healthcare and introduce integrated care across Europe with responses to local needs. This has been reported for example by the Horizon 2020 Project EURIPHI (European Innovative Procurement of Health Innovation). These learnings from EURIPHI can be tailored to pandemic preparedness and management.
- It is needed to move from a purely supply model to a partnership-based model to increase the resilience of the technologies supply and to ensure more resilient healthcare along the full continuum of care in all disease areas. Concretely, this implies to take action:
 - in anticipating crisis, by developing new innovation partnership agreements; and
 - in managing crisis, by cooperating on the needs and market availability and by using the existing innovative solutions to absorb, adapt or transform healthcare provision and to enhance healthcare systems' resilience.

I. Purchasing Medical Equipment in Times of Crisis: General Lessons Learnt from the COVID-19 Pandemic

Medical equipment is purchased through procurement instruments. Procurement mechanisms during the COVID-19 pandemic have been substantially stressed because of the abrupt increase in demand, significant supply chain and logistic issues, and the imperative need to supply the needed medical technologies.

Over the course of the COVID-19 pandemic, procurers across Europe have leveraged all procurement mechanisms at their disposal, at all levels, and often in parallel - **local, regional, national**. Furthermore, the EU has also acted at **European** level through the health crisis-related Joint Procurement Agreement (JPA). A general lesson learnt from this situation is the strong need for **better coordination** of all procurement actions across Europe and within Member States. Procurement should be initiated and led where the specific demands can be defined. The EU can have a strong role in coordinating and complementing procurement processes in times of public health emergencies across Europe.

Procurement issues came on top of supply chain and logistic issues in **limiting the availability** of the needed medical technologies to manage the COVID-19 pandemic and to ensure a continuum of care for all disease areas.

II. EU JPA: Lessons Learnt and Ways Forward for Effective Stockpiling

1. Lessons learnt on JPA procedures

At EU level, the Commission has issued several waves of procurement procedures under the EU JPA for Member States to purchase medical equipment needed to manage COVID-19. These procedures have been designed for the “*purchase of medical countermeasures for serious cross border threats to health*”.²

There are important lessons learned from this process:

1. The absence of coordination to measure the specific **net demands** for medical equipment has led to an ‘echo-effect’, i.e. where the demand for the same equipment is multiplied through the different procurement mechanisms (local, regional, national, and European). This led to unclarity for manufacturers on how to direct the supply and significant surplus of equipment committed to by manufacturers in the JPA (but not resulting in national contracts). This is **particularly detrimental in the case of the procurement procedure done for capital equipment** (eg. ventilators).

² See https://ec.europa.eu/health/preparedness_response/joint_procurement_en

More precisely, the procurement procedure on capital equipment did not reflect the actual demand by large: 110,000 ventilators were committed to by manufacturers in the procedure and only 55 were finally purchased by Member States. The industry is bound to secure availability of all this medical equipment upon any request from Member States for the total duration of the EU agreement (12 months). Furthermore, currently the EU has no legal possibility to convert this into stockpiling: this is an option that should be explored to mitigate surplus.

2. The JPA procedures aim to assist Member States to procure by combining **volumes with negotiated prices** but does not primarily focus on addressing **timely supply issues and the responsiveness to specific needs**.
3. Applying the closed negotiated tender procedure (through the European notification process), only **a few pre-selected suppliers** have been invited to submit their bid, limiting the potential number of suppliers on the European market, in particular from **local SME**. Instead of creating a new platform which had limited functionality, it is recommended to leverage the established processes and the available capacity of suppliers fulfilling selection criteria.
4. A JPA procedure for ventilators was open to offers for equipment **without CE mark**. If deployed, these devices must be removed from the market after the pandemic or brought to regulatory conformity. Going forward, EU Joint Procurement Agreement should not compromise on the quality of the procured equipment and there should be an EU-wide approach: eg. the granting of Union-wide derogations to such devices as per MDR, instead of fragmented national purchasing decisions.
5. A **holistic approach** favouring the most economically advantageous tender, using criteria such as quality, functional characteristics, after-sales service as well as price should be applied.
6. The implementation of the EU JPA has also been impeded by **market restrictions within the EU** which hampered manufacturers to provide the necessary technologies on time and in sufficient volume.

Therefore, EU JPA are better suited when preparing for a public health emergency. However, at times of crises, procurement mechanisms should be geared towards **ensuring supply continuity with improved time to market**.

2. An EU JPA would be best suited for stockpiling

The EU JPA is a traditional 'supply of goods' model³ and could therefore be more adapted for stockpiling for crisis preparedness. Yet, there are conditions to be fulfilled⁴⁵:

When the EU applies the **European Public Procurement Directive**, the most appropriate procurement procedure to award the contract is to be selected considering the market readiness of products and solutions available, safeguarding transparency by publication of a prior award notice on TED (Tendering Electronic Daily) and maximising market competition with the participation of a high number of 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.
- Before launching a new wave of JPA procurement procedures, it is crucial to ensure **clarity on 'net demands' of Member States and internal alignment and coordination** with local, regional and national procurement activities by the Member States. Avoiding duplications of demand is key so manufacturers can provide reliable offers on the basis of solid production planning. This would also contribute to avoiding surplus in case the amount committed for delivery in the specific procedure is lower than the amount actually purchased.
- On the other way round, setting a **pre-tender market consultation on specifications would help** to set realistic criteria on volume and technical specification in the EU JPA.
- The JPA should present the option to provide resources and support suppliers of **both devices and components** in the supply chain. It is crucial for successful tenderers in the JPA to ensure that their suppliers of components are deemed critical in the supply chain and are provided appropriate resources to ensure component delivery short term.

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.

⁴ See MedTech Europe Reflection on Effective and Sustainable Stockpiling for Emergency Preparedness: <https://www.medtecheurope.org/resource-library/reflection-paper-on-sustainable-and-effective-stockpiling-for-emergency-preparedness/>; As a general note, efficient stockpiling should take into account the global situation, solidarity across the globe and the possibilities of the suppliers to deal with that global demand. Suppliers are faced by tremendous pressure not to deliver their products not just to one specific institution but rather to have a non-discriminatory approach that relies on global solidarity. Rolling forecasts or purchase commitments over a period of time could be an alternative to stockpiling as suppliers could adapt their production and supply chain in a more flexible manner.

III. Purchasing through rescEU for stockpiling and crisis management

rescEU, which functions under the umbrella of the EU Civil Protection Mechanism, has the objective of enhancing both the protection of citizens from disasters and the management of emerging risks. In addition, rescEU establishes a new European reserve of resources (the 'rescEU reserve'). During the COVID-19 pandemic, the European Commission created a dedicated strategic rescEU medical stockpile and distribution mechanism.

rescEU seems to be a promising a **well-suited element for emergency preparedness (to build reserves) and to deliver needed medical equipment in times of crisis.**

MedTech Europe calls for safeguarding future EU procurement mechanisms and recommends considering the following elements, when deploying rescEU, and when applying any other procurement procedures either for crisis preparedness and or for during-crisis management:

- The lack of transparency throughout the COVID-19 crisis impacted the supply side, in particular at local/national levels: there has been no upfront publication of the tender on TED (Tenders Electronic Daily) for interested suppliers (and on the type of procedure used), nor publication afterwards on the awarded contracts. A **more transparent system** should be envisaged to leverage the full supply capacity, including from SMEs.
- The **most appropriate procurement procedure** to apply (open/restricted) should be chosen based on the equipment to be purchased.
- Likewise, the **appropriate contracting** should be ensured: the contract could include an option for additional purchase over time, which would require timepoints for decisions to be made.
- Purchasing should take into consideration the **potential differences of technical specificities across the EU**: the choice of medical equipment should make sure that the products' specifications match the actual needs. In the case of a single well-defined specification, additional options could cover the specific needs.
- The rescEU mechanism, specifically, should provide more flexibility to cover or assist **operationalization**, especially in manufacturers' freight costs when they deliver procured devices to EU Member States. With COVID-19, many planes had to be grounded and air freight costs skyrocketed.

IV. Future Purchasing: New Cross-border Collaborative Procurement Models and New Partnership Agreements

1. Cross-border collaborative procurement as a model to explore for crisis management

MedTech Europe invites the EU to apply new **cross-border collaborative models of procurement** that are specific to health crisis management. Models of cross-border collaborative procurement have been proposed in the **EURIPHI H2020 CSA (Coordinating and Supporting Action) for innovation procurement** and can be applied as well in health crisis management.

The cross-border collaborative procurement model has been developed in the framework of **EURIPHI**, which has proven beneficial for the supply and integration of innovative solutions in the healthcare systems⁶, and can be applied for any other (consumer or capital) equipment necessary.⁷ The model is based on a well-structured collaboration and knowledge sharing in the preparatory phase followed by a selection of a specific most valued procurement procedure, based on the market readiness. The different implementation models which result are:

- Full preparatory collaboration followed by the issue of individual local procurement procedures;
- Full cross border collaborative procurement having lots (ie. contracts) per locality;
- Full cross border collaborative procurement resulting in framework agreement(s) followed by specific contracts per locality.

The benefits of such a cross-border approach are:

- **Deeper understanding of opportunities for collaborative procurement and of availability on the market for medical technologies.** This increases the market readiness, responsiveness and ensures the efficient distribution of technologies from where they are available to where they are needed. This can help tackle supply limitations, surplus and significantly decrease time for reaction during a crisis, thanks to greater market visibility.
- **Accounting for the risks from differences among EU member states** as regards national transposition of the EU Procurement Directive, healthcare systems organization and reimbursement models, and linguistic and administrative variations.
- **Increasing the resilience of healthcare systems in times of crisis** through enhanced capacity for innovation, higher adaptation to maintain high quality healthcare delivery and greater co-investment in cross-border partnerships.

⁶ The model ensures the application of the Most Economically Advantageous Tendering approach for healthcare, proposed by the EU Procurement Directive: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32014L0024>

⁷ EURIPHI Reflection Paper 'Applying a value-based approach to innovation procurement in healthcare': <https://www.euriphi.eu/wp-content/uploads/euriphi-value-based-innovation-procurement-final-1.pdf>
EURIPHI Reflection Paper 'Advancing health systems in Europe through cross-border value-based innovation procurement': <https://www.euriphi.eu/wp-content/uploads/euriphi-cross-border-collaborative-procurement-final-1.pdf>

The EU, Member States and Regional Health Authorities can play a critical role in advancing the use of cross-border collaboration to unlock value-based innovation procurement. For example, the EU can do so via EU supported innovation procurement and Horizon Europe projects.

In times of crisis, the role of the EU would be crucial in ensuring a solid collaboration across Member States.

2. The benefits of moving from a supplier of goods model to new partnership agreements

The COVID-19 pandemic has demonstrated the crucial importance of ensuring both a continuous **supply of devices needed for the management of COVID-19** (e.g. PPE, tests, ventilators) and the **full continuum of care in all areas** (e.g. oncology, diabetes, cardiovascular diseases). The medical technologies industry can support in the delivery of care with solutions for crisis preparedness and management and to maintain a continuum of care. **New partnership agreements** are needed and should be explored.

Concretely, these new partnership agreements would encompass the following elements:

A. For crisis preparedness:

Innovation partnership agreements should be fostered to co-create innovative solutions: i.e. to support research and ensure the effective purchasing of the developed innovative solutions, provided that transparency and fair competition rules are respected. These innovation partnerships can be organised on the basis of the current and the new “innovation partnership” procedure under the Public Procurement Directive⁸.

B. For crisis management:

1. To manage the crisis itself:
 - Cooperation to determine supply needs and potential shortages;
 - Consultation on the availability of supply should be organised.
2. To ensure the continuum of care in all disease areas: the transformative capacity of the supply side by technologically innovative solutions should be leveraged: for example, shifting ambulatory and hospital care to community and home care when needed.⁹

MedTech Europe calls on health systems to focus on **innovating on the delivery of care** in partnership and collaborative models to ensure stress resilience and sustainability. This shift can be done in the most economic advantageous ways, by applying a value-based approach, with a strategic role for procurement.

⁸ https://ec.europa.eu/growth/content/8699-innovation-partnerships-keep-public-services-date_en

⁹ https://ec.europa.eu/health/sites/health/files/systems_performance_assessment/docs/2020_resilience_en.pdf

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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