Recommendations to improve tendering practices of vaccines in EU Member States

Vaccines Europe's Position Paper
April 2020

Summary

Vaccines are among the most successful and cost-effective public health tools for preventing diseases and death. Each year, vaccination programs save almost 3 million lives, and another 750,000 children from disability[i].

Nevertheless, the value of vaccines is often taken for granted and **tendering practices do not always reflect the value of the vaccination program beyond the vaccine itself, or consider the length and complexity of vaccines manufacturing**, the increasing global demand for existing and novel vaccines, or the limitations of the small base of manufacturers able to provide high-quality vaccines.

Governments should **consider increasing the funding of National Immunization Programs** (NIPs) (currently on average less than 0.5% of health care expenditure)[ii]. This will allow new vaccines to be adopted by NIPs **without adding pressure to current tendering practices**, which are used in most EU Member States. It will also address demographic changes, help to create a more sustainable vaccine ecosystem, support more efficient implementation of vaccination programs, e.g. by developing or improving existing Immunization Information Systems to guide vaccination policies and programs, and ensure immunization targets are reached.

Vaccines manufacturers are committed to improving vaccines availability in the EU. Together with Vaccines Europe, manufacturers work with relevant stakeholders to address the recommendations outlined in the EU Council Recommendation on strengthened cooperation against vaccine-preventable diseases and on supply and preparedness related activities of the Joint Action on Vaccination.

This paper outlines recommendations on national/regional public tender practices in the EU to improve timely and consistent availability of vaccines for EU citizens and citizens of the world.

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Current vaccine procurement trends in the EU

Vaccine procurement processes differ across EU Member States, however, national/regional procurement through tenders is most often used. In some EU Member States, vaccines are individually reimbursed (i.e. France, Germany), others have a mix of procurement and reimbursement models (e.g. Czech Republic). This paper focuses on current tendering practises in Europe.

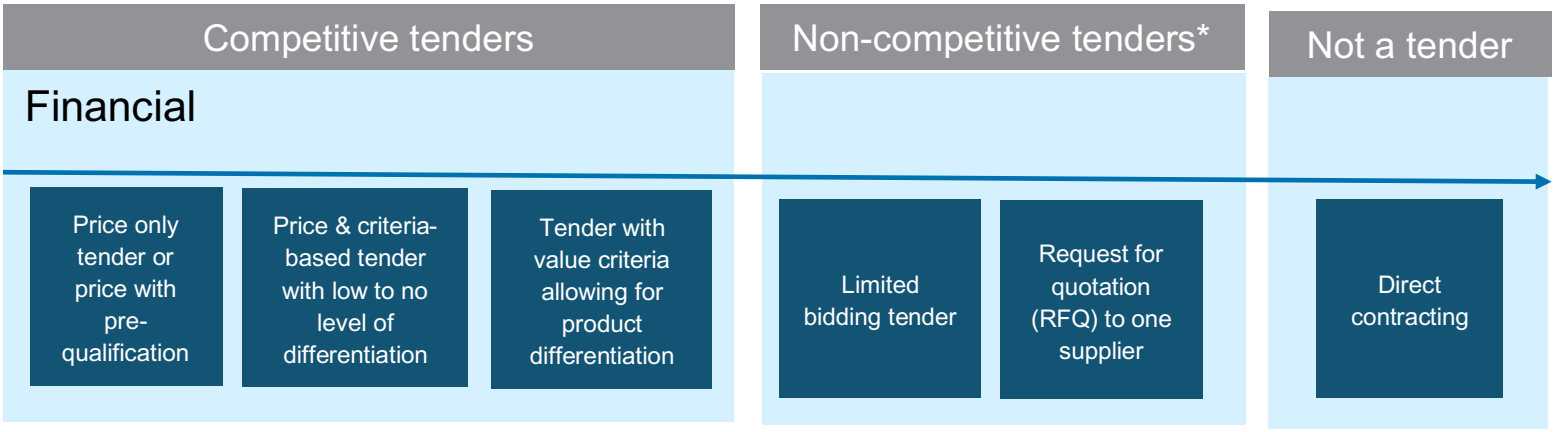
No tenders: Reimbursement and Out of Pocket models

A public reimbursement model allows governments to modulate reimbursement according to public health priorities. This offers budget flexibility e.g. providing a reimbursement framework ranging from fully Out of Pocket (OoP) to fully reimbursed vaccines. Furthermore, this model allows prescribers a choice of vaccines to more closely meet patient's needs.

Tender models

A tender is a formal public procurement process with defined specifications, commercial terms, timeframe and rules for the evaluation of bids and selection of suppliers.

Figure 1: Tender Archetype



* Specifications (mandatory requests) only enable one competitor to bid and be selected as supplier. Also applies if only one vaccine is on the market

Winner take all tenders: All the doses are allocated to a single supplier.

Split tenders: For vaccines which are considered interchangeable by purchasing authorities, awarding tenders to multiple manufacturers upon pre-set criteria can be beneficial in enhancing volume availability of vaccine, e.g. when one manufacturer experiences manufacturing issues. For example, the Dutch and many Nordic countries split influenza tenders 60/40. Also, UK paediatric tender conditions illustrate this practice: "Award criteria: The Authority may award contracts to more than one offeror in order to limit the impact of a failure to supply and offers which are dependent on a large proportion of the proposed contract volume may be rejected"[iii].

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Vaccines Europe calls for EU Guidelines on vaccines procurement to better integrate the following general principles

- **Reflect societal and public health needs and ensure continuity of National Immunisation Programs:** Tendering specifications should be consulted with stakeholders including patients, physician associations and public health experts. Tenders should not restrict patient access to innovative vaccines or limit immunisation choice.
- **Be supported by strong implementation of vaccination programs and monitoring of uptake, as well as public vaccination campaigns.** These should highlight the need for high target vaccination coverage rates and provide information that helps increase confidence in vaccines.
- **Ensure procurement policies and funding reflect the full public health and economic value of life-course vaccination** and support adoption of immunisation across the life course and timely uptake.
- **Comply with national, subnational and European legal frameworks on procurement**. (Appendix 1, page 5).

1.Tender specifications and award criteria should systematically be based on the following: (i) the concept of the Most Economically Advantageous Tender (MEAT)[iv] criterion, (ii) a call for tender participation, (iii) clear and well-defined tender specifications and award criteria, determined after preliminary market consultation, and (iv) a robust framework agreement.

- **Not be limited to price as the only decision-making criterion**. Clearly defined and transparent additional evaluation criteria, accounting for both product and outcome-related features, should be established. “Price – only” driven vaccines tenders sometimes result in “competitive” prices which are so low that the risks are bigger than the potential limited business margins. This will lead to manufacturers avoiding future tenders and diverting constrained supply to countries that support more sustainable business conditions.
- **Ensure that confidentiality agreements associated with local procurement negotiations are respected**. Protection of confidential information is a principle of good administration that binds public authorities in democratic societies. It is a principle that is enshrined in a wide range of legal instruments. Respect of confidentiality agreements should prevent the exchange of information between public authorities to allow for differentiated tailored agreements to the specific circumstances.

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2.Tender Practices should reflect the accountability of Health Authorities for programme continuity, anticipation, monitoring and performance to provide appropriate protection of European population against vaccine preventable diseases

- **Foster fair competition and sustainability of supply**. Avoiding excessive concentration of purchasing power is important to ensure the ability of Vaccines manufacturers to respond to Member States' needs. In countries procuring by national tenders, a manufacturer who loses a public bid loses all or nearly all access to the market for the duration of the tender; which may last for several years. The reduced demand may push the manufacturer below the level of production necessary to cover fixed costs and could potentially drive some manufacturers out of the market. Split tenders could be considered by purchasing authorities as a practical solution to counter-balance the possible negative effect of "winner takes all", when the products are deemed interchangeable by purchasing authorities.
- **Forecasting accuracy is critical for timely supply**: Continuous advanced dialogue on possible future changes of vaccine calendars and program implementation allows for timely production and supply. Manufacturing investment and capacity increase is taken at risk and over time; it takes 5-10 years to build a new factory and this represents a significant capital investment. Moreover, changes in NIP schedules to reflect demographic changes or changing public health needs and outbreaks need more timely and robust new ways of engaging with the vaccines industry to accommodate the long production lead times (12 to 36+ months).
- **Variable quantity contracts**: Some countries do not offer any firm volume commitments and request wide variations in volume demand. This does not constitute the best use of vaccine supply as it would force manufacturers to produce volumes at risk, could lead to wastage due to shelf life limitations and shortages in other countries in times of capacity constraint. Furthermore, the depreciation risk will increase making this kind of tender less attractive for manufacturers.
- **Adequate timelines**: The time between tender award and first delivery can be unrealistically short and lead to fewer/no bidders (the candidates not being able to fulfil the supply timeline) and, potentially, vaccination programme disruption. For multiple deliveries contracts, time between order and deliveries should be carefully defined considering volumes variation, shelf-life, etc.
- **Continuous interactions**: Changes in delivery quantity and timing should be discussed ahead of the planned vaccine introduction to allow for production planning and the opportunity for timely feedback.
- **Penalties**: Penalty systems can be counterproductive as producers might opt out of bidding if the business risk is unacceptable.
- **Reward services**: Manufacturers' support to effective implementation of NIP programs (e.g. via communication campaigns, education programmes, etc.) should be rewarded.
- Support vaccination infrastructure designed to ease access to vaccination for population and implement a vaccination coverage rate (VCR) tracking system to monitor implementation and which helps inform future demand and supply.

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Appendix 1
Legal / regulatory framework for public procurement in EU

Public procurement is regulated by the following legislation at EU level:

- Directive 2014/24/EU[v]. Replaced Directive 2004/18/EC. The Directive aims to ensure the public procurement is fair and open to all bidders across the EU and lays down EU rules for awarding contracts for public works, supplies and services. Describes the 'Innovation Partnership', which seeks to fill innovation gaps in the market, and ensures a fair public procurement process which is open to bidders from all EU[vi]
- Regulation (EU, Euratom) 2018/1046[vii]. Sets out operating principles and basic financial rules governing EU budget. Dictates that public procurement of all products should take one of the procedural forms outlined in EU Directive 2014/24/EU.

Award criteria of competitive procurement methods for publicly purchased commodities can either be based on the lowest price, or the "Most Economically Advantageous Tender (MEAT)"[viii].

- MEAT can be identified on the basis of weighted criteria such as: price or cost, performance, design, safety, quality assurance or conformity assessment; however, it should always include a price or cost element[ix].

References

[i] WHO; Global Alliance for Vaccines and Immunization (GAVI). Fact Sheet 169 Accessed October 2, 2017; Ehreth, J. The economics of vaccination from a global perspective: Present and future, Expert Rev Vaccines 2005. Wiccker, S, Maltezou HC. Vaccine-preventable diseases in Europe: Where do we stand? Expert Rev Vaccines 2014.
[ii] Olivier Ethgen, Vanessa Rémy & Katherine Wargo (2018) Vaccination budget in Europe: an update, Human Vaccines & Immunotherapeutics, 14:12, 2911-2915, DOI: 10.1080/21645515.2018.1504528.
[iii] PHE. Document no.2 - Terms of offer CM_PHV_12_5356 DTAP_IPV Plus HIB.
[iv] 2014 Directive on Public Procurement (Directive 2014/24/EU) aims to facilitate bidding for public contracts, will ensure the best value for money for public purchases whilst respecting the EU's principles of transparency and competition.
[v] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC Text with EEA relevance. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32014L0024.
[vi] EuropaBio. Buying Innovative. Available at: https://www.swissbiotech.org/sites/swissbiotech.org/files/news/files/buying_innovative_in_the_ealthcare_biotech_market_in_europe.pdf.
[vii] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012. Available at: https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:32018R1046.
[viii] Article 67. Directive 2004/18/EC.
[ix] Directive 2004/18/EC.