Vaccines Europe's Position on Joint Procurement of Vaccines in Europe

Vaccines Europe's Position Paper
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Executive summary

- Vaccines Europe supports possible solutions for sustainable and equal access to current and future vaccines in Europe, including COVID-19 vaccines.
- There are a variety of reasons for shortages of vaccines, however these reasons will not be solved by joint procurement.
- If vaccine challenges are addressed properly otherwise, they will support further sustainability of vaccines availability in Europe.
- Routine vaccination programmes are in principle a matter of national competence and it would be particularly complex to address country particularities through joint procurement.
- We support specific advance procurement agreements for extraordinary public health challenges where cross-border collaboration is helpful to the emergency response across Europe.
- Any procurement practices, including joint procurement, should foster fair competition, timely access, and reliable supply.

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Introduction

Joint procurement of medical countermeasures - including vaccines - is an important mechanism for Europe to secure more equitable access and an improved security of supply of those countermeasures to address an outbreak of a serious cross-border threats, such as the COVID-19, pandemic influenza and other pathogens of pandemic concern. At the same time, Joint Procurement (or Cross Border Procurement) of vaccines has been part of recent policy developments[1] as one of the solutions to address shortages of routine vaccines in the European Union (EU).

Joint procurement in Europe can take different forms, ranging from coordinated procurement by multiple contracting authorities, where each contracting authority conducts a separate procurement procedure, to procurement where different contracting authorities jointly conduct one procurement procedure either by acting together or by entrusting one contracting authority with the management of the procurement procedure on behalf of the other contracting authorities.

Advance Purchase Agreements (APA) is a contract under which the purchasing party secures the right to buy a specific amount of product in a given timeframe at a given price, from the provider. This contract then governs the commercial relationship between the purchaser and the provider and the terms and conditions under which the products are to be provided. APAs differ from regular contracts in that they typically contain upfront payments e.g., to support faster manufacturing of products which are not yet available.

The following EU rules provide a framework for joint procurement of pharmaceutical products by contracting authorities in two or more Member States (MSs):

1. Public procurement is regulated by Directive 2014/24/EU on public procurement and, at national level, by implementing laws. The Directive includes amongst its objectives facilitating cooperation between contracting authorities.
2. Decision 1082/2013/EU is aimed at improving cooperation of the EU and its MSs in dealing with serious cross-border threats to health, including the joint procurement by EU institutions and MSs of counter measures, that address serious cross-border threats which might require coordination at Union level in order to ensure a high level of human health protection, such as the pandemic flu or Ebola. In November 2020, the Commission put forward a Proposal for a Regulation on serious cross-border threats to health to repeal Decision 1082/2013/ EU and adapt the Joint Procurement Agreement given the lessons learned from the COVID-19 pandemic. In June 2022 the Council and the European Parliament reached an agreement on an amended version of the draft regulation[2].

[1] Council Recommendation on strengthened cooperation on vaccine preventable diseases and the Joint Action on Vaccination (JAV).
[2] https://www.consilium.europa.eu/en/press/press-releases/2022/06/23/provisional-agreement-on-new-eu-law-on-serious-cross-border-threats-to-health/

In addition, in 2020 and 2021, the EU concluded a number of advance purchase agreements for COVID-19 vaccines (candidates) with individual vaccine producers, whereby a part of the upfront costs to scale up manufacturing at risk, were financed from the Emergency Support Instrument. This funding was considered a down-payment on the vaccines that MSs purchase.[3]

Position

Vaccines Europe supports possible solutions for sustainable and equal access to current and future vaccines in Europe, including pandemic vaccines.

Vaccines Europe recognises that joint procurement of vaccines is complex. Therefore, it should only be used where it can improve access to vaccines and should be limited to situations where purchase and supply of products cannot be ensured by other means.

There are a variety of reasons for shortages of vaccines, such as complex life cycle management, growing and often unpredictable global demand, sudden increases of demand e.g., triggered by infectious disease outbreaks or competitor stock outs, suboptimal national forecasting practices and inflexible purchasing requirements[4]**. These reasons will not be solved by joint procurement.** However, if these challenges are addressed properly, they will support further sustainability of vaccines supply in Europe. Some of these challenges and solutions are part of separate position papers. In general, procurement practices and funding should reflect the full public health and economic value of vaccination programs[5,6].

When conducting joint procurement of vaccines, decision-makers should take into account the definition and implementation of national immunisation policies and programmes, as well as the specificities of vaccines manufacturing and the limited number of vaccine companies

With regard to joint procurement of vaccines in Europe, Vaccines Europe recommends the following;

- **We support specific advance procurement agreements for extraordinary public health challenges where cross-border collaboration is helpful to the emergency response across Europe (See the Appendix II for our specific recommendations on joint advance purchase agreements).**

[3] https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en
[4] https://www.sciencedirect.com/science/article/pii/S0168851021002876
[5] "*Recommendations to improve tendering practices of vaccines in EU Member States*" addressing specific recommendations by Vaccines Europe to improve procurement practices.
[6] *"Time to unlock the full value of vaccines"* addressing specific recommendations by Vaccines Europe on how to recognize the wider benefits of protecting populations from important infectious diseases.

- **Joint Purchasing of Vaccines under the 1082/2013/EU Decision (or future Regulation) should however remain reserved for serious cross border threats to health such as pandemics and potentially imminent outbreaks of vaccine preventable disease in Europe** that may necessitate coordination at Union level in order to ensure a high level of human health protection. Such measures should be proportionate to the situation and clearly limited in time. The Joint Purchasing Agreement, with its clearly defined competences and processes, should not be considered for joint purchasing of routine vaccines, given the complexity to implement, the risk of affecting the functioning of the current vaccine distribution system in each MS, the current internal EU market and potential distortion of competition potentially leading to unsolvable supply shortage.
- **Routine vaccination programmes**, covering the vaccines schedules, purchasing, distribution and implementation **are in principle a matter of national competence**. Also, public health needs, distribution and administration systems for vaccines vary between MSs, and have been historically set in a way that addresses MS epidemiology and fits into the organisation of the healthcare systems. As a result, joint procurement of vaccines is particularly complex when addressing country particularities (see Appendix I), including sub-national implementation (e.g., Italy, Spain, Belgium).
- **Any procurement practices, including joint procurement, should foster fair competition, timely access, and reliable supply**.
    - The vaccine market is characterised by a limited number of suppliers, particularly for some specific vaccines. It is crucial, that joint procurement arrangements are carefully considered, maintain reliable vaccine supply and avoid creating market distortion or any concentration of demand, which could further reduce competition and jeopardise the ability to respond to the MS needs.
    - Aggregation of volume risks increasing volatility of demand for manufacturers who lose bids, particularly where tenders cover supply requirements for multiple years. Reduction of significant volumes of demand over several years may mean that a manufacturer sees demand falling below the quantity threshold* and/or the level of production necessary to cover fixed costs, which could drive such manufacturers out of the market or could lead to business decisions to commit production of those vaccines towards other regions in the world, outside the EU.
    - Conversely, tenders that are short term in nature do not provide adequate planning time for manufacturers given lead times involved, nor provide enough certainty to invest in manufacturing expansion.
    - The other consequence is that several MSs would depend on a single supplier for a certain vaccine. This creates the risk of significant shortages should this supplier subsequently face manufacturing issues for an extended period. For this reason, multiple supplier representation through splitting of tender awards should be considered.

* Minimum quantity for which production site has been qualified and authorized

Appendix I

Cross Border Procurement of vaccines under the 2014/24/EU procurement directive as currently practiced for some vaccines in the Baltic States, is complex and does not necessarily guarantee broader and timely access to vaccines.

- Cross border procurement has not shown to solve supply of constrained vaccines where global demand is higher than global manufacturing capacity.
- Contracting authorities from different MSs will have to agree on, for instance, the applicable law, procedure, language, tender specifications, contracts with successful tenders and the distribution of roles and responsibilities among the participating authorities.
- Contracting authorities will also need to ensure that cross-country processes do not conflict with national rules and regulations such as differences in national competences on vaccine purchasing, distribution systems and specific requirements with regards to individual vaccines.
- National processes should be adapted to directly integrate the outcome of supra-national decisions into the national process, i.e., where the supra-national route is chosen, it should replace any domestic process.

Appendix II

Between June and September 2021, the European Federation of Pharmaceutical Industries and Associations (EFPIA) and Vaccines Europe (VE) conducted interviews across eight companies who signed a contract with the European Commission on COVID-19 vaccines and therapeutics, which provided a basis to the below-mentioned recommendations.

The aim of these recommendations is to help the EU be prepared for future health crises by increasing the speed and effectiveness of negotiations with manufacturers in the context of joint advance purchase agreements for cross border health emergencies. These recommendations could also feed into other initiatives the Commission is planning to improve the bloc's pandemic preparedness and resilience, such as HERA. That said, and as explained in this position paper, there is a clear consensus amongst manufacturers that joint purchasing agreements outside of pandemic situations would not work in the current context.

1.Take a more holistic approach to the negotiations

1.a Broaden dialogue with the manufacturers

While the Commission successfully signed contracts with both vaccine and therapeutic manufacturers, these negotiations were predominantly focused on the purchasing of vaccines or therapeutics. This narrow approach to the negotiations, exclusively focused on procurement, impeded the Commission from immediately being able to identify and support

companies with other issues of critical importance such as sourcing of raw materials, supply chain challenges, manufacturing, production scale-up and distribution of supply. As the world was facing its worst pandemic, it would have been beneficial to broaden the dialogue with manufacturers beyond product purchasing.

1.b Go beyond purchasing with joint investment and further risk sharing

While the EU secured a strong portfolio of COVID-19 vaccines and therapeutics, it could take a more prominent role in investing earlier in the development and scale-up to further strengthen the EU's crisis preparedness and resilience. The EU Health Emergency Preparedness and Response Authority (HERA) provides one avenue to do so.

2.Develop a framework / standard operating procedure

2.a Involve regulatory experts as well as sectoral and scientific experts on manufacturing and production in the Commission's negotiating team

While the Commission's negotiating team was fully engaged and committed, all interviewees noted that the negotiation process seemed to be a steep learning curve for Commission officials as well as all stakeholders involved. Negotiations could have been sped up if the team had more sectoral expertise on the manufacturing and production of vaccines and therapeutics as well as regulatory knowledge, potentially coming from the European Medicines Agency (EMA). In addition, adequately resourcing the Commission team involved is key, as parties noted that an increase in manpower could have accelerated the process.

2.b Provide more clarity on the overall process and expectations

While there is an understanding that purchasing vaccines or therapeutics at EU level is a negotiation process, companies would have welcomed more structured and clearer communication, especially with regards to the negotiation steps and timelines. This could happen in the inter-pandemic period as part of HERA Joint Industrial Cooperation Forum. Providing more clarity in future negotiations, e.g., in the form of publicly disclosed standard operating procedure, would help simplify interactions throughout the negotiation process and help manufacturers better anticipate requirements. This would enable companies to collate necessary information ahead of time and speed up the overall process.

2.c Prioritise timeliness for documentation and limit bureaucracy

While it is understood that there are a number of legal documents that the Commission requires to sign a purchase agreement, it would be helpful for the Commission to have a certain flexibility in times of crisis to prioritise the most critical documents (for example, criminal records with specific validity were difficult to obtain in light of crisis situation and in short periods of time). This could entail allowing submission of additional documentation at a later stage or, alternatively, to forego on others in a pragmatic and crisis-adjusted matter as appropriate.

3.Strengthen legal framework

3.a Negotiate overarching standards on no-fault compensation and liability that can be activated in pandemic times

While the Commission focused on getting contracts signed during the COVID-19 crisis, the absence of an overarching EU no-fault compensation (NFC) and adequate liability framework in case of health crises led to significant delays in the signing of contracts. Going forward, it is critical that the Commission proposes clear and common rules at EU level for NFC and liability[7]. Overall, aligning these elements ahead of time would significantly speed-up and facilitate future negotiations during times of crisis.

3.b Utilise an opt-out instead of an opt-in system within a specific time frame

While all EU MSs were part of the EU deals for vaccines deals by default, EU MSs have to opt-in for the therapeutic deals. This means that therapeutics and vaccines purchasing had different opt-in and opt-out modalities. On the opt-in side, back and forth between Member states and the European Commission led to significant delays in the procurement.

[7] A joint EFPIA and Vaccines Europe white paper on establishment of the Health Emergency Preparedness and response authority: https://www.efpia.eu/media/602659/hera-white-paper_efpia_ve.pdf.