



EVM Reply to the Green Paper on the modernisation of EU public procurement policy - Towards a more efficient European Procurement Market

Introduction

The European Vaccine Manufacturers (EVM)¹ would like to welcome the Commission initiative on modernising the EU public procurement rules in Europe.

The vaccine industry: a strategic asset for Europe

The global vaccine industry is predominantly based in Europe; indeed, 90% of EVM members' vaccine production and 70% of their vaccine research projects take place in the EU, thus contributing to the region's competitiveness, science base and knowledge economy.²

A highly regulated sector

The vaccine industry is highly regulated. Before a new vaccine is approved for use, its quality, efficacy and safety are assessed by regulatory authorities. Under the centralised procedure, this assessment is performed by the European Medicines Agency. Once granted by the European Commission, a centralised marketing authorisation is valid in all EU and EEA-EFTA Member States. In addition, all vaccines are monitored after regulatory approval, both to ensure appropriate quality control and quality assurance, and to detect and monitor rare adverse events which may not have become apparent during the clinical trials development.

Structure of the vaccine market

The vaccine market is characterised by a relatively small number of suppliers: in some cases only two manufacturers are able to supply a given vaccine:

“Some analysts have concluded that the economic dynamics of the vaccine market preordain a small number of suppliers for any given product class. Although this “winner take all” dynamic does not guarantee a single, monopolistic supplier, there appears to be a general tendency for vaccine markets to drift toward one or few producers for a given product class because of the cost structure of vaccine production coupled with relatively low levels of demand for vaccine products.(...) If multiple members of the limited field of vaccine suppliers elect to produce

¹ EVM's member companies are Abbott Biologicals, AstraZeneca, Baxter, Crucell, GlaxoSmithKline Biologicals, MSD, Novartis Vaccines, Pfizer, sanofi pasteur and SPMSD. They are all major vaccine producers who together account for 70% of global vaccine production and 91% of vaccine revenues worldwide.

² Source of the data: Vaccines' contribution to Europe's future - March 2010 European Vaccine Manufacturers http://www.evm-vaccines.org/pdfs/H54302_EVM_bklt.pdf

substitutable vaccine products, price competition among firms with high start-up costs, high fixed costs, and relatively low variable costs will be fierce.”³

The use of public procurement for acquisition of vaccines in Europe

In some EU countries, public tenders are used by Member States for the acquisition of vaccines.⁴ However, vaccines should not be considered as a commodity. Indeed, authorities are not interested in the vaccines *per se*, but in their ability to provide health and protection against diseases for the entire population. Thus the acquisition of vaccines is motivated by a health policy objective. In addition, vaccines are highly technological biological products requiring a very specific production process and know-how, both of which may vary from one vaccine to another. In turn, vaccines which target the same disease may have different properties, including different antigens, adjuvants and/or design which result in differences in their scope, efficacy and effectiveness. In some cases, it may not be possible to consider them as interchangeable, even though they target the same disease. For all these reasons, the acquisition of vaccines involves specific considerations which do not apply to the acquisition of commodities in general.

As the acquisition of vaccines is governed by EU public procurement rules, those rules have an impact on the effectiveness of vaccination policies, patients' access to vaccination and, ultimately, public health. The EVM strongly believes that the modernisation of EU procurement rules should ensure that:

- Member States can acquire vaccines which fulfil their public health objectives and the needs of the population;
- The procurement rules reward the value of new vaccines appropriately, to maintain strong incentives for vaccine manufacturers to innovate and deliver new vaccines; with important public health and individual benefits
- The rules do not compromise the sustainability of the vaccine sector or vaccine supply, which would be detrimental to public health
- The award criteria should not lead to discretion or discrimination by the tendering authorities, and wherever possible, they should be applied uniformly throughout the EU.

In line with these general comments, the EVM would like to give the Commission its views on some questions of the Green Paper which are specifically relevant to vaccines. Please note that for simplification purposes, in some cases this reply regroups interrelated questions together.

Detailed Comments

Question 15 on “(...) guaranteeing that contracting authorities obtain best value for money” and Question 70 on “Using the most appropriate award criteria”

³ Salinsky E, Werble C. The vaccine industry: does it need a shot in the arm? National Health Policy Forum Background Paper. 25 January 2006: 12. National Health Policy Forum website: <http://www.nhpf.org/library/details.cfm/2506>

⁴ ÖBIG Report on Tendering of Pharmaceuticals in EU Member States commissioned by the Commission in the context of the High Level Pharmaceutical Forum: http://ppri.oebig.at/Downloads/Publications/Final_Report_Tendering_June_08.pdf.

The EVM considers that the “lowest price” awarding criterion in the current directive is inappropriate for the acquisition of vaccines, and that the awarding criterion for tender should instead be “the most economically advantageous”, for the following reasons.

- As explained above, vaccines should not be considered as normal commodities. They play a key role in ensuring the health of the population. From that perspective, the acquisition of vaccines should be motivated by health outcomes and benefits for the population, rather than driven by cost-containment objectives.
- Vaccines are high-technology products requiring a significant amount of time and investment in R&D activities. That being so, the criterion of “the lowest price” constitutes a disincentive for R&D investment in new vaccines. This seems to contradict the Europe 2020 strategy call “to improve framework conditions for business to innovate”. The Green Paper also stresses the strategic use of procurement for other objectives. The promotion of public health and innovation certainly qualify as strategic objectives, so it is essential that the procurement rules should encourage innovation in health. As stated in the Green Paper, the “most economically advantageous” criterion seems to be best suited for pursuing these policy objectives.
- Finally the “lowest price” criterion is only relevant to products which are totally interchangeable. As explained above, this is unlikely to be the case for vaccines. The EVM recommends that public procurement/tenders should be designed to favour the most cost-effective vaccine rather than the cheapest one, which may ultimately not offer the best health outcomes. In addition, the authorities should assess the cost-effectiveness of a vaccine from a broad perspective, including its benefits to society and budgetary impact.

Questions 19, 20, 21 on “more negotiations” and question 62: “Do you consider that the rules on technical specifications make sufficient allowance for the introduction of considerations related to other policy objectives technical specifications”

The EVM considers that it would be helpful if the EU procurement rules allowed structured negotiations

- Vaccines are high-technology products with limited interchangeability and a potentially varying impact in terms of health outcome. Their acquisition therefore constitutes a highly technical and complex topic, which requires specialist procurement expertise.
- For this reason, it would be valuable to allow structured negotiations, to ensure that potential bidders and procurers discuss the tender specifications openly prior to publication so that the authorities may fully understand the different solutions available. In addition, the EVM would like to propose that this dialogue between bidders and procurers should continue after the specifications are published.

Questions 34, 35, 36, 37, 38 on “appropriate tools for aggregation of demand / Joint procurement”

The EVM would like to express some concerns regarding aggregation of demand for vaccines between Member States.

- The epidemiology of infectious diseases and the expected impact of vaccination vary between countries, due to factors such as differences between national health care systems, alternative preventive measures in place and national or regional epidemiology. This leads to differences between national vaccination programmes and strategies in the Member States, and hence their needs in terms of acquisition of vaccines (volume, duration, choice of product, etc.) inevitably differ. Consequently, the aggregation of demand between Member States seems irrelevant and inappropriate for the implementation of national vaccination policies.
- The concentration of demand might have a negative impact on competition and on the sustainability of vaccine supply. On the supply side, the vaccine market is characterised by high fixed costs and (relatively) lower variable costs, so it is important for vaccine manufacturers to reach a certain level of production in order to recoup their initial R&D investment. On the demand side, the market is characterised by relatively low and inelastic demand. In addition, in markets functioning by public procurement, a supplier who loses a public bid thereby loses all or nearly all access to the market for the duration of the tender (generally many years). The decrease in demand resulting from this exclusion may push a supplier below the level of production necessary to sustain the high fixed costs of continued production. The aggregation of demand could potentially magnify these elements and drive some suppliers completely out of the market. Thus the concentration of demand is likely to increase the risks inherent in the vaccines business and endanger the sector's sustainability.
- The acquisition of vaccines relates to the management of national health systems, which is a national competence under the Treaty. That being so, the aggregation of demand between Member States is questionable.

Question 43 on “changes concerning the contractor and termination of contracts”

The EVM considers that it would be useful for the Commission to consider methods of protecting suppliers from abusive and unilateral termination of contracts.

- Vaccine production lead-times are quite long, meaning that investments to produce significant quantities over a long period cannot be compensated if the contract is ended at short notice.
- To protect bidders against abusive terminations **in the private sector**, French law (article L.442-6-1-5° of the *Code de Commerce*) requires the other party to respect a "sufficient notice period" which may be longer than the contractual notice period. This sufficient notice period gives the bidders sufficient time to find economic solutions to compensate for the loss of the contract. Bidders do not enjoy similar legal protection when dealing with public entities. The EVM considers that it would be extremely useful if the Commission would consider regulating this kind of aspects at European level.

Questions 53, 54, 55, 58, 60, 61 on the “promotion of competition in market with limited competition”

- As noted above, vaccine markets are characterised by a limited number of suppliers, but also by fierce competition.
- Considering the importance of vaccines for public health, it is essential that the promotion of competition does not compromise the public health

objectives of vaccination programmes. In this context, some proposals in the Green Paper seem highly inappropriate for the vaccine sector. For instance, the possibility of including less demanding criteria could put the quality of bids at risk.

- In addition, it is worth noting that EU competition law already provides for clear principles to ensure that exclusive supply agreements do not disrupt competition. Those principles should be part of any public procurement procedures likely to favour the concentration of suppliers.
- There are some systems which help to encourage competition while also respecting the specificities of acquiring vaccines. For instance, in Canada the authorities can in some cases use “dual awards” or “split tenders” which enable the tender to be awarded to two manufacturers at two different prices. How the tender is split depends on price and/or product differences. This process encourages competition to secure vaccine supply by multiplying the number of suppliers. In addition, by allowing price differences between two suppliers, it takes into account the limited interchangeability of the two vaccines. However, as noted above, in some cases, vaccines cannot be considered as interchangeable at all, even though they target the same disease. Therefore, this system might therefore not be applicable to all vaccines. In addition, even using such a system, tenders should be designed to take into account the cost-effectiveness of the products, including their broader benefits to the society and should not focus solely on cost-containment.

Questions 111 and 112 on “access of third countries suppliers to the EU Market”

EVM considers that the EU procurement market should not offer our international partners more favourable treatment than the conditions laid down under the WTO GPA.

Questions 113 on “any other issues”

Finally, the EVM is also concerned about the requests introduced in some Member States for compulsory contingency stocks. These stocks, which may represent a considerable percentage of the overall purchase, must be produced and stored by manufacturers. They are only used and paid for by authorities if the situation requires it, meaning that manufacturers are forced to bear the entire risk for the production and use of these contingency stocks. The EVM understands the rationale behind contingency stocks, especially in the case of an unforeseen emergency. However, the use of this system should also take into account the negative impact it may have.

- Compulsory contingency stocks may mobilise manufacturers’ capacities unnecessarily, which constitutes an inefficient use of resources.
- Mobilising manufacturers’ capacities might put them in a position where they cannot supply demands from other Member States. This would adversely affect access to vaccination and therefore be detrimental to public health

The EVM would like to urge that this system should be used carefully and reasonably.