

POLICY BRIEF 21

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

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This policy brief is one of a new series to meet the needs of policy-makers and health system managers. The aim is to develop key messages to support evidence-informed policy-making and the editors will continue to strengthen the series by working with authors to improve the consideration given to policy options and implementation.

### **What is a Policy Brief?**

A policy brief is a short publication specifically designed to provide policy-makers with evidence on a policy question or priority. Policy briefs:

- Bring together existing evidence and present it in an accessible format
- Use systematic methods and make these transparent so that users can have confidence in the material
- Tailor the way evidence is identified and synthesised to reflect the nature of the policy question and the evidence available
- Are underpinned by a formal and rigorous open peer review process to ensure the independence of the evidence presented.

Each brief has a one page key messages section; a two page executive summary giving a succinct overview of the findings; and a 20 page review setting out the evidence. The idea is to provide instant access to key information and additional detail for those involved in drafting, informing or advising on the policy issue.

Policy briefs provide evidence for policy-makers not policy advice. They do not seek to explain or advocate a policy position but to set out clearly what is known about it. They may outline the evidence on different prospective policy options and on implementation issues, but they do not promote a particular option or act as a manual for implementation.

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

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## ACRONYMS

<b>EMA</b>	European Medicines Agency
<b>EPSCO</b>	Employment, Social Policy, Health and Consumer Affairs Council
<b>ERN</b>	European reference network
<b>ESIP</b>	European Social Insurance Partners
<b>EU</b>	European Union
<b>EUnetHTA</b>	European network for Health Technology Assessment
<b>GDP</b>	gross domestic product
<b>HTA</b>	health technology assessment
<b>ICT</b>	information and communications technology
<b>IPR</b>	intellectual property rights
<b>IT</b>	information technology
<b>JPA</b>	Joint Procurement Agreement
<b>MEA</b>	managed entry agreements
<b>MEDEV</b>	Medicine Evaluation Committee
<b>MoCA</b>	Method of Coordinated Access to Orphan medicinal products
<b>PAHO</b>	Pan American Health Organization
<b>PCP</b>	pre-commercial procurement
<b>R&amp;D</b>	research and development
<b>SME</b>	small- and medium-sized enterprises
<b>TFEU</b>	Treaty on the Functioning of the European Union
<b>TRIPS</b>	Trade-Related Aspects of Intellectual Property Rights
<b>UNICEF</b>	United Nations Children's Fund
<b>WHO</b>	World Health Organization

## BOXES, FIGURES AND TABLES

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**How do Policy Briefs bring the evidence together?**

There is no one single way of collecting evidence to inform policy-making. Different approaches are appropriate for different policy issues so the Observatory briefs draw on a mix of methodologies (see Figure A) and explain transparently the different methods used and how they have been combined. This allows users to understand the nature and limits of the evidence.

There are two main ‘categories’ of briefs that can be distinguished by method and further ‘sub-sets’ of briefs that can be mapped along a spectrum:

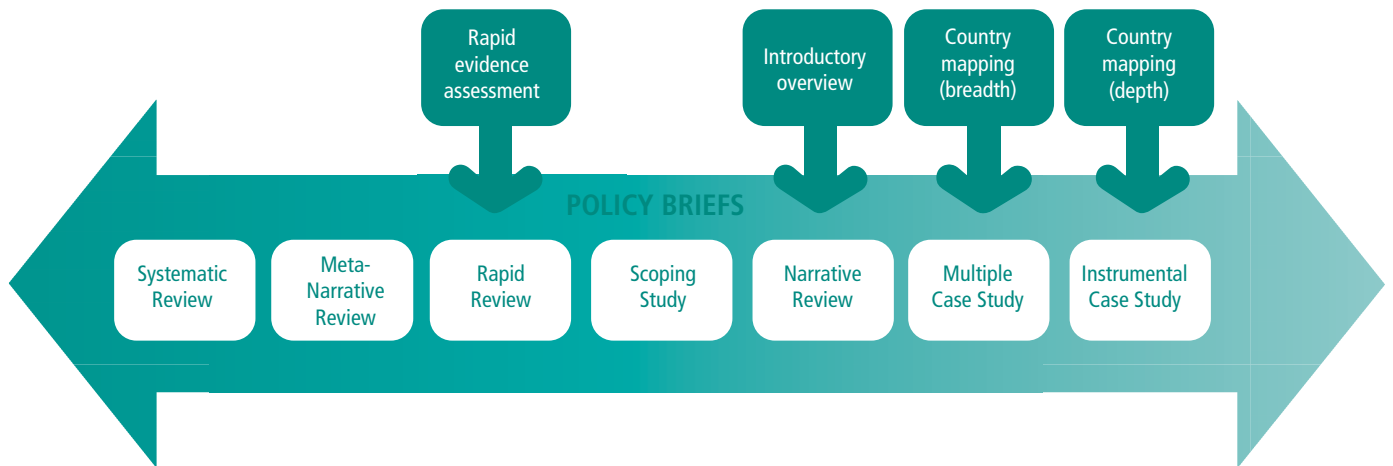
- **A rapid evidence assessment:** This is a targeted review of the available literature and requires authors to define key terms, set out explicit search strategies and be clear about what is excluded.

- **Comparative country mapping:** These use a case study approach and combine document reviews and consultation with appropriate technical and country experts. These fall into two groups depending on whether they prioritize depth or breadth.

- **Introductory overview:** These briefs have a different objective to the rapid evidence assessments but use a similar methodological approach. Literature is targeted and reviewed with the aim of explaining a subject to ‘beginners’.

Most briefs however, will draw on a mix of methods and it is for this reason that a ‘methods’ box is included in the introduction to each brief signalling transparently that methods are explicit, robust and replicable and showing how they are appropriate to the policy question.

**Figure A: The policy brief spectrum**



Source: Erica Richardson

## KEY TERMS

**Health technology** is the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives. In procurement this most often refers to innovative medicines as less attention is paid to other forms of technology (devices, equipment and health information technology (IT) systems), even though these now account for a considerable and growing portion of health care spending in Europe.

**Public procurement** refers to the purchase by governments or state-owned enterprises of goods, services and works.

## KEY MESSAGES

- 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.
- Changes in health technologies markets, such as the generalization of managed entry agreements (MEAs) and the prevailing lack of price transparency – particularly in price discounts – require different approaches to those applied in the past.
- There is a sound 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.
- 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.





## EXECUTIVE SUMMARY

### The policy issue: ensuring access to innovative health technologies in a changing market environment.

Technological innovation is one of the main drivers for change in the health sector and for improving its effectiveness in tackling diseases. At the same time, the increasing prices charged for new technologies are putting pressure on health budgets, which are already suffering from fiscal constraints. Thus, in order to ensure availability to patients, individual health systems need to meet the challenge of anticipating and managing the impact of technological innovation by engaging in horizon-scanning activities, mobilizing capacity to assess the value of new technologies and negotiating affordable prices.

While some of these innovations contribute to achieving better outcomes and in some cases even mitigating costs, for others added value is either not proven or does not justify higher prices compared to existing alternatives. Consequently, there is an increasing need for countries to access information on a new technology's effectiveness, safety, quality and price, in order to effect strategic purchasing. Furthermore, public purchasers often have relatively low bargaining power when confronted with the introduction of new, patent-protected health technologies. This is particularly relevant when they are purchasing for smaller populations, either because the country itself is small or the condition in question is rare and the target patient population limited. In these cases, it may be helpful for countries to join forces in public procurement processes and to establish forms of collaboration across borders to ensure access to health technologies.

### Cross-border collaboration in public procurement

The characteristics of markets for health products have dramatically changed since the 1990s. Globalization has had a significant impact on the nature of the supply chain. A series of high-profile industry mergers has reduced competition in many medicines markets. The generalization of intellectual property rights, the globally widespread practice of external reference pricing and the removal of tariff barriers through multilateral and bilateral trade agreements, especially in the EU, have radically changed the international pricing policies of global pharmaceutical companies. Furthermore, the Single European Market has made it more difficult for suppliers to follow independent policies in each country. The reality of parallel trade and the spill-over effects of international reference pricing have led companies to develop international pricing strategies, including confidential price discounts and managed entry agreements (MEAs). These in turn forced pricing and reimbursement authorities as well as procurement agencies to accept price confidentiality on the (questionable) assumption that they could obtain lower prices than other purchasers.

Cross-border collaboration in the field of public procurement is often put forward as a promising strategy to address some of the existing imbalances and challenges of the

health technologies market. In the procurement of health technologies, the rationale for increased voluntary collaboration between countries is to:

- enhance transparency through better information sharing
- enable cross-country learning by sharing experience
- strengthen bargaining power and mitigate overly high transaction costs by pooling skills, capacities and joint negotiations
- ensure sustainable access to health technologies by sharing resources through cross-border exchange of products in short supply.

The achievement of sustainable prices through economies of scale attained by a group of entities that pool all or some of the purchasing functions, or collaborate in carrying them out, is the most commonly cited goal for cross-border collaboration in procurement. However, other objectives, such as improving the quality of purchased goods, ensuring supply security and availability, and fostering certain innovations, are also receiving increasing attention.

### Facilitators and barriers

Although there is a lack of conclusive evidence, it remains clear that both within and across borders, successful joint procurement depends on a number of essential pre-conditions to be fulfilled by the purchasers:

- 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 the conditions of the procurement agreement.

Political will and mutual trust among the partners are obvious conditions for any form of cross-border collaboration. Mutual confidence and trust can be progressively built by countries starting with less intensive and demanding collaboration approaches, e.g. those implying only the exchange of information and experiences, time-limited collaborations, initiatives limited to one single technology or disease, etc. The longevity of such arrangements also seems to influence their effectiveness.

**Policy implications: supporting cross-border collaboration**

While actual initiatives on cross-border collaboration in procurement in Europe are still few and have evolved only recently, there is an increasing interest in exploring the potential of this option as a way to improve access to innovative medical technologies and contribute to health system sustainability. This is not only reflected in an increasing number of activities in voluntary collaboration agreements and moves towards joint procurement among EU Member States, but also in a changing EU framework that facilitates cross-border cooperation between contracting authorities and helps clarify the applicable law and responsibilities of the different parties involved. While it remains highly challenging to make suppliers adapt to new ways of working which could impact their profit margins, there is evidence that cross-border collaboration in public procurement can be effective, particularly for small markets, in maintaining access through pooling resources. Therefore, collaborations in public procurement, when they are tailored to meet the specific needs of the countries involved, present one solution that can help offset imbalances in the medical technologies market and better serve the goals of public health.

## Introduction

Technological innovation is one of the main drivers for change in the health sector and the speed at which it hits the markets seems to be increasing. For individual health systems it is an important goal and at the same time a formidable challenge to anticipate this change and to manage its impact. Health systems need to mobilize capacity in order to properly assess the value of new technologies, negotiate affordable prices and ensure availability to patients. This may be particularly difficult for smaller countries and countries with limited resources, as well as for specific products. In these cases, it could be helpful for agencies tasked with the procurement of health technologies and related institutions to join forces and establish forms of collaboration within and across borders.

This policy brief lays out the context and legal framework in which cross-border collaboration between EU Member States takes place in the area of public procurement of health technologies; discusses existing experiences and practices; and seeks to assess their transferability. It builds on evidence gathered in the 2016 WHO report on challenges and opportunities in improving access to medicines through efficient public procurement in the European Region [1], to identify some of the barriers and facilitators that countries are likely to face when seeking to collaborate in this area and to present ways forward, specifically within an EU context, that support and encourage cross-border collaboration in health. It also presents some ideas for tackling the challenges countries are likely to face when seeking to collaborate in this area, and details some of the barriers to and facilitators for implementation.

### Policy questions

This policy brief focuses on the overall question:

***“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?*

### Innovation and access to health technologies

Ensuring access to innovative health technologies is an ongoing challenge for health systems in all European countries. The increasing prices charged for new technologies have been pushing up the pressure on health budgets, which are already facing growing fiscal constraints as a result of the financial crisis and subsequent economic recession. At the same time, the ever higher prevalence of chronic diseases and multimorbidity are spurring the

#### Box 1: Methods

This policy brief builds on evidence gathered for the 2016 WHO report on challenges and opportunities in improving access to medicines through efficient public procurement in the WHO European Region [1]. It uses two main methods for approaching the idea of cross-border collaboration for procurement. It combines a literature study with expert interviews. The literature review focused on identifying scientific and grey literature that could provide an answer to the central research question: How can voluntary cross-border collaboration in public procurement improve access to health technologies in Europe? In addition, semi-structured interviews were conducted to gain a more in-depth understanding of how collaboration for procurement has been supported by different international organizations. Interviews were conducted with European policy officers and professionals dealing with collaboration for procurement in Ministries of Health. The interviews were conducted in English by phone and email. Attendants at the WHO Europe Regional Meeting on strategic public procurement in September 2016 also provided important information for this policy brief, especially for elaborating ongoing initiatives, which have not yet been fully evaluated. A full description of the methods is included in Appendix 1.

demand for innovative health technologies that would enable better management of these conditions. These challenges call for effective and efficient procurement processes.

While some of these innovations contribute to achieving better outcomes, and in some cases even mitigating costs, for others added value is either not proven or does not justify higher prices compared to existing alternatives. Increasingly, countries are establishing mechanisms to scrutinize and assess the additional value of high-cost innovative health technologies as a basis for determining price and/or reimbursement. However, acquiring information on a new technology's effectiveness, safety, quality, price and other relevant characteristics, which is indispensable to the efficient implementation of strategic purchasing, is both challenging and costly. Furthermore, public purchasers often have relatively low bargaining power when confronted with the introduction of new, patent-protected health technologies. This is particularly relevant when they are purchasing for smaller populations, either because the country itself is small or the condition in question is rare and the target patient population limited. Achieving supply security to ensure access in these cases may be difficult as well. Thus, access can be endangered both in regard to the affordability and the availability of new health technologies.

According to the World Health Organization (WHO), health technology refers to “the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives” [2]. While this brief follows this broad definition, relevant research and analysis on collaboration in procurement most often focuses on innovative medicines and less attention is paid to other forms of technology (e.g. devices, equipment and health IT systems), even though these now account for a considerable and growing portion of health care spending in Europe. As a consequence, the evidence and

experience described below relate mainly to collaboration in the field of medicines. Although lessons from these areas can partly be applied to other health technologies, transferability is sometimes limited by the characteristics of different technology types. For example, medical devices are much less standardized than medicines and there is substantially less evidence on their safety and efficacy at the time of market entry. Health care services, on the other hand, must be customized to the characteristics of the users and demand is therefore less amenable to consolidation of purchaser organizations of different jurisdictions for procurement purposes.

## A changing context in pharmaceutical markets

The characteristics of the markets for health products have dramatically changed since the 1990s and globalization has had a significant impact on the nature of the supply chain. A series of high-profile industry mergers has reduced competition in many medicines markets. National health systems, on the other hand, have in several cases become more decentralized in relation to procurement [1]. This has led to a situation where knowledge and power distribution between suppliers and buyers in the health care market have become more unbalanced and asymmetrical in favour of suppliers. The generalization of intellectual property rights that followed the approval of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement and the globally widespread practice of external reference pricing, as well as the removal of tariff barriers through multilateral and bilateral trade agreements, especially in the EU, have radically changed the international pricing policies of global pharmaceutical companies. This is particularly relevant for new technologies protected by patents and other exclusivity rights.

In the past, pharmaceutical companies confronted a country-segmented market and were used to charging each country as much as the market could bear in order to maximize global profits. South European countries, for example, traditionally demonstrate substantially lower prices for on-patent medicines [3]. But the Single European Market has made it much more difficult for suppliers to price-differentiate and, in general, to follow independent policies in different countries. The reality of parallel trade where technologies are imported from other countries in the Single Market rather than directly from suppliers, plus the spill-over effects of international reference pricing, have led companies to develop international pricing strategies, including confidential price discounts and managed entry agreements (MEAs). These force pricing and reimbursement authorities as well as procurement agencies to accept price confidentiality on the (questionable) assumption that they can thus obtain lower prices than other purchasers. In this new scenario, which finds many applications in European countries, it becomes increasingly difficult for purchasers to observe the real transaction prices of medicines and, as a consequence, to make informed and efficient decisions and assess the effects of policies and procurement practices [1].

These new features of the medicines markets have led to a fundamental transformation of the context in which procurement takes place and have influenced the incentives and opportunities for cross-border collaboration. Both suppliers and purchasers of health technologies in the EU have become accustomed to price confidentiality, and both industry and policy-makers might refrain from engaging in collaborative initiatives if they perceive such initiatives to present the risk of losing the benefits they believe they derive from confidentiality.

## Public procurement of health technologies and its potential

Public procurement refers to the purchase by governments or state-owned enterprises of goods, services and works. The procurement of products and services accounted for 19% of the gross domestic product (GDP) of the EU in 2013 [4]. When used strategically, public procurement can serve as a major, highly dynamic policy tool that has great potential to steer industrial policy, promote environmental and social objectives, encourage innovative solutions and create more affluence [5].

There are different types of procurement, which are summarized in Box 2.

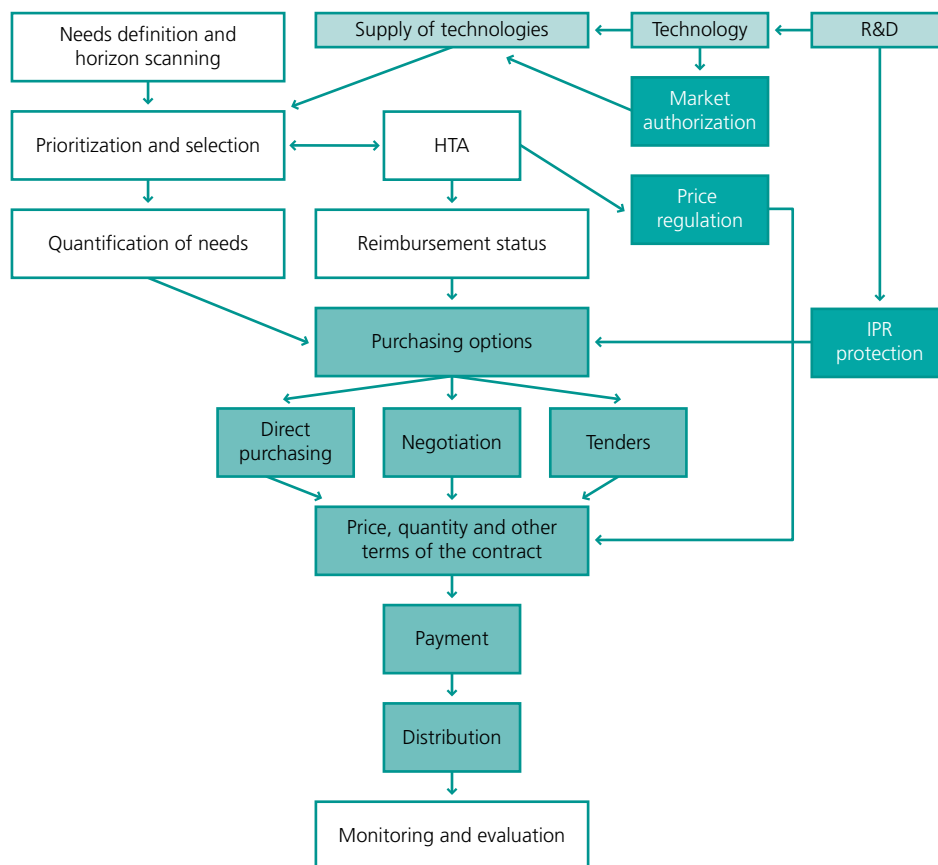
### Box 2: Procurement methods

Most types of public procurement can be used for multi-source and single-source products under different circumstances, except direct procurement, which makes sense only for single-source products, as it does not compare prices of different suppliers.

- **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.

Source: [1].

**Figure 1: Activities leading to procurement and access to health technologies**



Source: Authors' own compilation.

However, the various types of procurement rely on a common foundation in terms of process. The public procurement process is the sequence of activities starting with the assessment of needs through awards to contract management and final payment [6]. Figure 1 shows four types of activity related to the procurement of health technologies:

1. Activities that form the core procurement functions (*medium green boxes*) as they are closely linked to the economic transaction that characterizes procurement.
2. Activities closely related to the core procurement functions (*white boxes*) – mainly gathering and analysing information with the aim of improving the effectiveness and efficiency of procurement.
3. Activities usually carried out by the private sector (*light green boxes*) that condition and influence the implementation and outcomes of the procurement process, such as R&D activities leading to the production and ultimately to the supply of health technologies.
4. Regulatory activities carried out by the public sector (*dark green boxes*), which also condition and influence the implementation and outcomes of the procurement process.

An efficient procurement process can improve the prices, quality and supply availability/reliability from a given set of suppliers, by: planning and forecasting needs and supply; setting priorities as the basis of rational choices; obtaining the best achievable purchase conditions; and monitoring and evaluating the whole procurement process in order to learn from past experience and improve future performance.

## Collaboration in procurement

### Definition

There is no single term to cover the act of several buyers collaborating and pooling resources to negotiate or to buy medical goods and supplies at more favourable conditions. In the EU setting, joint procurement is the most commonly used term. It is used in the EU Public Procurement Directives to denote the situation where several buyers come together, in a single process, to get better prices or access. At the international level, pooled procurement is also a commonly used term for the same concept. Other closely related terms are central procurement, group procurement and group purchasing. Joint procurement can take various formats. The operational definition for joint procurement used in this policy brief encompasses different possible levels of collaboration, further elaborated below.

### Box 3. BeNeLuxA – collaboration on procurement of pharmaceuticals for rare diseases

This initiative to jointly negotiate prices for medicines for rare diseases was initiated by Belgium and the Netherlands (April 2015), and was later joined by Luxembourg (September 2015) and Austria (June 2016). This group of countries, known as 'BeNeLuxA', intends to collaborate more closely across a range of areas: health technology assessment (HTA); horizon scanning; exchange of information on pharmaceutical markets, prices and disease-specific cross-border registries; and pricing and reimbursement, including joint negotiation. The ultimate aim is to ensure access to innovative drugs, initially orphan drugs, at affordable prices for the respective populations. By being able to present a bigger patient pool to pharmaceutical companies, it is hoped to increase purchasing power and it is also hoped that more countries will join the initiative.

This pilot-project followed the difficult national negotiations over certain high-priced drugs such as, for instance, the Hepatitis C drug sofosbuvir. Through better sharing of information and closer collaboration, it is believed that governments could obtain reduced but fair prices. For the pharmaceutical industry the benefit is direct access to a larger patient population and more streamlined market access as they only need to provide one dossier, not one per country, managed in a coordinated decision process.

This coordinated procurement relies on a set of principles: setting clear, common goals; being clear on the mutual benefits; a pragmatic approach focusing on the desired outcomes and having a lean organizational structure; understanding that cooperation is not the solution to all problems; voluntary participation; and a strong political will. The project has no fixed 'roadmap': the degree of collaboration depends on what is required with a stepwise approach to participation. This is a key difference compared to the EU Joint Procurement Agreement (see Box 6), where the Commission leads on the negotiations rather than individual countries and the framework for collaboration is more fixed.

Sources: [10–13].

### Rationale

Cross-border collaboration in the field of public procurement is often put forward as a promising strategy to address some of the existing imbalances and challenges of the health technologies market described above. In the procurement of health technologies, the rationale for increased voluntary collaboration between countries is to:

- share experience, pool skills and capacity
- enhance transparency and enable cross-country learning
- shape the market through information sharing to avoid asymmetries of information and joint negotiation
- tackle high prices through economies of scale and building market power
- tackle high transaction costs by pooling resources.

The achievement of sustainable prices through economies of scale attained by a group of entities that pool all or some of the purchasing functions, or collaborate in carrying them out, is the most commonly cited goal. However, other objectives, such as improving the quality of purchased goods, ensuring stable supply and availability, and fostering certain innovations are receiving increasing attention.

Availability is becoming increasingly important, especially in Central Eastern European and South Eastern European

countries where lower price levels generate parallel exportation to higher price countries in Western and Northern Europe. Manufacturers also tend to withdraw their products from certain countries with smaller populations if their profit margins are deemed too small to justify marketing their drugs there. Through joint negotiations these countries hope to ensure supply as manufacturers are dealing with a larger net population. Given the changes in pharmaceutical markets observed in recent years, the scope for collaboration between buyers intuitively becomes more compelling. Although small or lower-income countries will be more likely to benefit from collaboration in procurement, collaboration can also be an attractive option for large, higher-income countries when it comes to small-volume products, such as orphan drugs (for example, BeNeLuxA; see Box 3) [1]. It is possible that collaboration between large/high-income countries and small/lower-income countries might also occur, spurred on by the motives of solidarity and political influence in the absence of direct economic benefits.

### Different forms

Cross-border collaboration in procurement can take different forms, with varying intensity and scope of activities. WHO provides a four-level classification of regional collaboration for procurement experiences in health technology, based on an increasing degree of cooperation (see Figure 2):

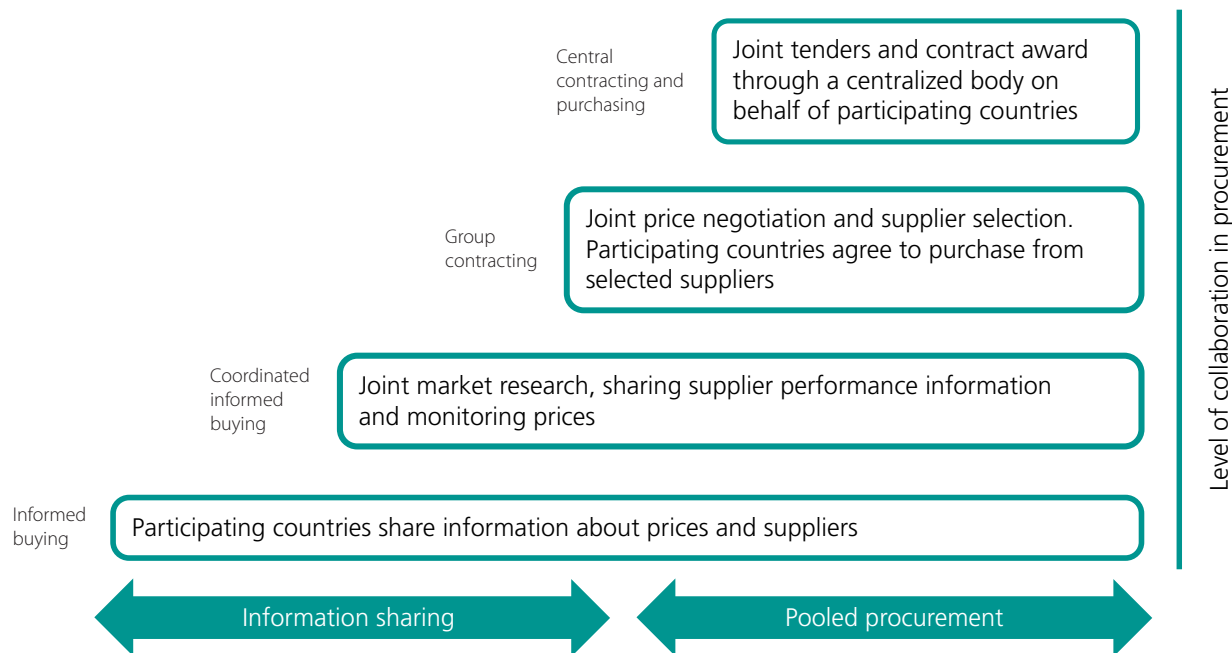
- **Informed procurement:** countries share information about prices and suppliers.
- **Coordinated informed procurement:** countries may also undertake joint market research, share supplier performance information and monitor prices.
- **Group contracting:** involves jointly negotiating prices and selecting suppliers.
- **Central contracting and purchasing:** participating countries jointly conduct tenders and award contracts through a central purchaser working on their joint behalf.

This classification considers two broad potential areas of collaboration:

- The collection, elaboration and exchange of information; and
- The activities more closely related to actual contracting and purchasing.

Thus, the model can be interpreted as suggesting a 'natural route' of increased intensity and/or commitment in collaboration, starting by just sharing information on prices and suppliers, up to joint procurement by a centralized body. It also suggests that the types of collaboration placed higher in the classification include the activities pooled at lower levels, in line with the notion that it may often make sense for countries to initially adopt less committed and risky arrangements and move to more intense types of collaboration down the line. From the purchaser perspective, the core/key component in the chain of activities in a procurement process (see also Figure 1) is the mechanism for selecting the supplier(s) and agreeing on a contract

Figure 2: Levels of collaboration in procurement



Source: Adapted from [1].

with a set of conditions. In fact, public procurement includes a large number of activities/functions and partners might collaborate in different clusters or combinations of activities. This means that a much larger number of types of collaboration is feasible, beyond the four considered in Figure 2. Other models of collaboration in procurement have also been described beyond the realm of health technologies but with potential for applicability in this area as well, such as 'piggy-backing', whereby a contracting authority carries out the procurement on its own but allows other contracting authorities the option of using the contract [7].

In general, important characteristics that define and differentiate cross-border collaboration for procurement of health technologies are [8]:

- **Ownership:** the collaboration might belong to the individual, pooled units (usually, national governmental procurement units) or to an organization specifically created by the government(s); alternatively, it might be owned by a larger international organization.
- **Financing mechanism:** there are several potential combinations of external donors and national partners and of the financing structure, which imply various models of distributing the economic responsibility and solvency.
- **Procurement activities:** activities such as placing orders with suppliers can be centralized or left to the pooled units. Contracting and purchasing can be the responsibility of a central unit. Alternatively, a central unit can negotiate the price (with some estimations and responsibility for the volume of products that each partner expects to purchase).

- **Timeframe:** the collaboration can be permanent or occasional.
- **Range of products or services involved:** the collaboration can include all health technologies or be restricted to a specific class, e.g. orphan drugs.
- **Purchasing mechanism:** the collaboration can rely on bulk contracting, where one supplier is awarded all tendered items or opt for a framework (time-bound) contract, where the suppliers are not necessarily awarded a guaranteed specific quantity.

## Findings

### European experiences of voluntary cross-border collaboration in procurement of health technologies

Public procurement for health technologies has been supported by the EU, as one area for cross-border collaboration but impetus for greater coordination and collaboration between Member States followed the H1N1 influenza pandemic in 2010 and the Ebola epidemic in 2014 [9]. During these public health emergencies, countries were competing with each other to get hold of scarce supplies, and prices went up in response. To reduce the chances of similar events occurring in the future, the EU Joint Procurement Agreement (see Box 4) was signed, in order to maintain access to vaccines, medicines and medical equipment that address serious cross-border threats. However, there were also many other initiatives that have been put in place by Member States since 2010 (see Table 1). Many of the cross-border collaborations in the EU are very new and still evolving in some cases, and have thus

#### Box 4: Joint procurement of vaccines under the Baltic Partnership Agreement

Collaboration under the Baltic Partnership Agreement was started at the end of 2014 and the first joint procurement focused on vaccines, as all three Baltic States have similar immunization schedules and the price of vaccines is mostly influenced by purchased volumes and long-term delivery schedules.

The first open procedure (for the BCG vaccine) was announced in 2015. It was organized according to the Public Procurement Law of Latvia, as Latvia was the lead partner. The procedure was terminated in Spring 2015 because no tender was submitted. As the procurement technical specifications only allowed vaccines with valid marketing authorization in all three Baltic States, there was only one producer with a suitable registered product and he declared serious production problems within the tender submission timescale. The tender had to be drawn up for joint procurement through competing wholesalers as the manufacturer was not interested in participating in the joint procurement process directly for such a small market and small amount – despite the three countries pooling their leverage to jointly negotiate prices with suppliers. For example, the necessity of producing uniform packaging in the three languages was not considered to be cost-effective by the manufacturer.

After renewed discussions in the working group, the object of the joint procurement was changed. Estonia and Latvia identified a rotavirus vaccine as the next most promising choice (Lithuania does not have rotavirus vaccine in its immunization schedule). Also, it was decided that Estonia will be the lead partner and Latvia will delegate all the obligations of the procurement process up until the signing of the framework agreement to Estonia. The joint procurement for rotavirus vaccine was announced on 21 October 2016 and the opening of the tenders was on 8 December 2016. There is also an ongoing collaboration between Latvia and Lithuania for the procurement of pneumococcal vaccine.

An important component of the Partnership Agreement is the lending of centrally procured medicines, which enables countries to prevent and alleviate shortages of medicines. Since 2012, there have been several lending processes, which have helped countries to solve serious shortage problems.

Source: Eveli Bauer.

not yet been fully evaluated in terms of whether they meet their objectives.

The scope of most of the seven cross-border collaborations in public procurement identified in this brief involves medicines – most commonly innovative medicines. While the Baltic Partnership Agreement also explicitly covers medical equipment, in practice, it has only been used so far for the procurement of vaccines (see Box 4). The barriers to joint procurement encountered in the initial attempts under the Baltic Partnership Agreement serve as useful illustrations of the challenges that need to be overcome in order to increase leverage for reducing prices and ensuring availability. However, the importance of cross-border collaboration for access to medical technologies in small markets is also clear as these countries were successful in pooling resources to borrow stocks from neighbouring countries in order to maintain supplies. Similarly, the Romanian and Bulgarian Initiative (see Table 1), while hoping to use joint price negotiation to reduce costs, will also involve cross-border exchanges for medicines that may be in short supply in either country.

Cross-country collaborations in the procurement of health technologies have been running for a considerably longer time outside the European context. Two major reviews of joint procurement experiences in other parts of the world have been conducted [8,14]. Several of the initiatives identified therein were considered to be failed or inactive at the time of investigation. While some of the more successful collaborations reviewed reflect the initiative of a group of countries (Organisation of Eastern Caribbean States Pharmaceutical Procurement Service; Gulf Cooperation Council), the majority are the result of an international organization taking the lead and running the collaborative procurement as one of its functions Pan American Health Organization (PAHO) Revolving Fund; Global TB Drug Facility; United Nations Fund for Population Activities Procurement Services Branch; United Nations Children's Fund (UNICEF)(ARIVA).

### The current EU framework for supporting voluntary cross-border collaboration in procurement of health technologies

#### General framework on public procurement

The EU rules on public procurement are in the first place meant to ensure transparent, fair and competitive awarding of public contracts for purchasing goods, works and services throughout the EU. The legal framework was revised in 2014 with **Directive 2014/24/EU on public procurement**, which repeals Directive 2004/18/EC on public works. The new rules, which had to be transposed into national law by April 2016, simplify procurement procedures, make them more flexible and help public purchasers to incorporate and implement strategic objectives for protecting the environment, promoting social integration or fostering innovation.

Directive 2014/24/EU on public procurement covers the issue of cross-border joint procurement. Article 39 explicitly allows for contracting authorities from different Member States to act jointly in the award of public contracts. In order to facilitate this kind of cross-border cooperation between contracting authorities, the Directive helps to clarify the applicable national law and responsibilities of the different parties involved. Where procurement is centralized through one purchasing body, the purchasing activities are governed by the national rules of the Member State where the central purchasing body is located. If contracting authorities from different Member States work together to jointly award a public contract, conclude a framework agreement or operate a dynamic purchasing system, the respective responsibilities of the various parties need to be clarified in an international agreement that is either concluded between Member States or between the participating contracting parties. Contracting authorities from different Member States can also set up a joint legal entity under national or EU law, in which case an agreement on which national procurement rules apply is also needed.



**Table 1. European experiences of cross-border collaboration in procurement of health technologies**

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

Source: Based on [1].

Article 39 of the public procurement Directive also states that the possibilities for cross-border joint procurement should not be used for the purpose of avoiding the application of mandatory public legal provisions to which contracting authorities are submitted in their own Member State. In the same sense, cross-border collaboration in procurement is not supposed to infringe on EU competition law. Related guidelines have been set out in the Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union (TFEU) to horizontal co-operation agreements (2010).

### Structured cross-border cooperation in health

The definition of health policy and the organization and delivery of health services and medical care are the exclusive responsibility of the Member States. These responsibilities include exclusive competence in the management of their respective health systems and medical care, and the allocation of resources assigned to them. However, according to Article 168(2) TFEU, the EU has an obligation to promote cooperation between Member States in the field of health. Based on this, the European Commission has developed a wide range of actions under the EU's public health programme that organize and support cooperation activities in various fields. The Commission's Communication on effective, accessible and resilient health systems (2014),

which sets out a future EU health policy agenda, also highlights the potential of improved cooperation in the field of medicines through building mechanisms for increased transparency and better coordination to minimize any unintended effects that current national pricing systems may have in terms of accessibility throughout the EU.

The **Directive 2011/24 on patient rights and cross-border health care** may be viewed as having provided a new approach to structured cross-border cooperation between health systems, while fully respecting Member States' competence in organizing and delivering health care. Chapter IV of the Directive specifies how structured cooperation is to be organized in areas like European reference networks (ERN), rare diseases, health technology assessment (HTA; see Box 6) and e-health. As some of these strands further build on cooperation structures and networks that initially developed as projects, they can provide useful lessons for developing structured cooperation in the procurement of health technologies. This is clearly the case with the development of a voluntary network connecting national authorities or bodies responsible for health technology assessment designated by the Member States (Article 15). The creation of ERNs (Article 12) may also be a relevant tool for supporting cooperation in procurement. Since they particularly focus on rare diseases and the delivery of highly specialized services, ERNs may in

**Box 5: EU Joint Procurement Agreement on medical countermeasures**

The EU Joint Procurement Agreement (JPA) was adopted in April 2014 and came into force in June 2014, when the first 14 Member States signed the Agreement. Based on Decision No. 1082/2013/EU, the JPA seeks to strengthen health security in the EU by improving its preparedness against cross-border threats to health through joint procurement or advance purchase of medical countermeasures. Its development was accelerated by the 2009 H1N1 influenza pandemic when Member States competed to access vaccine supplies rapidly and frequently paid relatively high prices for medicines they ended up not using.

The JPA is a voluntary agreement to purchase jointly. The prospective benefits of joint procurement include: better access to markets; more equitable access for Member States to medical countermeasures, anti-infectives or vaccines against cross-border health threats; improved security of supply; and more stable pricing.

The administrative arrangements are set out in detail in the policy instrument. The European Commission plays a key role, acting as the Permanent Secretariat and as the body responsible for ensuring the preparation and organization of the joint procurement procedure. A separate committee is established for each specific procurement procedure to determine the technical specifications and allocation criteria for medical countermeasures. The formulation allows Member States some flexibility but also details the processes and procedures to be followed.

A first call for tender for Personal Protective Equipment in EU hospital settings was launched in March 2016 by five Member States (Belgium, Croatia, Cyprus, Italy and Malta) and the European Commission.

Source: [9].

fact be an important lever for ensuring access to innovative health technologies. As ERNs will pool patients with low prevalence, complex or rare diseases, they could be instrumental not only in reinforcing research and developing good practice guidelines but also in exercising negotiating leverage with pharmaceutical and medical technology companies.

The most concrete example of European Commission action on cooperation in the field of procurement of health technologies is **Decision No. 1082/2013/EU of 22 October 2013 on serious cross-border threats to health (and repealing Decision No 2119/98/EC)**, which was developed at the request of the Employment, Social Policy, Health and Consumer Affairs (EPSCO) Council and the European Parliament following the H1N1 crisis in 2009. Based on Article 168(1) TFEU, 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, with Sweden and Finland

**Box 6: Collaboration in health technology assessment (HTA)**

The European Commission has supported collaboration in HTA across countries since the early 1990s [16]. In 2004, it set HTA as a political priority, followed by a call towards establishing a sustainable European network on HTA. The call was answered by 35 organizations throughout Europe and led to the introduction of the European network for Health Technology Assessment (EUnetHTA) Project in 2007. Based on the project's results, the EUnetHTA Collaboration 2009, the EUnetHTA Joint Action 2010–2012, EUnetHTA Joint Action 2 2012–2015 and EUnetHTA Joint Action 3 2016–2020 have been consistently supported by the European Commission.

Cross-border collaboration in HTA is now anchored in EU law through Directive 2011/24/EU on the application of patients' rights in cross-border health care. Article 15 states that "The Union shall support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or bodies responsible for health technology assessment designated by the Member States." The Directive sets out both the network's goals and activities for which additional EU funds may be requested. It also explicitly reinforces the principle of subsidiarity by stating in the final paragraph of Article 15 that "measures adopted pursuant to this Article shall not interfere with Member States' competences in deciding on the implementation of health technology assessment conclusions and shall not harmonize any laws or regulations of the Member States and shall fully respect the responsibilities of the Member States for the organization and delivery of health services and medical care."

In October 2016, a public consultation was launched on the Inception Impact Assessment "Strengthening of the EU cooperation on Health Technology Assessment (HTA)", which reinforces the Commission's commitment to enforcing collaboration in HTA and offers five policy options, the most integrative of which proposes cooperation on the production of joint full HTA reports. This would include the evaluation of cost-effectiveness and organizational aspects (which are more topical) along with clinical effectiveness and safety. The consultation period ends in January 2017.

The European Commission's impact assessment was based on evidence from the EUnetHTA activities of previous years, which showed that collaboration in producing joint methodologies and assessments themselves can improve both the quality and quantity of produced assessments while avoiding duplication of work. However, evaluative research on these collaborative activities also shows that collaboration in evaluating effectiveness and safety was not without its challenges, particularly with respect to the alignment of the process with national needs and processes; this primarily concerned the timely availability of joint assessments, the relevance of each jointly selected topic for individual HTA agencies and difficulties with integrating jointly produced reports in national templates and procedures [17]. Joint assessment production needs to carefully consider its collaboration model to avoid inefficiencies; for example, by involving no more than a certain number of agencies in drafting each report and including others as reviewers [18].

While one of the Commission's goals in further strengthening HTA from 2017 onwards is to ensure the better functioning of the EU internal market for health technologies, at this juncture it is considered unlikely that national (or regional) decision-making competencies on pricing and reimbursement will change in the near future [17,19,20].

having expressed their intent to join as well (see Box 5) [15]. While the Decision leaves quite some discretion to Member States to decide on the scope of products to procure jointly, it is by nature limited to only medicines, medical devices and other goods or services that are aimed at combating “serious cross-border health threats”. It is thus not intended to cover any health technologies beyond this scope, for example, for treating chronic conditions.

### Promoting cross-border cooperation in procurement

In addition to establishing the regulatory framework within which cross-border joint procurement can be developed, various EU policy initiatives seek to facilitate cross-border collaboration in public procurement. In 2011, the European Parliament adopted a Resolution on a Single Market for Enterprises and Growth, in which it called on the Commission to explore how cross-border joint procurement can be facilitated. This is part of a wider attempt to boost innovation, including in public procurement, under the Europe 2020 Flagship Initiative on the Innovation Union. Within the European Commission, DG Growth (the Directorate General responsible for Internal Market, Industry, Entrepreneurship and Small- and Medium-sized Enterprises (SMEs)), is supporting Innovation Partnerships to keep public services up to date. Based on the possibilities under the new EU public procurement legislation, the Commission promotes the idea of making procurement practices more efficient, including by stimulating cross-border cooperation between contracting authorities and facilitating joint procurement. This is believed to help lower pressure on health budgets (see Box 7). Also, the importance of pre-commercial procurement (PCP) was emphasized as a way to both innovate and improve quality and effectiveness of public services. Pre-commercial procurement is intended for situations where there are not yet any near-to-the-market solutions and new R&D is needed. PCP can then compare the pros and cons of alternative competing solutions. This will in turn reduce the risk for the most promising innovations step-by-step via solution design, prototyping, development and first product testing. One PCP project is Anti-SUPERBugs, a consortium of health care procurers from Spain, Italy, Germany and the UK.

## Discussion

While a desire for cross-border collaboration in the procurement of health technologies appears to be gathering pace, as demonstrated by the examples above, the body of evidence on the effects of different procurement types is too weak to allow for the conclusive identification of good practices in voluntary collaboration. This is related both to the relatively recent establishment of many of these initiatives and to the fact that evidence in this area is highly context-specific and not necessarily applicable to other settings [1].

Furthermore, due to the substantial changes in health technology markets in recent years – increased market exclusivity, reduced price transparency, generalization of

### Box 7: Innovating in public procurement through cross-border collaboration in the EU

**HAPPI European procurement platform:** The Healthy Ageing Public Procurement of Innovations (HAPPI) is a collaboration of 12 purchasing bodies and innovation experts from 8 Member States (France, UK, Germany, Italy, Belgium, Luxembourg, Austria and Spain), which is supported by the European Commission. The consortium’s aim is to identify, assess and purchase innovative and sustainable health products, services and solutions, which will improve ageing well. So far, the partners have developed and purchased over 150 innovative medical solutions with the help of their procurement strategy. It comprises early market studies and communication of the tender to a multitude of companies including SMEs. The use of functional rather than technical specifications in the tender notices was crucial in this project [21,22]

**German–Dutch–Austrian cooperation in hospital procurement:** The German Purchasing Association GDEKK, which since 1998 acts as a central non-profit purchasing body on behalf of 75 municipal hospitals in Germany, extended its geographical scope to also include public hospitals in Austria and university hospitals in the Netherlands. Despite the legal differences in health-related procurement, it is believed that through further economies of scale, cost reductions can be achieved for all participating bodies in this enhanced European cooperation for health procurement. The association set up a professionalized procurement system, which includes defining common procurement needs, market analysis and establishing quality criteria [22,23].

**Anti-SUPERBugs:** This is a project led by a consortium of health care procurers from Spain, Italy, Germany and the UK. Anti-SUPERBugs is part of the pre-commercial procurement (PCP) initiative funded by the European Commission’s Health 2020 framework programme. The aim of the project is to enable smart information and communications technology (ICT) solutions to be developed that will detect the presence of resistant micro-organisms, give real-time feedback to the user and share this information with the health care provider’s electronic record systems linking the infection with the place of detection. The project, which was launched in September 2016, is expected to last for four years and is focused on the acquisition of research and development (R&D) of new innovative solutions before they become available on the market. The contracting authority shares the risks and benefits with the R&D services provider. This mode of procurement is an exception to the application of the European public procurement rules [24,25].

**MEDEV:** The Medicine Evaluation Committee (MEDEV) was established in 1998 as a standing working group of the European Social Health Insurance Forum. Today, MEDEV represents the drug experts and pharmacologists of national social insurance organizations and HTA agencies in 18 EU Member States. The principal purpose of MEDEV is to provide the national health insurance organizations and other competent bodies with timely analyses of drug-related trends and innovations at both national and European level. While it focuses mostly on HTA, national exchange of experience and information also relates to the definition of parameters for cost-benefit analyses and international price analyses. The group also follows cross-border procurement initiatives. Particular attention was given to the early dialogue with companies developing orphan medicinal products, the Method of Coordinated Access to Orphan medicinal products (MoCA). This dialogue has mainly covered clinical study issues but has also addressed some novel procurement models [26].

MEAs and other forms of contracting – most reported international experiences developed outside Europe in the 1990s might not provide lessons applicable to EU countries at the present time. Due to the specificity of the European market, where national authorities have retained responsibility for health policy, including the pricing and reimbursement, regulation and procurement of medical products, there are few cases where countries have actually worked together to successfully influence the market and achieve sustainable supplies of new medicines or other medical goods.

However, a number of points can tentatively be made based on the European and international experience that highlight both the necessary elements for a fruitful collaboration and possible challenges that need to be overcome.

As quality assurance becomes an increasingly important goal in many European countries, it merits consideration that small countries or purchasers often cannot afford the fixed costs or do not have the necessary specialist expertise required to appropriately carry out some of the related procurement market/health assessments. As technologies become more complex, the pace of innovation increases and novel market entry modalities such as adaptive licensing start to enter the debate, the sharing of professional resources and specialist expertise further gains importance and could function as a driver for collaborative initiatives.

Cross-border collaboration is one way for two or more procurement agencies to attain a larger operating scale and, hence, acquire the advantages of economies of scale. The benefits of cross-border collaboration primarily derive from the increased size effect and efficiency of procurement planning, rather than from the cross-border aspect itself. In fact, collaboration is likely to be more successful – other things equal – if the units that collaborate in procurement belong to the same country (e.g. regions, hospitals) than if they are in different countries (cross-border). This is because the benefits of collaboration are likely to be offset by the costs of coordinating between partner organizations, which are likely to be higher if the organizations belong to different countries, with different regulations, legislation, marketing practices, language, etc. Therefore, potentially, countries should pursue internal collaboration in procurement – between regions or hospitals – before turning to cross-border collaboration. However, in a number of cases, particularly for the treatment of rare diseases or for small countries, where complex technologies or innovative treatments are concerned, collaboration beyond national borders could be pursued to capitalize on socioeconomic gains.

Beyond increasing collaboration costs, the different types of national regulations on prices and public contracting can hinder joint procurement initiatives, as they might not be compatible with the procedure agreed. Countries that believe they are able to achieve lower prices and privileged conditions of supply under confidential price agreements might not want to risk their privileged position by adopting a procurement approach that could lead to a single price, which might be higher than the one they were paying

individually (large, high-income countries by exerting monopoly power in the negotiations; or small, low-income countries by benefiting from humanitarian or responsible corporate policies). Similarly, if one of the pooled countries is a potential parallel exporter, suppliers are likely not to grant the low price they otherwise would have charged to some countries, for fear that the first country might divert products to higher-priced countries.

While language diversity seems not to have posed demonstrable challenges in parallel trade regarding translating, relabelling and/or repackaging products, it may be a complicating factor in cross-border joint procurement processes. Evidence from the Baltic Partnership Agreement on procurement suggests that language issues are not negligible; in this case using English as the only language for the initiative was desired but not possible, because the State Language Centre of the Republic of Latvia required tender documents to be drawn up with an additional translation in the official state language (Latvian) in order to be valid.

### **What conditions are needed to make cross-border collaboration in procurement work?**

Both within and across borders, successful joint procurement depends on a number of essential pre-conditions: strong political commitment; trust between collaborating parties; good governance that helps curb opportunistic tendencies which could erode the value of the procurement process; price transparency; effective communication between internal and external stakeholders; 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; and, finally, sharing of information and good practices. Ideally, information sharing would entail the development of shared databases on key issues such as prices, patent status, pre-qualification of suppliers and medicines registration [27].

Political will and mutual trust among the partners are obvious conditions for any form of cross-border collaboration, as exemplified here by the BeNeLuxA guiding principles (see Box 3). Mutual confidence and trust can be progressively built by countries starting with less intensive and demanding collaboration approaches, e.g. those implying only the exchange of information and experiences, time-limited collaborations, initiatives limited to one single technology or disease, etc. The longevity of such arrangements also seems to influence their effectiveness, as ongoing market share over time can be more important to inspiring competition among suppliers than the volume of sales over a limited time [8]. As such, cross-border joint procurement arrangements should be part of an overall customized strategy that seeks to fulfil and balance the needs of the collaborating countries [27].

**Table 2. Potential gains of collaboration in specific procurement-related activities**

Activity	Potential gain from cross-border collaboration
<b>Horizon scanning</b> (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]	<b>High</b> 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].
<b>Needs assessment</b>	<b>Limited</b> 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.
<b>Health technology assessment</b>	<b>Partial</b> 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).
<b>Economic evaluation</b> (mainly seen as part of HTA but often carried out by different agencies)	<b>Limited</b> 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.
<b>Prioritization and selection</b> – defining reimbursement status and quantification of needs	<b>Partial</b> 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.
<b>Purchasing and contracting</b>	<b>Limited</b> 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.

### For what types of health technology and types of activity would cross-border collaboration be most appropriate?

An obstacle to cross-border joint procurement frequently mentioned in the literature is that the products might not be authorized or marketed in all participating countries. This is further exemplified here in the experience of the Baltic Partnership Agreement (see Box 4). Cross-border joint procurement is therefore most often indicated when the products or services are homogeneous and standardized and are, or can be, easily authorized and marketed in any country. In the EU, this condition is normally met for medicines relevant for joint procurement (new medicines or those with a higher therapeutic value and high costs), thanks to the role played by the European Medicines Agency (EMA) and its centralized procedure for market authorization of medicines. Variability of available products should therefore not be an obstacle for cross-border collaboration in procurement. However, standardization remains a very real problem for other technologies such as medical devices, as the requirements for marketing authorization are considerably less strict and show a certain degree of heterogeneity across EU Member States.

A unified, uniformly accepted nomenclature of devices is not yet available. This is also in part illustrated by the experiences of the Baltic Partnership Agreement (Box 4).

High-cost technologies, e.g. new products that are on-patent or under any form of market exclusivity, which often have a monopolistic position, are also a logical target for joint procurement due to the greater potential for price reductions that can be attained by pooling the volumes of small purchasers. When markets are so competitive that suppliers already operate at a price very close to the marginal cost, a larger (pooled) purchaser may not be able to achieve significant further price reductions. However, they could help in keeping low-price products on the market and avoiding the exit of manufacturers. Cross-border collaboration may also be indicated for low-volume products, especially if they are essential in terms of health impact, as a way to minimize the risk of supply discontinuities and stock-outs. The same applies to products that have an uncertain but potentially high demand, e.g. medicines for unpredictable epidemics.

Finally, it may be a more rewarding option to explore opportunities for collaboration in those components of

the procurement process (see Figure 1 and Table 2) that may reduce costs and improve performance by pooling concrete functions or activities of formerly independent organizations. Most procurement and procurement-related activities – collection and elaboration of information, contracting, negotiating, purchasing, logistics, etc. – are likely to experience economies of scale. Some procurement activities, such as collecting information on prices and quality, payment conditions, reliability of the purchaser, etc., imply spending fixed costs, irrespective of the number of partners that use the information, because information is a public good.

### **How can voluntary cross-border collaboration in procurement be encouraged and supported by the EU?**

Participating countries and their citizens are the main potential beneficiaries of voluntary cross-border collaboration in procurement, in the form of greater availability and affordability of health technologies. However, the EU can contribute to, promote and facilitate initiatives by:

- Providing support and investing resources, either at the initial stages of the initiative or for its duration.
- Enacting or amending legislation to facilitate cross-border initiatives.

As shown above, the EU is already applying these two strategies in several cases. However, such policies face constraints and potential conflicts. Firstly, the EU must comply with the principle of subsidiarity, which means that participation by countries must be voluntary. Secondly, policies aimed at reducing expenditure mean potentially reduced revenues and profits for the suppliers, the health technology industry, which is a highly innovative and dynamic sector that EU policies are trying to boost. This is likely to cause conflict between the consumer and supplier interests. Policies therefore need to be carefully designed and implemented in order to ensure the balance between health and industrial objectives. There is also scope for the EU to provide a platform of information on existing collaborative initiatives to enable dissemination and knowledge exchange between Member States. For example, the innovations highlighted in Table 1 and Box 7 might be useful for other countries too.

Since the Single Market was set up, EU policies have faced an apparently irresolvable dilemma. On the one hand, it has been established as an overriding principle in which social policy, including health, needs to fit. On the other hand, Article 168(7) TFEU holds that EU action shall respect the responsibilities of the Member States in the definition of health policy and for the organization and delivery of health services and medical care.

### **Policy implications**

While actual initiatives on cross-border collaboration in procurement in Europe are still few and have evolved only recently, there is an increasing interest in exploring

the potential of this option as a way to improve access to innovative medical technologies and contribute to health system sustainability. This is not only reflected in an increasing number of activities in voluntary collaboration agreements and moves towards joint procurement among EU Member States, but also in a changing EU framework that facilitates cross-border cooperation between contracting authorities and helps to clarify the applicable law and responsibilities of the different parties involved. While it remains highly challenging to make suppliers adapt to new ways of working which could impact their profit margins, there is evidence that cross-border collaboration in public procurement can be effective, particularly for small markets, in maintaining access through pooling resources. Therefore, collaborations in public procurement, when they are tailored to meet the specific needs of the countries involved, present one solution that can help offset imbalances in the medical technologies market and better serve the goals of public health.

Cross-border collaboration in public procurement of health technologies can be facilitated by: ownership, equity, transparency, flexibility, standardization and gradual development. Procurement policies are harmonized at EU level but there is still little uniformity at the national level in terms of standardized procurement processes and procedures, which can hamper collaboration. For this reason, flexibility and transparency are needed in the approach to cross-border cooperation. In successful collaborations, the parties also have a sense of ownership over the cross-border collaboration and they are cooperating on equitable terms. The literature and experience show that cross-border collaborations develop gradually over time, where there is real political will for countries to work together to overcome common challenges.

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## **Conclusions**

While actual initiatives on cross-border collaboration in procurement in Europe are few, there is increasing interest in exploring the potential of this option and a growing body of legislative work that is intended to provide the basis for collaborative initiatives. The international experience provides a few examples of regional joint purchasing of health technologies that have been running for more than two decades. While some are led by a group of countries and others by an international organization, there is insufficient evidence to recommend one model over another. Moreover, the evolution of the health technologies markets towards new products and forms of contracting, such as advanced purchase agreements, confidential discounts and MEAs, has made the traditional experiences of joint purchasing obsolete under the new conditions.

The trade-offs between the potential benefits and costs of cross-border collaboration undoubtedly depend on the characteristics of the activities, technologies and countries involved. Larger, higher-income countries are likely to get less benefit from pooled procurement if they are already able to reap most of the potential benefits from economies

of scale. Thus, cross-border collaboration for procurement is certainly not an automatic solution for all the problems of availability and affordability of technologies with small target populations. Therefore, alternative solutions should also continue to be explored.

Nevertheless, collaboration in public procurement, tailored to meet the specific needs of the countries involved, presents one solution that can help offset imbalances in medical technologies markets and better serve the goals of public health. Through collaboration in the procurement process purchasers can achieve a larger size. This increases their market power and they reach either a critical mass or economies of scale in performing their procurement activities that potentially achieve lower acquisition prices, lower operating costs, but also improved quality of purchased goods and better purchasing conditions.

It is important that 'young' initiatives are carefully and continuously evaluated to obtain much-needed, robust evidence on best practices in this area in order to improve sustainable access to innovative medical technologies or medical countermeasures and to contribute to health system strengthening.

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## Appendix 1. Methods

This policy brief combined a literature study with semi-structured interviews and desk-based research.

### 1. Rapid review of the literature

The review aimed to identify publications, in both the scientific and grey literature, that could provide an answer to the central research question: How can voluntary cross-border collaboration in public procurement improve access to health technologies?

The scientific literature review focused on the concept of “joint procurement”, so the main literature search was made (on 4 July 2016) in PubMed using as the key terms: (“Pharmaceutical Preparations” [Mesh] OR medicines) AND (“Group Purchasing” [Mesh] OR “joint procurement”).

The grey literature review and websites review played an important role in this policy brief as many of the experiences in the field of cooperation for joint procurement are new, with little documentation in scientific journals as yet, so searching websites, especially the European Commission site, was a key strategy. A Google Scholar search using the standard terms: “medicines” AND “pharmaceutical” “collaboration” AND “procurement” AND “tender” OR “joint procurement” also identified some useful grey literature.

### 2. Semi-structured interviews

To gain more in-depth insight into the different experiences in cross-border collaboration for procurement, semi-structured interviews were conducted with:

- European policy officers to gain understanding of the experiences and results of the different initiatives launched at EC level
- WHO/PAHO professionals dealing with joint procurement in the Latin-American region
- other experts in the field.

### Approach

Only three full interviews were completed but several other contacts were made in order to clarify specific points about international experiences in cross-border collaboration. Attending the Strategic Procurement Meeting (22–23 September 2016, WHO Regional Office for Europe, Copenhagen) proved particularly important for gathering unpublished information in this area.

A topic guide was used to guide and direct the semi-structured interviews. Key items in the guide included:

- Can you explain to us any experience you personally have had, or are aware of, in relation to national or international joint procurement of health technologies?
- What are the main potential benefits and obstacles to the joint procurement of health technologies in general and to its application among EU Member States?

- Can you indicate other professionals or organizations that can provide us with information and evidence on the impact of pooled procurement of health technologies?
- Do you think that cross-border collaboration on procurement in the EU can have a relevant impact in improving the availability and affordability of health technologies for some countries?

In order to clarify the topic of the discussion for respondents, a note with some clarifications was included:

“Pooled procurement (also called joint procurement, central procurement and group purchasing) has been defined as: ‘Purchasing done by one procurement office on behalf of a group of facilities, health systems or countries.’ The main purposes of pooled procurement are to attain lower prices and to improve other procurement conditions through the economies of scale attained by several entities that put together (or collaborate in carrying out) all or some of the procurement functions. The pooled entities might belong to one or several countries, in which case it is referred to as regional, international or cross-border joint procurement.”

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