How can voluntary cross-border collaboration in public procurement improve access to health technologies in Europe?

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Challenges and opportunities in improving access to medicines through efficient public procurement in WHO European Region
Content

• Policy Question
• Background information and clarifications
• European Legislation and experiences
• Key messages
“How can voluntary cross-border collaboration in public procurement improve access to health technologies in Europe?”

More specifically, the following issues are addressed:

1. What conditions are needed to make cross-border collaboration in procurement work?
2. For what types of health technology and types of activity would cross-border collaboration be most appropriate?
3. How can voluntary cross-border collaboration in procurement be supported by the EU?
Traditional procurement mechanisms

- **Open tender**: bids are invited from any supplier, subject to the terms and conditions specified in the tender document. All suppliers interested in the tender may bid.

- **Restricted tender**: interested suppliers need to be approved in advance, for example, through a formal pre-qualification process that takes into account adherence to good manufacturing practices, previous performance, financial viability, etc. The process of pre-qualification is often open to any supplier. A reverse auction is a 2-step variation of a restricted tender. In a reverse auction, the lowest priced offer is published without naming the bidder and qualified bidders are invited to submit lower offers. The process continues until no more offers are made. This procurement method has been seldom used for medicines.

- **Competitive negotiation**: the buyer invites a preselected number of suppliers to submit price offers; negotiation may follow to achieve a better price or particular service arrangements. International or local shopping is based on the same principle but negotiation is not permitted.

- **Direct procurement**: technologies (e.g. single-source products) are obtained at list prices or negotiated prices from a single supplier. In general, single-source products may be procured either via negotiated procurement, direct procurement or tendering of the single-source product and therapeutic substitutes, so as to create a competitive environment.
Figure 2: Levels of collaboration in procurement

- Central contracting and purchasing:
  Joint tenders and contract award through a centralized body on behalf of participating countries.

- Group contracting:
  Joint price negotiation and supplier selection. Participating countries agree to purchase from selected suppliers.

- Coordinated informed buying:
  Joint market research, sharing supplier performance information and monitoring prices.

- Informed buying:
  Participating countries share information about prices and suppliers.

Information sharing → Pooled procurement

Source: Adapted from [1].
Review

The logical underpinnings and benefits of pooled pharmaceutical procurement: A pragmatic role for our public institutions?

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- Reductions in unit purchase prices as distinguished from total costs
- Improved quality assurance through preventive measures
- Reduction or elimination of corruption in procurement
- Rationalized choice through better-informed selection and standardization

- Reduction of operational costs and administrative burden
- Creation of a professional network and increased equity between members
- Improvements in other aspects of supply chain management
- Strengthened role of the host organization
- Improved supply of commodities to populations in need
Facilitators and barriers

- **strong political commitment**
- trust between collaborating parties
- good governance that helps curb opportunistic tendencies that could erode the value of the procurement process
- **price transparency**
- market analysis
- effective communication between internal and external stakeholders
- efficient financial management, including prompt payment of purchases made
- continuity through multi-year contracting that enables stable supply sources and fosters closer ties between participants
- **clarity on management responsibilities for the joint procurement process** and their remuneration
- **sharing of information and good practices**
- ongoing commitment to honour
Earlier international experiences outside Europe on cross border joint procurement

Some experiences but probably biased evidence on impacts and success
Changes in the health technology markets

• Increase in **Intellectual Property (IP)** protected share of the market (monopolisation)

• **Less scope for tendering** probably due to *increasing role of direct negotiation* (Risk Sharing Agreements, Managed Entry Agreement, Patients Entry Schemes) and confidential pricing = lack of price transparency

• **New procurement tools**: horizon scanning, HTA, competition policies, value based pricing, IP management, market analysis, innovative procurement, innovation-inducing procurement,...
Key components and conditioning factors of the procurement process

- Needs definition and horizon scanning
- Quantification of needs
- Prioritization and selection
- Reimbursement status
- Supply of technologies
- Technology
- R&D
- Market authorization
- Price regulation
- IPR protection
- Purchasing options
- Direct purchasing
- Negotiation
- Tenders
- Price, quantity and other terms of the contract
- Payment
- Distribution
- Monitoring and evaluation
European Legislation enabling cross-border collaboration in procurement (I)

Directive 2014/24/EU on public procurement

**Article 39** explicitly allows for contracting authorities from different Member States to act jointly in the award of public contracts. Directive helps to **clarify** the **applicable national law and responsibilities** of the different parties involved.

<table>
<thead>
<tr>
<th>One Purchasing body</th>
<th>Joint Contract different MS</th>
<th>Joint National Entity under EU or national law</th>
</tr>
</thead>
<tbody>
<tr>
<td>National rules of the MS where central purchasing body is located</td>
<td>Framework agreement / dynamic purchasing system about the responsibilities</td>
<td>Agreement on which national procurement rules apply</td>
</tr>
</tbody>
</table>
European Legislation (II)

- **Decision No. 1082/2013/EU of 22 October 2013 on serious cross-border threats to health (and repealing Decision No 2119/98/EC),** which provides for EU action to complement national policies for combating serious cross-border threats to health. This decision **not only** extended the scope for action to also **cover serious cross-border health threats** beyond communicable diseases (e.g. biological or chemical agents or environmental events), it also widened the **coordination mechanisms to address health security crises** at an EU level.

- It includes the possibility for Member States to engage on a **voluntary basis in a joint procedure to procure medical countermeasures** (Article 5). By September 2016, the Joint Procurement Agreement (JPA), specifying the joint procurement procedure and its governance, had been signed by 24 Member States.

*Health policies are MS responsibilities, but according to Article 168(2) TFEU, EU has the obligation to promote cooperation between Member States in the field of health.*
European experiences of cross-border collaboration in procurement of health technologies

<table>
<thead>
<tr>
<th>Name of collaboration</th>
<th>Start date</th>
<th>Countries involved</th>
<th>Scope</th>
<th>Aspects of procurement covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central Eastern European and South Eastern European Countries Initiative</td>
<td>November 2016</td>
<td>Romania, Bulgaria, Croatia, Latvia, Poland, Serbia, Slovakia, Slovenia, Republic of Moldova, FYR Macedonia</td>
<td>Pharmaceuticals</td>
<td>Price negotiation</td>
</tr>
<tr>
<td>Southern European Initiative</td>
<td>June 2016</td>
<td>Greece, Bulgaria, Spain, Cyprus, Malta, Italy, Portugal</td>
<td>Innovative medicines</td>
<td>Information sharing on prices and markets, collaboration on R&amp;D</td>
</tr>
<tr>
<td>Declaration of Sofia</td>
<td>June 2016</td>
<td>Bulgaria, Croatia, Estonia, Hungary, Latvia, FYR Macedonia, Romania, Serbia, Slovakia, Slovenia</td>
<td>Pharmaceuticals</td>
<td>Information sharing on prices and markets, with potential for joint purchasing in the future</td>
</tr>
<tr>
<td>Nordic Pharmaceuticals Forum</td>
<td>June 2015</td>
<td>Denmark, Iceland, Norway, Sweden</td>
<td>Innovative medicines</td>
<td>Horizon scanning, information sharing on prices and markets</td>
</tr>
<tr>
<td>Romanian and Bulgarian Initiative</td>
<td>June 2015</td>
<td>Romania, Bulgaria</td>
<td>Pharmaceuticals</td>
<td>Joint negotiations in purchasing to get lower prices for pharmaceuticals and cross-border exchange of medicines in short supply to ensure continuity of access</td>
</tr>
<tr>
<td>BeNeLuxA</td>
<td>April 2015</td>
<td>Belgium, Netherlands, Luxembourg, Austria</td>
<td>Innovative medicines</td>
<td>HTA, horizon scanning, information sharing on prices and markets, joint negotiation for purchasing to ensure affordability (see Box 3)</td>
</tr>
<tr>
<td>Baltic Partnership Agreement</td>
<td>May 2012</td>
<td>Latvia, Lithuania, Estonia</td>
<td>Pharmaceuticals and medical devices</td>
<td>Centralized joint purchasing (tenders, negotiation, payment and distribution) to reduce expenditure and ensure continuity of access (see Box 3)</td>
</tr>
</tbody>
</table>
Potential gains of collaboration in specific procurement-related activities

<table>
<thead>
<tr>
<th>Activity</th>
<th>Potential gain from cross-border collaboration</th>
</tr>
</thead>
</table>
| Horizon scanning (also known as early awareness and alert systems, early warning systems): aims to identify, filter and prioritize new and emerging health technologies (and to assess or predict their impact on health, costs, society and the health care system; to inform decision-makers [28]) | High  
Health technology is at present a global market, where suppliers offer the majority of new products almost simultaneously worldwide to all countries where they can expect to make profit. Collaborative initiatives in this area could build on the experience of EuroScan. Established in 1997, the EuroScan International Network comprises 14 member countries (November 2016) who work together to achieve the Network’s goals [29]. |
| Needs assessment                              | Limited  
Requires data collection at country level. Advantages of collaboration would probably be restricted to the use of a common methodology, although this use might be constrained by the different characteristics and format of the data available in each country. As a result, potential efficiency gains are questionable. |
| Health technology assessment                  | Partial  
Some aspects of the HTA process may be easier to harmonize, namely the assessment of scientific evidence on effectiveness, safety etc. More context specific elements, such as organizational and economic consideration, may require a more country-specific approach (see also Box 6). |
| Economic evaluation (mainly seen as part of HTA but often carried out by different agencies) | Limited  
While multinational companies usually develop a core model for economic analysis, based on all available clinical evidence, and then customize it at a second stage to fit individual country models, collaboration on the purchaser side may be inefficient as cost and budget impact parameters may differ substantially between countries. |
| Prioritization and selection – defining reimbursement status and quantification of needs | Partial  
Although part of the forecasting and planning exercise, i.e. assessing the supply of new products, can be done centrally, the specific products and volumes to be purchased by each partner and consequent budgetary requirements needs to relate specifically to the local context (population, epidemiology, resources available and priorities), so there is little to gain from collaboration apart from the chance to share methodologies. |
| Purchasing and contracting                    | Limited  
Despite the numerous difficulties countries are likely to encounter (divergent national regulations and purchasing practices, price intransparency, etc.), this is the frequent focus of collaboration, on the understanding that if purchasers are able to collaborate in pooling their demands, they will not only improve their levels of information but also gain market power and negotiating capacity. In practice, in the current market and regulatory environment, this potential has been hard to realize to date. |
Key Messages (I)

• There is a growing interest in further developing cross-border collaboration in the field of health, both at a bilateral and a multilateral level. This is supported by European Union (EU) legislation and policies, and extends to improving access to health technologies.

• There is a clear rationale for increased voluntary collaboration between countries in the procurement of health technologies:
  ▪ to enhance transparency through better information sharing
  ▪ to enable cross-country learning by sharing experience
  ▪ to strengthen bargaining power and mitigate overly high transaction costs by pooling skills, capacities and through joint negotiations
  ▪ to ensure sustainable access to health technologies by sharing resources through cross-border exchange of products in short supply.

But also factors against it, e.g. big/wealthy countries may find more convenient to procure independently as they might get better conditions than under pooled procurement.
Key Messages (II)

• However, in practice, developing sustainable cross-border collaboration in procurement seems to be challenging. Experiences in Europe are still limited and too recent to really allow clear lessons to be drawn about their effectiveness and impact.

• Nevertheless, it is clear that related initiatives would require strong political commitment and mutual trust between purchasing partners in order to succeed. It is therefore advisable that they be built progressively, starting with collaboration in information sharing and knowledge exchange, before moving towards joint purchasing activities.
Thanks for your attention

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