Implementation of Directive 2014/24/EC on public procurement in the EU healthcare sector

AmCham EU calls for a more strategic use of procurement to stimulate innovation uptake

POSITION PAPER

Executive summary

In an effort to contribute to the ongoing policy discussions on public procurement at the European and national levels, AmCham EU has run a consultation among its members to better understand some of the challenges associated with the current procurement of healthcare goods and services in EU Member States. This paper outlines the survey findings and provides recommendations to ensure that future procurement practices facilitate innovation uptake and better serve consumers. These recommendations include achieving better outcomes for healthcare systems and patients, fostering competition and long-term sustainability of supply and placing emphasis on importance and benefits of innovative goods and services.

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AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled €2 trillion in 2014 and directly supports more than 4.3 million jobs in Europe.

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Introduction

Public procurement accounts for approximately 20% of the European Union (EU)'s gross domestic product (GDP) across sectors.[1] It is often regarded as one of the most effective market-based instruments to achieve smart, sustainable, and inclusive growth in Europe. [2]

Public procurement can play a significant role in achieving the objectives laid out in the EU health strategy, which include fostering good health in an ageing Europe; protecting citizens from health threats; and supporting dynamic health systems and new technologies.[3]

Over the past decade, the proportion of healthcare products acquired through public procurement has gradually increased. According to a report entitled 'Tender systems for outpatient pharmaceuticals in the European Union' prepared for the European Commission, procurement by tendering can easily be used for up to 25% of medicines in a hospital setting.[4] In France, 60% of medical product purchases are made by state-run hospitals. Each year, 1,100 French public hospitals buy more than €3 billion worth of medical equipment and €4 billion worth of disposable supplies.[5] In 2012, a study conducted for Eucomed placed public procurement as the second most important driver for innovation right after reimbursement and funding.[6] Suppliers rely on contracting authorities to apply the procurement rules in a correct and fair manner so as to ensure that the most competitive and innovative offerings are selected.

Recently, European national authorities' interest in joint procurement has translated into the creation of a European facility for the joint procurement of medical countermeasures in the context of cross-border health threats (i.e. communicable diseases).[7] For other non-communicable diseases, the revision of the general rules on public procurement in the EU[8] has clarified the possibility for EU national public authorities to engage in multinational or joint procurement including for pharmaceuticals. For example, the revised legislation explains that: 'Several contracting authorities

[1] http://ec.europa.eu/growth/industry/innovation/policy/public-procurement/index_en.htm
[2] http://ec.europa.eu/growth/industry/innovation/policy/public-procurement/index_en.htm
[3] http://ec.europa.eu/health/strategy/objectives/index_en.htm
[4] p. 9 Tender systems for outpatient pharmaceuticals in the European Union: Evidence from the Netherlands, Germany and Belgium, Panos Kanavos, Liz Seeley and Sotiri Vandoros LSE Health, London School of Economics, October 2009. This document has been prepared in the framework of a service contract with the European Commission (Directorate -General for Enterprise and Industry);
http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/study_pricing_2007/tendering_systems_en.pdf
[5] EMDT: Hospital Procurement: The Importance of "Buying French", http://www.emdt.co.uk/daily-buzz/hospital-purchasing-importance-buying-french
[6] Eucomed: Centralized Public Procurement, Decision Makers, Tenders and Innovation;
http://www.eucomed.org/uploads/_mediacentre/blog/20120328_procurement/20120309_simonkucher_procurement_innovation.pdfhttp://www.eucomed.org/uploads/_mediacentre/blog/20120328_procurement/20120309_simonkucher_procurement_innovation.pdf
[7] EU Decision 1082/2013/EU (22 October 2013). Medical countermeasures are defined as any medicine, medical device, other goods or services that are aimed at combating serious cross-border health threats.
[8] Directive 2014/24/EU of 26 February 2014. In February 2014, the EU adopted a legislative package for the modernization of public procurement, which included a revision of the EU Directive on public procurement (Directive 2004/18/EC). Directive 2014/24/EU of the European Parliament and Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC is of particular relevance for healthcare products. The new rules on entered into force on the 17 April 2014. EU Member States have to implement them by 18 April 2016. They have a direct impact on the way healthcare products are procured in the EU.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32014L0024

from different Member States may jointly award a public contract, conclude a framework agreement or operate a dynamic purchasing system'.[9]

Some Member States have expressed an interest in learning more about the potential benefits associated with joint negotiations for the acquisition of pharmaceuticals. In 2015, the Health Ministers of Belgium and the Netherlands announced that they had agreed to negotiate jointly with the pharmaceutical industry for the reimbursement of certain medicines.[10]

In an effort to contribute to the ongoing policy discussions on public procurement at the European and national levels, the American Chamber of Commerce to the European Union (AmCham EU) has run a consultation among its members to better understand some of the challenges associated with the current procurement of healthcare goods and services in EU Member States. This paper outlines the survey findings and provides recommendations to ensure that future procurement practices facilitate innovation uptake and better serve consumers.

Consultation responses

Our members' responses focused on two main elements: a) award criteria, and b) tender terms, processes and administrative burden.

Award criteria

Challenges associated with award criteria in procurement received the highest level of attention amongst member companies. The new criterion of the 'most economically advantageous tender' (MEAT) in the award procedure as laid out in Article 67 of Directive 2014/24/EU should lead contracting authorities to put more emphasis on quality, innovation and life-cycle costs relative to price (as opposed to price only).[11] Contrary to the spirit of Public Procurement Directive 2014/24/EU

[9] Article 39 of 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;
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32014L0024

[10] http://www.deblock.belgium.be/fr/remboursement-des-m%C3%A9dicaments-orphelins-les-pays-bas-et-la-belgique-n%C3%A9gocient-ensemble-avec-le

[11] Public Procurement Directive 2014/24/EU, Article 67 - Contract award criteria
1. Without prejudice to national laws, regulations or administrative provisions concerning the price of certain supplies or the remuneration of certain services, contracting authorities shall base the award of public contracts on the most economically advantageous tender.
2. The most economically advantageous tender from the point of view of the contracting authority shall be identified on the basis of the price or cost, using a cost-effectiveness approach, such as life-cycle costing in accordance with Article 68, and may include the best price-quality ratio, which shall be assessed on the basis of criteria, including qualitative, environmental and/or social aspects, linked to the subject-matter of the public contract in question. Such criteria may comprise, for instance:
(a) quality, including technical merit, aesthetic and functional characteristics, accessibility, design for all users, social, environmental and innovative characteristics and trading and its conditions;
(b) organisation, qualification and experience of staff assigned to performing the contract, where the quality of the staff assigned can have a significant impact on the level of performance of the contract; or
(c) after-sales service and technical assistance, delivery conditions such as delivery date, delivery process and delivery period or period of completion.
The cost element may also take the form of a fixed price or cost on the basis of which economic operators will compete on quality criteria only.
Member States may provide that contracting authorities may not use price only or cost only as the sole award criterion or restrict their use to certain categories of contracting authorities or certain types of contracts.

and in particular Article 67, members felt that, by and large, award criteria were still heavily price-based and very often price was the only criteria considered in the award decision. Other criteria, such as technical characteristics, ease of use for patients and healthcare professionals, healthcare professional training in local language, customer service, product support, productivity gains and supply chain assessment (including a manufacturer's ability to supply and prevent shortages), were often not taken into consideration. Ultimately, this can lead to a situation where the most competitive offerings are not selected, to the detriment of contracting authorities, health systems and patients.

Members pointed to the use of 'price-only tenders' for medical devices. When price-only tenders occur, renewal will start from the lowest price seen in the previous contract, thereby making it very difficult for new, innovative products to compete. In addition, despite ongoing healthcare reforms and greater emphasis on value-based healthcare (better outcome combined to a lower cost of care delivery) in the Member States, tenders are often structured in such a way that they do not reward products which demonstrate greater value (e.g. reduction of the number of patient complications and of length of stay in hospital).

In addition, price-only tenders appear to be in contradiction to the spirit of the green public procurement criteria for electrical and electronic equipment in the healthcare sector. In 2014, the Commission has adopted the criteria for Green Public Procurement of Electrical and Electronic Devices in the Healthcare sector. Today, these criteria do not seem to be implemented by the national procurement authorities in a systematic manner. Without additional incentives and more comprehensive programs to transform national procurement regimes, there will be little change in the way that national authorities execute their purchasing decisions.

For pharmaceuticals, members pointed to the use of winner-take-all tenders even for medicines, which are not regarded as interchangeable by national medicine agencies. Such tenders can disrupt treatment continuity as products may disappear from hospital pharmacy formularies and, consequently, prescribing physicians will be constrained to switching patients onto a new medicine even if patients were successfully stabilised with a previous treatment.

In addition, winner-take-all tenders limit a hospital's ability to avoid or mitigate shortages of medicines since a hospital would be relying on one product and one manufacturer only to address a specific need. Winner-take-all tenders will lead the companies that have lost the tender to stop supplying. Should a shortage occur with the product selected through the tender (due to delays, product quality issues, recalls or raw material shortages), patients would no longer have access to their

3. Award criteria shall be considered to be linked to the subject-matter of the public contract where they relate to the works, supplies or services to be provided under that contract in any respect and at any stage of their life cycle, including factors involved in:
(a)the specific process of production, provision or trading of those works, supplies or services; or
(b) a specific process for another stage of their life cycle even where such factors do not form part of their material substance.
4. Award criteria shall not have the effect of conferring an unrestricted freedom of choice on the contracting authority. They shall ensure the possibility of effective competition and shall be accompanied by specifications that allow the information provided by the tenderers to be effectively verified in order to assess how well the tenders meet the award criteria. In case of doubt, contracting authorities shall verify effectively the accuracy of the information and proof provided by the tenderers.
5. The contracting authority shall specify, in the procurement documents, the relative weighting which it gives to each of the criteria chosen to determine the most economically advantageous tender, except where this is identified on the basis of price alone.
Those weightings may be expressed by providing for a range with an appropriate maximum spread.
Where weighting is not possible for objective reasons, the contracting authority shall indicate the criteria in decreasing order of importance.

treatment. And, it could take a number of weeks for other companies to fill the gap. Shortages are unfortunately a common issue for hospital pharmacists. According to a report issued by the European Association of Hospital Pharmacists (EAHP) in 2014, over 86% of hospital pharmacists experience difficulties in sourcing medicines with 66% reporting this as a daily or weekly problem.[12] The top affected areas are medicines to fight infection, cancer drugs and anesthetics.

European Biopharmaceutical Enterprises (EBE) has highlighted the complexities of designing and conducting tenders for biologic medicines and proposed that procurement practices for biologic medicines should consider the following elements: [13]

- Contain a variety of selection criteria (including services, devices, manufacturing excellence) and not only price (based on the drug/treatment under consideration and adjusted over time);
- Provide for a sufficiently broad choice of products (i.e. instead of a single medicine, a variety of biological medicines should be available for patients);
- Include an independent scientific committee in the decision-making process (ideally with the participation of physicians and patients in addition to pharmacists), and respect and safeguard the autonomy of clinical choice;
- Allow continuation of treatment (i.e. any decision to switch remains a clinical decision for the treating physician); and
- Recognise whether the medicine is still under patent, in order to make note for future innovation in new treatments.

EuropaBio also shared some insights on the procurement of biological medicines in a recent study.[14]

Tender terms, processes and administrative requirements

In many countries, there is little consistency in the way tenders are managed across procurement authorities. Procedures are complex and pressure on healthcare budgets is leading to placing more frequent and smaller orders often with shorter timelines.

For the same product, assessment criteria used by technical committees will vary across procurement authorities. Ultimately, purchasing decisions are driven by a procurement management committee, which often does not include or take into account the needs of healthcare practitioners (e.g. physicians, surgeons, nurses) or patients.

In addition, some contracting authorities are arranging increasingly wide tenders, for which suppliers will be unable to meet the full requirements of the contracting authority on their own. Suppliers need to bid in consortium. This adds complexity and cost to the suppliers, and can raise compliance concerns. Wide tenders appear to be going against the spirit of the new public procurement framework, according to which wider tenders should be discouraged so as to enable small and medium enterprises (SMEs) - with narrower product and service offerings - to participate in tenders.

Recommendations

[12] http://www.eahp.eu/press-room/patients-suffering-medicines-shortages-all-european-countries
[13] Op cit at (3).
[14] http://www.europabio.org/sites/default/files/europabio_white_paper_on_public_procurement_of_biological_medicines_final.pdf

One of the goals set by the Commission is to 'improve public procurement practices, promote the demand of innovative goods and services in Europe, and foster the uptake of innovation in the EU.'[15] Considering the growing interest in the public procurement of healthcare products at European and national level, and in light of the EU innovation strategy, AmCham EU has outlined the following recommendations for European policymakers:

- **Achieve better outcomes for healthcare systems and patients:** Whenever possible, procurement by tendering should allow health services to make the best decisions for patients and for health systems. Price might not always be the most meaningful award criterion. An optimal price-quality ratio rewarding valuable innovation should be ensured.

- **Foster competition and long-term sustainability of supply:** Losing a tender in several markets can mean that one or more suppliers will be excluded from those markets for a long period of time. These suppliers may decide to stop making the necessary investments to sustain production and supply in certain markets.

- **Place emphasis on importance and benefits of innovative goods and services:** Award criteria should go beyond price and recognise the added value innovative products bring to patients and health systems in Europe.

Conclusion

When innovation is not facilitated, hospitals and health systems are deprived of potential efficiency gains, greater effectiveness, productivity, and ultimately, better health outcomes for patients.

In view of ongoing discussions around public procurement and in particular the implementation of the revised European public procurement legislation, AmCham EU invites relevant European institutions and the Member States to consider the challenges current procurement practices pose to innovation uptake in Europe.

AmCham EU would welcome the opportunity to exchange views on best practice in the procurement of healthcare products. In addition, in light of Europe's innovation strategy, it invites European institutions to consider developing guidance for European hospitals on the implementation of the revised public procurement legislation. Sector-specific guidance should be developed in collaboration with relevant stakeholders to guarantee the uptake of value-based procurement. Initiatives, such as the methodology for the Most Economically Advantageous Tenders, currently being developed by MedTech Europe[16], could be leveraged and promoted by the Commission. The Commission could also consider the potential value of commissioning a report assessing the impact of procurement practices on innovation and access to healthcare across the EU.

Members of AmCham EU are convinced that, in many instances, a more strategic assessment of 'value for money' can be achieved to stimulate investment in innovation and foster effective, resilient and accessible health systems in Europe.

[15] http://ec.europa.eu/growth/industry/innovation/policy/public-procurement/index_en.htm
[16] Expected to be finalised and published by the end of 2015