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

Vaccines Europe's Position Paper
June 2020

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 is 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 current COVID-19 pandemic. 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 public 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.

Two sets of EU rules provide a framework for joint procurement of pharmaceutical products by contracting authorities in two or more Member States:

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 of EU institutions and MSs of counter measures, that address serious cross-border threats which might necessitate coordination at Union level in order to ensure a high level of human health protection, such as the pandemic flu or Ebola.

Position

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, 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**. These reasons will not be solved by joint procurement**. However, if these challenges are addressed properly otherwise, they will support further sustainability of vaccines availability in Europe. Some of these challenges and solutions are part of separate position papers. In general, procurement

[1] Council Recommendation on strengthened cooperation on vaccine preventable diseases and the Joint Action on Vaccination (JAV).

practices and funding should reflect the full public health and economic value of vaccination programs[2],[3].

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.

When joint procurement of vaccines is considered, national competences, including immunisation policies and programmes, the specificities of vaccines manufacturing and the limited number of vaccine companies should be taken into account.

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. Joint Purchasing of Vaccines under the 2013 Decision (JPA) 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 JPA, 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 internal EU market and potential distortion of competition potentially leading to unsolvable supply shortage.
- **Routine vaccination programmes**, covering the vaccine immunisation calendar, schedules, vaccine purchasing, distribution and implementation **are in principle a matter of national competence**. Also, public health needs, distribution and administration systems vary between Member States. As a result, joint procurement of vaccines is particularly complex when addressing country particularities (see appendix), 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

[2] "*Recommendations to improve tendering practices of vaccines in EU Member States*" addressing specific recommendations by Vaccines Europe to improve procurement practices.
[3] *"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.

further reduce competition and jeopardise the ability to respond to the Member State's 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 quality 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 of time. 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

Cross Border Procurement of vaccines under the 2014 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.

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