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# Challenges and opportunities

in improving access to medicines  
through efficient public procurement  
in the WHO European Region





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## Abstract

This report maps different methods used by countries to conduct more efficient procurement and to improve access to treatment, with a focus on procurement of medicines. Efficient procurement involves more than just obtaining the lowest price – it is about creating a healthy market where high-quality products are available at the right time at affordable prices and at the right quantity. Strategic procurement encompasses all activities aimed at improving procurement efficiency. These include, for example, activities to minimize low-value repetitive purchases, to increase the benefit of economies of scale and to reduce transaction and transport costs. In pharmaceutical procurement additional instruments can be leveraged to improve efficiency: using of generics or biosimilar products; reducing the number of medicines procured in a particular therapeutic area, implementation of clinical guidelines and formularies; and creating a competitive market through therapeutic tenders. A country consultation was organized to review national procurement experiences and explore opportunities for collaboration between countries to address key challenges faced in introducing new medicines. It was noted that access to new medicines in Europe could be further facilitated through regional or subregional country collaboration on public procurement of medicines. Discussion points were formulated on how to improve access to new medicines by enhancing the efficiency of procurement systems. A number of initiatives have been set up in recent years. Voluntary collaboration between countries in Europe could also increase efficiency in procurement, and discussion about the possibility of increasing this is growing.

## Keywords

ACCESS TO MEDICINES  
COST CONTROL  
DRUG COSTS  
EUROPE  
GENERIC PRODUCT  
INTERNATIONAL COOPERATION  
PHARMACEUTICAL PREPARATIONS – ECONOMICS  
PROCUREMENT  
TENDER

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# Preface

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In 2015 the WHO Regional Office for Europe, with academic and international partners, conducted a technical review of policy initiatives and opportunities for collaboration and research relating to the process of introducing new and expensive medicines.<sup>1</sup> In September 2015 the Regional Office organized a country consultation to review national experiences and explore opportunities for collaboration between countries to address key challenges faced in introducing new medicines. It was noted that access to new medicines in Europe could be further facilitated through regional or subregional country collaboration on public procurement of medicines.

In line with the country consultation, the Regional Office, in collaboration with other partners, mapped the current procurement processes for medicines in place in countries in the Region. As a result of this analysis, discussion points were formulated on how to improve access to new medicines by enhancing the efficiency of procurement systems. These were discussed during a WHO consultation on strategic procurement on 22–23 September 2016 in Copenhagen, Denmark. This report presents the findings of these activities and outlines future directions based on the conclusions of the consultation with Member States and key partners.

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<sup>1</sup> Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research. Copenhagen: WHO Regional Office for Europe; 2015 (<http://www.euro.who.int/en/health-topics/Health-systems/health-technologies-and-medicines/publications/2015/access-to-new-medicines-in-europe-technical-review-of-policy-initiatives-and-opportunities-for-collaboration-and-research-2015>, accessed 13 October 2016).

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# Abbreviations

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APA	advance purchase agreement
ARV	antiretroviral (medicine)
ATC	Anatomical Therapeutic Chemical (classification system)
CCPNM	Coordinating Commission for Negotiating the Price of Medicines and other Health Inputs
DSP	Division of Health Systems and Public Health
EU	European Union
EUnetHTA	European network for Health Technology Assessment
GDF	Global Drug Facility
GDP	gross domestic product
HIC	high-income country
HPV	human papillomavirus
HTA	health technology assessment
IHR	International Health Regulations
LSE	London School of Economics and Political Science
MEA	managed entry agreement
NHS	National Health Service (of the United Kingdom)
PAHO	Pan American Health Organization
PCP	pre-commercial procurement
PHP	price-halving population
PPP	purchasing power parity
QALY	quality-adjusted life-year
RADS	Danish Council for the Use of Expensive Hospital Medicines
TB	tuberculosis
TRIPS	Trade-related Aspects of Intellectual Property Rights (Agreement)
UNICEF	United Nations Children's Fund
UNRWA	United Nations Relief and Works Agency for Palestine Refugees in the Near East
VEN	vital, essential and nonessential (analysis)
WTO	World Trade Organization

# Introduction

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## Rationale and scope of the report

As the number of new medicines introduced in Europe rises, governments are finding it increasingly difficult to afford them. The introduction of new medicines and other medical technologies, rising expectations from patients and demographic changes are threatening the fiscal sustainability of health care systems (1, 2). Countries across Europe face similar problems, but the challenge is even greater in those experiencing financial pressures. Ensuring affordable prices and supply security is important; therefore, procurement strategies must consider both.

This report reviews how different public procurement practices can influence prices and ensure supply security for pharmaceuticals. Further, it discusses the use of increased collaboration as a means to improve procurement outcomes. In particular, it seeks to provide insights into the following question: how can public strategic procurement and increased collaboration, within and across countries, contribute to improving access to high-cost medicines in Europe?

Responsible use of medicines, from both a clinical and a financial perspective, requires up-to-date policies and regulatory frameworks, as well as cooperation of all parties involved to ensure their implementation.

## Access to high-price medicines

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Decisions to adopt and finance new medicines are increasingly based on value-for-money considerations, including cost-effectiveness and cost-utility analyses. Nevertheless, not all countries in Europe are equipped to operationalize the concept of incremental cost for an added unit of value (such as a quality-adjusted life-year (QALY)). Further, even in countries with mature health technology assessment (HTA) systems, the capacity for procurement-related negotiations on price for new products and negotiation power varies. As a result, prices that countries pay for their medicines may be disproportionately high and incompatible with their purchasing power.

A comparative study of ex-factory prices for new cancer medicines in 16 European countries, Australia and New Zealand found price differences between the highest-paying and lowest-paying countries of between 28% and 388% (3). At first sight those absolute prices may appear to be unfair. Yet from a differential pricing<sup>2</sup> perspective, they would only be unfair if countries with greater ability to pay also paid lower prices than countries with more limited ability to pay. The study appeared to show an overall trend, with Portugal (gross domestic product (GDP) per capita US\$ 21 619), Greece (US\$ 21 843), Spain (US\$ 29 371) and the United Kingdom (US\$ 42 295) paying lower prices on average than Germany (US\$ 45 601), Sweden (US\$ 60 283), Denmark (US\$ 60 362) and Switzerland (US\$ 84 669) (4).

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<sup>2</sup> Understood as an equity or affordability pricing policy (not as the business strategy of "Ramsey pricing", where companies set the prices).

Some studies have found selected medicines to be more expensive in low- and middle-income countries than in high-income ones. One example is the price of Novo Nordisk's 10 ml vial of soluble human insulin in the private sector in different countries. In 2010 it was priced higher in Namibia (US\$ 46.85), Argentina (US\$ 42.78), Fiji (US\$ 37.00), South Africa (US\$ 32.89–33.48 depending on the location) and Indonesia (US\$ 31.07–50.16 depending on the location) than in New Zealand (US\$ 30.85), Australia (US\$ 25.05–29.13 depending on the location) and Canada (US\$ 18.40) (5).<sup>3</sup> Similar results were found for Pfizer's pneumococcal conjugate vaccine, whose price per dose at the manufacturer level in 2014 was higher in Lebanon (US\$ 78.00), Tunisia (US\$ 67.30; hospital price), Morocco (US\$ 63.70; hospital price) and Hungary (US\$ 61.50) than in France (US\$ 58.40) (6). Merck's retail price per dose for human papillomavirus vaccine in 2013/14 was also higher in Lebanon (US\$ 187.77) and Czechia (US\$ 180.38) than in France (US\$ 163.92) (5).<sup>4</sup>

When undertaking such price comparisons in the private retail sector it is important to take into account the possibility of price segmentation within a country. Particularly in low- and middle-income countries, medicines may have higher prices in retail pharmacies targeting wealthier customers while lower prices are offered to the public sector. It then becomes important to verify in which sector medicines are accessed by the majority of the population – particularly those less able to pay. Greater access through the public sector is particularly the case for insulin and vaccines, which are generally purchased and distributed via national programmes benefiting from lower prices. Notably, countries eligible to support from Gavi, the Vaccine Alliance, have benefited from lower vaccine prices. Unfortunately, those countries that cease to be eligible for such support (those whose gross national income per capita grows higher than US\$ 1570, triggering a five-year funding phase-out period), lose funding support and access to vaccines at negotiated low prices. The affordability challenge is even greater in middle-income countries that have never been eligible for funding from Gavi, the Vaccine Alliance (6).

A study comparing ex-factory prices of two new medicines to treat hepatitis C (sofosbuvir and ledipasvir-sofosbuvir) found these to vary substantially between countries worldwide, raising serious concerns about the viability of reducing the global hepatitis C burden (7). After adjusting for average 2015 exchange rates and purchasing power parity (PPP), the study revealed that the cost of treating the entire hepatitis C-infected population in each of the 30 countries examined would range from 10.5% of total pharmaceutical expenditure in the Netherlands to 190.5% in Poland. The high price of ledipasvir-sofosbuvir in England, United Kingdom, led the National Health Service to restrict treatment to the most severely ill patients, despite a positive recommendation by its HTA advisory body the National Institute for Health and Care Excellence (8). The price of a course of sofosbuvir, without other costs, was equivalent to a year or more of the average annual wage of individuals in 12 countries, ranging from 0.21 years in Egypt to 5.28 years in Turkey (7).<sup>5</sup> The study concluded that countries with comparatively fewer resources may be paying higher adjusted prices than wealthier countries.

Despite the limitations affecting the studies described (4–7, 9), even assuming a smaller price difference or no price difference across countries, medicines will be less affordable to less wealthy countries because of their limited ability to pay. The situation for patients in these countries is even worse because they generally operate less comprehensive insurance coverage schemes; thus, patients are more reliant on out-of-pocket payments to finance medicines.

<sup>3</sup> Data from individual pharmacies collected by volunteers on 11 March 2010 and submitted to Health Action International. The number of observations per country varies and may not be nationally representative.

<sup>4</sup> Price data were mostly sourced from websites of official government bodies (such as national insurance companies, ministries of health and similar). Additional sources include literature searches, press searches and personal communications.

<sup>5</sup> The authors assumed a 23% price reduction from the published price in all countries, except those with a negotiated tiered price (Egypt and Mongolia). This estimate was based on the legislated rebate obtained by the US Centers for Medicare & Medicaid Services.

Several suggestions have been made to address the high prices of new medicines. These include:

- delinking the final price of the medicine from research and development costs (10, 11);
- increased use of voluntary licenses (11);
- a voluntary licensing and patent pool (12);
- use of equity pricing to increase access in developing countries (13, 14);
- pricing medicines according to consumers' willingness to pay (9);
- implementing value-based pricing (15); and
- developing a model of fair pricing (16).

All these approaches have their weaknesses. For example, authors also noticed that equity pricing alone is unlikely to be sufficient to increase access in all countries (7), and that equity pricing is inferior to compulsory licensing (17). Further, equity pricing can lead to reduced transparency and anti-competitive behaviour and may be associated with high transaction costs relative to the benefits gained (18). Caution has been called for on value-based pricing as it could lead to unsustainable prices for high-value products like antibiotics (19), and the experience of the United Kingdom shows that its implementation is not straightforward. Despite a lack of agreement on the best tools to influence prices of new medicines, however, there is general agreement that current prices are too high and are limiting access to patients.

Influencing prices and therefore increasing affordability of medicines is a complex matter. Multiple prongs of pharmaceutical policy, legislation and processes need to be activated in a synergistic manner, and stakeholder collaboration within and across countries is required – no one can do it on their own. One important tool that countries could use to influence prices and ensure sustainable supply is strengthening efficient procurement and supply management. This report focuses on the role of procurement as a component in the complex process of securing sustainable access to quality medicines at affordable prices.

# Procurement practices

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## Features of good procurement

Public procurement should ensure compliance with the principles of transparency, competitive tendering and equal treatment for all suppliers. For example, the Treaty on the functioning of the EU (20) established the following principles of good procurement, which apply to any goods and not just medicines:

- transparency – contract procedures must be transparent and contract opportunities should generally be publicized;
- equal treatment and non-discrimination – potential suppliers must be treated equally;
- proportionality – procurement procedures and decisions must be proportionate;
- mutual recognition – giving equal validity to qualifications and standards from other Member States, where appropriate (21).

These apply to all procurement activities, independent of their value.

Management Sciences for Health also identified key elements that are expected to lead to a good procurement outcome:

- reliable payment and good financial management;
- procurement by generic name (international nonproprietary name);
- procurement limited to essential medicines list or formulary list;
- formal supplier qualification and monitoring;
- competitive procurement;
- monopsony<sup>6</sup> commitment;
- order quantities based on reliable estimates of actual need;
- transparency and written procedures;
- separation of key functions;
- a product quality assurance programme;
- annual financial audits with published results;
- regular reporting on procurement performance (22).

Four strategic objectives and 12 operational principles for pharmaceutical procurement were developed and endorsed by the Interagency Pharmaceutical Coordination Group in 1999, involving pharmaceutical advisers from UNICEF, the United Nations Population Fund, WHO and the World Bank (23). The four strategic objectives are:

- to procure the most cost-effective medicines in the right quantities;
- to select reliable suppliers of high-quality products;
- to ensure timely delivery;
- to achieve the lowest possible total cost.

The 12 principles cover the areas of efficient and transparent management, medicines selection and quantification, financing and competition, supplier selection and quality assurance.

In 2007, WHO reported on multicountry regional pooled procurement of medicines experiences in selected African, Caribbean and Pacific Island countries, to identify key principles for enabling pooled procurement. These include shared political will, models of pooled procurement, organization, pricing, patents, financing, sharing of information and experience, capacity-building and harmonization (24).

In addition to the principles set out in these documents, having a strategic outlook when planning procurement is also important. This requires a well structured and knowledgeable procurement function and collaboration with key clinical experts to prioritize actions. Indeed, engaging with clinicians is crucial to achieve responsible use of medicines, as they are ultimately the ones prescribing the medicines. Furthermore, reliable forecasting of demand and monitoring of use are required for sustained impact. This type of dynamic strategic procurement can influence and contribute to shaping markets. This is particularly true for high-volume buyers – either large countries or collaborative procurement networks.

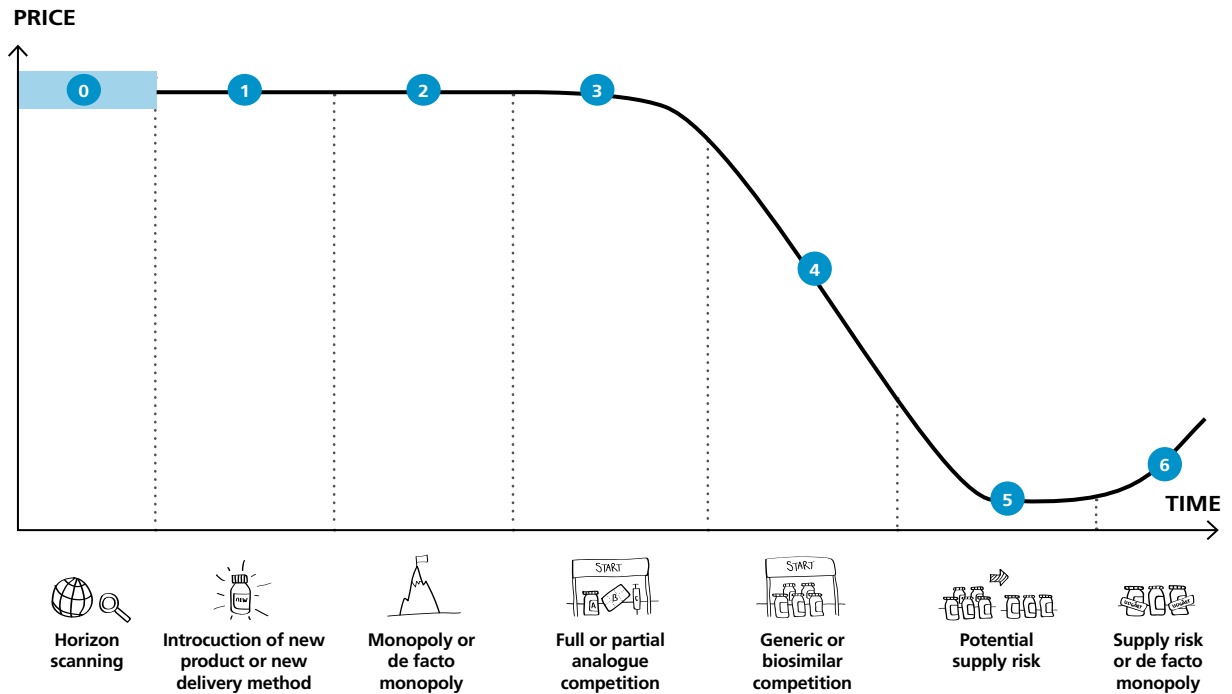
## The product lifecycle

The stage in the lifecycle of a medicinal product has an important influence on its price and availability (Fig. 1). Different procurement scenarios are relevant during the lifecycle to optimize the power of the buyers and address shortcomings in the market like lack of availability, affordability, competition and similar. When new medicines come to market these are patent-protected and competition can only take place as analogue competition. At the opposite end of the spectrum, when many generic products have been in competition, market exit may lead to a new monopoly. In both these extremes

<sup>6</sup> A market situation in which there is only one buyer.

the buyer has limited market power. In between these two points the market has the opportunity to develop, and both industry and buyers have an influence. Affordable prices and ensuring supply security are important and therefore procurement strategies must consider both.

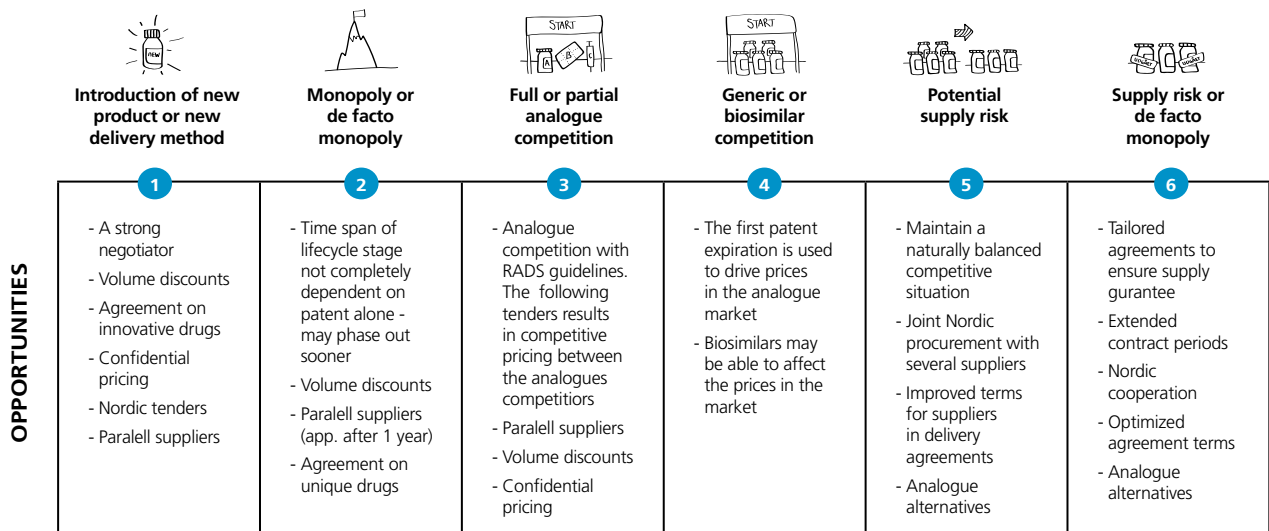
**Fig. 1 |** Pharmaceutical lifecycle stages and generalized price development for a specific disease area or condition



Source: Amgnos, unpublished presentation at the WHO consultation on strategic procurement on 22–23 September 2016 in Copenhagen, Denmark.

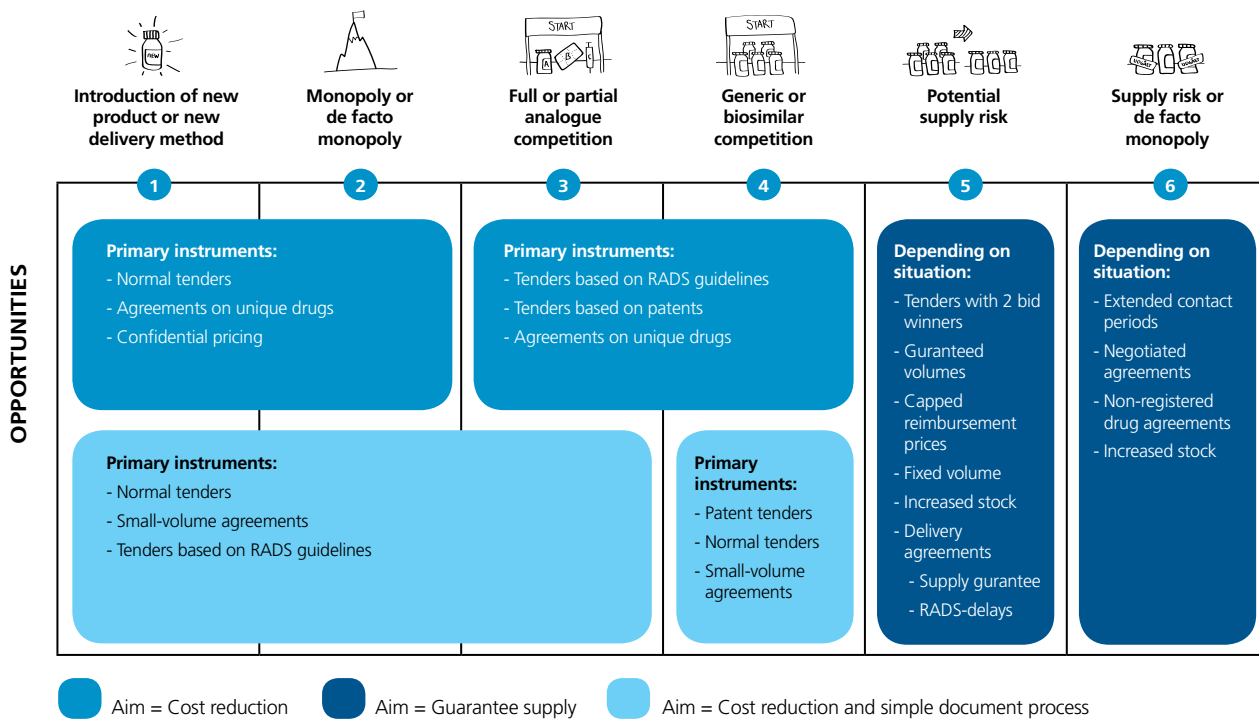
To achieve a healthy market it is therefore essential to consider the product lifecycle (establishing, for example, whether it is a new product or about to go off-patent; an essential or nonessential product). Further, market characteristics should be analysed, examining how many suppliers are in the market, the market production capacity, whether there is high demand for the product, its cost, the plans for its use in the future – short, medium and long term – and so on. This intelligence should guide the choice of procurement method and type of award to use, and should highlight opportunities and risks. Fig. 2 and Fig. 3 use the example of Denmark in analysing lifecycle procurement opportunities.

**Fig. 2 |** Identifying present and future lifecycle opportunities



Note: RADS = Danish Council for the Use of Expensive Hospital Medicines.

Source: Amgnos, unpublished presentation at the WHO consultation on strategic procurement on 22–23 September 2016 in Copenhagen, Denmark.

**Fig. 3** | New category strategy based on the lifecycle model combined with a classification of top-100 drugs (turnover)

Note: RADS = Danish Council for the Use of Expensive Hospital Medicines.

Source: Amgro, unpublished presentation at the WHO consultation on strategic procurement on 22–23 September 2016 in Copenhagen, Denmark.

## Procurement practices in the Region

Through national legislation, countries in the WHO European Region have provided different mandates and frameworks to their institutions responsible for procurement of medicines. Even within the European Union (EU), despite wide harmonization of procurement rules,<sup>7</sup> there are important differences in the way they are implemented (25). Indeed, countries face different challenges and barriers when conducting public procurement for pharmaceuticals. Some have legal frameworks or laws that limit the use of multiyear tenders and agreements owing to annual budget planning cycles.

In addition, some countries facilitate analogue competition (see “Analogous substitution” in the glossary; Annex 1) by allowing bidding at Anatomical Therapeutic Chemical (ATC) classification system level 4 (chemical subgroup), while others restrict bidding to ATC level 5 (chemical substance). Bidding using ATC level 4 specifications can foster analogue competition and is useful when no competition is otherwise possible. As a result, countries use different processes when they are conducting medicine purchasing. These fall into four main groups: open tender, restricted tender, competitive negotiation and direct procurement (22) (Annex 2). This report does not cover the legal status of the national procurement agencies in Europe with the outcomes of their procurement practices. Indeed, several models of national procurement agencies exist in Europe (parastatal or semi-autonomous, fully autonomous, fully statal or government agency).

<sup>7</sup> On 18 April 2016, three new EU directives relating to procurement entered into force: Directive 2014/24/EU on public procurement; Directive 2014/25/EU on procurement by entities operating in the water, energy, transport and postal services sectors; and Directive 2014/23/EU on the award of concession contracts (21).



## Assessing procurement performance

In a healthy market, high-quality medicines are readily available at competitive and affordable prices from a range of suppliers (26). To assess the performance of a market and the need for intervention to shape it, different frameworks of analysis have been proposed (Table 1). To ensure supply security and a healthy market, multiple suppliers are usually required and will be awarded the contract for the same product (not just the bidder offering the lowest price). This avoids dependence on one supplier and creation of a monopolistic situation.

Various procurement agencies have developed frameworks to define the determinants of a healthy market. A summary of these is provided in Table 1.

**Table 1** | Frameworks for market analysis and intervention

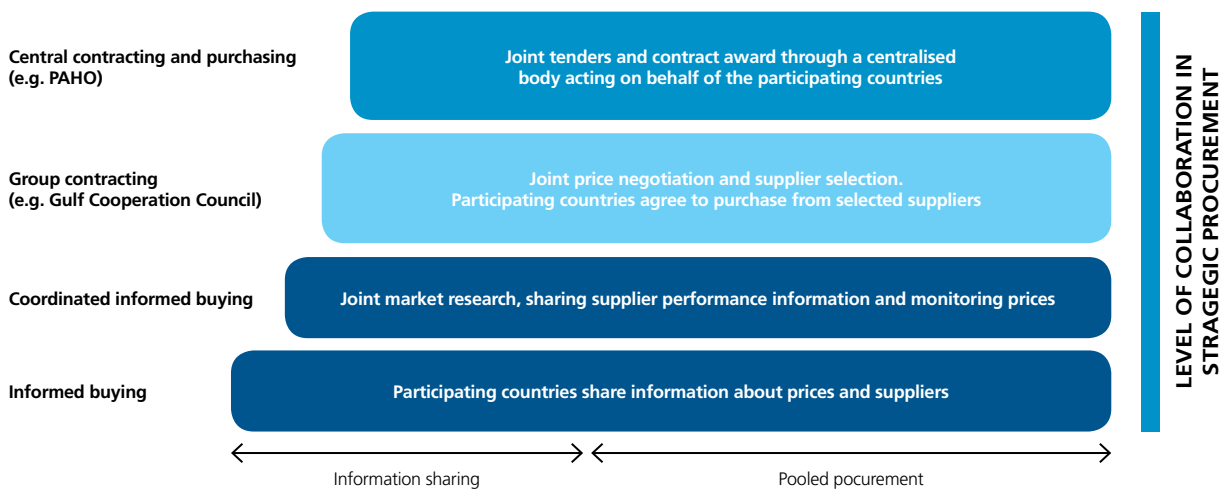
	UNITAID market dynamics dashboard (27)	United Nations Children's Fund (UNICEF) market dashboard (28)	Reproductive Health Supplies Coalition (29)	Results for Development Institute and Global Fund (30)	Healthy markets framework (31) <sup>8</sup>
<b>Dimensions assessed (determinants of a healthy market)</b>	Availability, affordability, quality, acceptability/adaptability, delivery	Availability, affordability, competition, quality, acceptability/adaptability, delivery, funding security	Appropriate design, high-quality products, secure supply, affordable prices, availability to the end user	Market size, market growth potential, supplier power, buyer power	Inadequate supply, supply meeting demand and country specifications, buffer capacity, individual supplier risk, national regulatory agency risk, total system effectiveness, long-term competition, product innovation
<b>Aim</b>	To provide a snapshot of current market dynamics and opportunities for intervention to improve access to treatments, diagnostics and preventives for HIV/AIDS, tuberculosis (TB) and malaria	To provide a high-level analysis of 67 key supply markets for women and children that is of relevance to governments, agencies and partners that procure supplies for children, and for manufacturers and press that follow market trends, opportunities and constraints	To outline the dimensions by which the market's effectiveness, efficiency or functionality can be judged	To provide a framework for market analysis and intervention for antiretrovirals (ARVs) and beyond	To better articulate desired market outcomes, improve the assessment of risks and benefits of market interventions and procurement tactics, and measure improvements in health across markets in a clear and consistent manner

<sup>8</sup> Developed by Gavi, the Vaccine Alliance; UNICEF Supply Division; and the Bill and Melinda Gates Foundation.

## Initiatives to increase collaboration between countries

Countries should be encouraged to work on processes to bring efficiency into their procurement and supply management systems but may individually find it difficult to address issues. Discussion about the possibility of increasing collaboration between countries in Europe is increasing. When considering cross-country collaboration on public procurement for pharmaceuticals, countries should assess how regulatory issues, legal frameworks and financial laws could have an impact on feasibility. Collaborations can take place at various levels, varying from informed buying – where participating countries share information on prices, suppliers and HTA methodologies but conduct their own procurement individually – to central contracting and procurement – where participating countries conduct joint tenders through a central buying unit (22) (Fig. 4).

**Fig. 4** | Levels of collaboration



Note: PAHO = Pan American Health Organization.

Source: Modified from Management Sciences for Health (22).

A number of initiatives have been set up in Europe in recent years. Voluntary cooperation between 24 EU governments has been established to conduct joint procurement of pandemic vaccines and medical countermeasures (32).<sup>9</sup> An EU-supported project called “Healthy Ageing – Public Procurement of Innovations (HAPPI)” was set up in 2012 to enable public health purchasers to collaborate on detecting and purchasing innovative and sustainable solutions to facilitate healthy ageing (33). The European Commission has been asked to investigate the possibility of organizing joint procurement for hepatitis C treatments, although this will not happen before the first half of 2017 (34).

Under the Dutch Presidency, the Council of the EU released a series of recommendations on how to strengthen the balance in the pharmaceutical systems in EU Member States (35). The Council invited Member States to strengthen voluntary collaboration between relevant authorities and payers on pricing and reimbursement matters, with the aim of increasing affordability and improving access. Further, the Council invited Member States and the European Commission to explore synergies between the work of HTA bodies and payers, and to strengthen collaborations between countries, particularly under Joint Action 3 of the European Network of Health Technology Assessment (EUnetHTA). Finally, the Council invited the European Commission to conduct, with the close involvement of Member States, an analysis of the impact of incentives to facilitate investment in research and development and in marketing authorization provided by the EU legislation on innovation, availability and accessibility of both originators and generic medicines.

<sup>9</sup> Article 2 of the Joint Procurement Agreement provides that medical countermeasures are “any medicines, medical devices, other goods or services that are aimed at combating serious cross-border threats to health, as referred to in Decision 1082/2013/EU”.

In April 2015 Belgium and the Netherlands, later joined by Luxembourg, signed a memorandum of understanding to exchange information on and, in selected cases, jointly negotiate prices for medicines for rare diseases, particularly orphan drugs (36). On 17 June 2016 Austria signed a letter of intent to join this scheme. The group, now referred to as “Beneluxa”, intends to strengthen exchange of information relevant to pharmaceutical policy, collaborate on horizon scanning and HTA and jointly negotiate prices (37). In June 2015 Bulgaria and Romania announced that they intended to procure high-price medicines jointly (36). During the same month a Nordic pharmaceutical forum was set up with the intention of achieving collaboration between purchasers of medicines in Denmark, Iceland, Norway and Sweden, sharing experiences and jointly tackling common challenges around new and expensive medicines, horizon scanning and supply chain safety (38). In a further initiative, at the end of a ministerial meeting on 2–3 June 2016 in Sofia, representatives of Bulgaria, Croatia, Estonia, Hungary, Latvia, Romania, Serbia, Slovakia, Slovenia and the former Yugoslav Republic of Macedonia signed a declaration that they would collaborate on issues affecting access to medicines. Issues of mutual concern include the availability of essential medicines, high prices of innovative medicines, cost–effectiveness analysis, information sharing and mutual transparency in pharmaceutical policy (39).

These EU-wide and more localized initiatives demonstrate a growing interest from countries in Europe to increase voluntary collaboration on access to new medicines and other medical products.

## Regional procurement initiatives in other WHO regions

A number of regional procurement initiatives have been launched since the late 1970s (24, 40, 41), although some have been discontinued (including the Central America Revolving Fund for Essential Drugs, launched in 1986 (42), and the Arab Maghreb Union, launched in 1988). Among the operational initiatives, the extent to which they are active varies widely, and there has been limited evaluation of these initiatives in general – particularly independent evaluation. Among the most active in conducting joint procurement is the Pan American Health Organization Drug Revolving Fund, established in 1979. Among its many achievements was the negotiation of a reduced price for human papillomavirus (HPV) vaccine (US\$ 13.79 per dose for the quadrivalent vaccine in 2013); this increased access to the specific vaccine in the region. The Organisation of Eastern Caribbean States Pharmaceutical Procurement Service (formerly the Eastern Caribbean Drug Service), was established in 1986 (43). The average cost savings it negotiated for 25 selected items over a five-year period (1998–2002) are reported to be 37% (24). The Gulf Cooperation Council was launched in 1976 (44). In Africa the Association Africaine des Centrales d’Achats de Médicaments Essentiels was set up in 1996 (45), the regional pooled procurement of medicines in the East African Community in 2008 (46, 47) and the Southern African Development Community Strategy for Pooled Procurement of Essential Medicines and Health Commodities in 2007 (project started in 2013 and will end in 2017) (48). The Joint Bulk-Purchasing Scheme for the Pacific Island Countries started in 1999 (40).

## Global procurement initiatives

In addition, in the past 15 years supranational/global financing and procurement initiatives relating to specific interventions and diseases have had a tremendous impact on access to new high-quality medical products. These include Gavi, the Vaccine Alliance; the Global Drug Facility (GDF); the Global Fund to Fight AIDS, Tuberculosis and Malaria; and similar (49–52). The initiatives conduct global tenders for specific products and have managed to develop the market and enhance availability of affordable generic medicines. An example of GDF achievements is the reduction by up to 26% in the cost of treating a multidrug-resistant TB patient for 24 months, with second-line drugs costs falling from US\$ 7890 in 2011 to US\$ 5822 in 2013, at nominal prices.

# Consultation on strategic procurement of new medicines

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The WHO Regional Office for Europe, in collaboration with other partners, mapped the current procurement processes for medicines in place in countries in the Region. A country consultation was organized to review national procurement experiences and explore opportunities for collaboration between countries to address key challenges faced in introducing new medicines. It was noted that access to new medicines in Europe could be further facilitated through regional or subregional country collaboration on public procurement of medicines. As a result of this analysis, discussion points were formulated on how to improve access to new medicines by enhancing the efficiency of procurement systems.

The Regional Office then organized a consultation on strategic procurement of new medicines with 42 Member States in the WHO European Region and key partners (including the Austrian Public Health Institute, European Commission, London School of Economics and Political Science, Organisation for Economic Co-operation and Development and UNICEF), which was held on 22–23 September 2016 in Copenhagen, Denmark. During the consultation a number of countries and partners presented their experiences with increasing collaboration in the area of procurement. The following topics were discussed during the consultation (see Annex 3 for the meeting agenda).

## **1. Analysing spending on medicines in hospitals – what can be achieved? How can this information be used proactively in developing specific approaches to procurement for specific categories of medicines?**

Working groups discussed the use of product lifecycle analysis (Fig. 1, Fig. 2) to inform the choice of procurement method and examine how the method can affect the final price and supply sustainability. The following topics were addressed:

- how to set up an effective procurement system;
- categorization of products;
- advantages and limitations of having a centralized body for procurement;
- use of e-procurement tools;
- planning and forecasting;
- market analysis;
- monitoring and evaluation;
- contract management/monitoring of supplier performances: delays, shortages, quality issues.

## **2. Greater procurement collaboration can increase price transparency and can lead to greater fairness and improved affordability.**

Working groups discussed how price transparency (nationally as well as through international cooperation) could be improved to support strategic procurement, looking at:

- existing platforms to share information;
- new initiatives to increase transparency.

## **3. Informed purchasing through collaborative procurement enhances negotiation power, increases efficiency and contains costs.**

The benefits of informed purchasing include increased price transparency, sharing of supplier performance, sharing of strategic plans, sharing of technical capacity in efficient procurement practices through study tours and conducting regional training on forecasting and negotiation strategies. Topics for discussion at the session on “joint procurement – challenges and successes” included:

- components of procurement (in a broad sense) that might benefit from collaboration between buyers;
- the impact of different types of contract/agreement on price and volume, including supply security;
- the circumstances in which price negotiations have the highest impact;
- methods for provision of access to information/practitioner networks (informed buying), including supplier performance, price and minimum order quantity;
- subregional collaboration on strategic procurement – whether creating “togetherness” might improve opportunities for supply sustainability.

**4. Voluntary procurement collaboration may be the most efficient model for collaboration in the European context, as legal frameworks vary substantially and may become barriers to closer collaboration.**

The following topics were discussed during the final panel discussion:

- developing common goals and value definition related to introduction of new medicines;
- how to ensure a lean structure and operation;
- the importance of abiding by agreed frameworks.

## Methods applied

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To facilitate discussion of the discussion points and provide insight into the main question under consideration (how can public strategic procurement and increased collaboration, within and across countries, contribute to improving access to high-cost medicines in Europe?), primary and secondary data collection were undertaken to inform the evidence generation process. For secondary data a literature review collected information on procurement methods used worldwide and assessed their impact on price, expenditure and volume of medicines. This was complemented by primary data collection through a survey on pharmaceutical procurement practices and needs in the WHO European Region (see Annexes 4 and 5). A summary of the findings of these two evidence generation processes is provided in the next section, while a more detailed presentation is included in Annex 4 (survey results) and Annexes 6–14 (literature review findings), along with two case studies (Annex 15).

The focus of this report is on strategic procurement of new and high-cost medicines. The term “high-cost medicine” has not yet been clearly defined in the literature, but is generally used when referring to on-patent medicines for the treatment of cancer, biopharmaceuticals for chronic conditions like rheumatoid arthritis and psoriasis and any other medicinal products whose cost, if not covered by mandatory health insurance, is likely to preclude access to most patients. To increase access to new medicines, securing competitive prices is crucial. This also leverages budget savings that can be generated through increased use of generics and biosimilars. The savings can be used to procure more medicines to treat more patients.

# Key findings from the literature review and survey

For many of the following procurement practices, the evidence from the literature is too weak to conclude that they represent universal “best practices” in the procurement of medicines. This is due to the diversity of studies providing evidence on their impact. The findings are mostly based on individual studies of a single country’s procurement method; they use different methods and analyse different products, making the evidence very context-specific and not necessarily generalizable to other settings.

Under specific circumstances and in specific settings, the following practices in the area of strategic procurement have been found to lead to competitive prices and increased access for patients (Tables 2 and 3).

**Table 2** | Procurement practices likely to lead to more competitive prices and increased access for patients

Procurement practice	Countries using the practice
A centralized body to negotiate prices of on-patent medicines	Denmark, France, Greece, Italy, Norway, Malta, Mexico, Spain, United Kingdom
Analysis of the market and products	Denmark, France, Italy, Norway, Spain, United Kingdom
Pooling volume at different levels	Brazil, Bulgaria, Cyprus, Croatia, Denmark, England (United Kingdom), Finland, Georgia, Greece, Hungary, Iceland, Italy, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Malta, Poland, Portugal, Republic of Moldova, Republika Srpska (Bosnia and Herzegovina), Romania, Russian Federation, Serbia, Slovenia, Spain (various regions), Tajikistan, Ukraine, United Kingdom
Involvement of clinical staff in the procurement process to ensure products procured are in line with clinical needs and development of new clinical guidance before introduction of the new products	Denmark, Italy, Norway, Scotland (United Kingdom), Sweden
Use of framework agreements with suppliers	Belgium, Bulgaria, Croatia, Czechia, Denmark, Finland, France, Greece, Hungary, Iceland, Italy, Norway, Portugal, Republika Srpska (Bosnia and Herzegovina), Romania, Slovenia, Spain, United Kingdom, United States
Bidding at ATC level 4 (analogue competition)	Belgium, Bulgaria, Cyprus, Denmark, France, Hungary, Lithuania, Norway, Poland, Slovenia, United Kingdom
Price–volume agreements for expensive medicines	Denmark, France, Italy, Lithuania, Spain
International procurement agencies	GDF, United Nations Development Programme, UNICEF, United Nations Relief and Works Agency for Palestine Refugees in the Near East (UNRWA)

Note: Information is taken from findings from the literature review, the survey and information from WHO networks. The list is not exhaustive.

**Table 3** | Gaps and barriers that need to be addressed (risk mitigation) to secure competitive prices and better access for patients

Gap to be addressed	Findings from the literature review (no geographical limit)	Findings from the survey (respondents in the WHO European Region)
Ensuring the availability of supportive legislation and policies	Cyprus, several Latin American countries, sub-Saharan Africa	Belgium, Italy, Ukraine
Limited human resource capacity: sufficient number of trained staff for the task and with the right skills	Greece, Mexico	Bulgaria, Croatia, Kyrgyzstan, Republic of Moldova, Ukraine, United Kingdom
Accurate forecasting of needs	While the extent to which this issue affects procurement outcomes varies across countries, it is a challenge in all countries independently of the level of development of their procurement functions.	
Fragmentation of procurement responsibilities across hospitals, in- and outpatient products or simply different products	Estonia (HIV/AIDS, TB, antidotes, methadone)	Austria (fragmentation between outpatient and inpatient sectors), Poland (HIV/AIDS), Spain (various regions)
Small market	Cyprus, Estonia, Iceland, Latvia, Lithuania, Malta, Sweden	Bulgaria, Cyprus, Iceland, Malta
Insufficient monitoring and evaluation of procurement bodies (governance aspects, public availability of national and international prices for benchmarking) and supplier performance; lack of use of this information for future decisions relating to procurement	Mexico (procurement bodies), Denmark (suppliers)	Croatia, Republic of Moldova
Tender award criteria (price is a blunt instrument if other criteria are not taken into account at the same time)		Bulgaria, Kazakhstan, Kyrgyzstan
Lack of transparency, particularly relating to public availability of procurement prices	Multicountry studies (EU)	Albania, Belgium, Czechia, Hungary, Norway, Slovenia, Republic of Moldova

In the survey, countries expressed interest to work on the following products (numbers of countries): orphan medicines (6), vaccines (6), high-price medicines (5), new TB and HIV medicines (4), cancer medicines (3), new hepatitis C medicines (3), all medicines (3) and medicines for unmet medical needs (1) (see the section on collaboration in Annex 4). Further, most countries expressed interest in participating in the consultation to share their procurement experiences.

Due to the specificity of the European market, few cases exist in which countries have worked together to influence the market jointly for sustainable supplies of new medicines. Examples of country collaborations in procurement were presented during the September consultation (Annex 3).



# Key findings from the consultation

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The following topics were discussed during the WHO consultation with Member States. This section sets out a summary of the main points raised.

## **1. Analysing spending on medicines in hospitals – what can be achieved? How can this information be used proactively in developing specific approaches to procurement for specific categories of medicines?**

The consultation confirmed that countries' public procurement practices are very different among European countries. Some countries have developed public agencies for procurement that negotiate and manage the introduction of new high-price medicines into the hospital sector. In these countries, clinicians are involved in the process of development of the tender document to ensure alignment in the introduction, management and use of medicines in the inpatient sector and to foster their responsible use. Analysing spending on medicines in hospitals is an important tool in these cases. The focus is on efficiency and reduction of waste, sustainable access to innovation and efficient use of public resources.

Other countries have limited control over what products are procured and used in their hospital sectors; there is limited or no collaboration between hospitals on pricing, procurement and/or fostering efficiency and reduction of waste linked to use of public pharmaceutical expenditures.

Whether or not countries have public responsibility for procurement for the hospital sector it is considered important to analyse both hospital spending on medicines and the market to obtain efficiency, best prices and supply sustainability.

It seems likely that analysing spending on medicines in hospitals can be strengthened in many countries through voluntary collaboration by relevant partners. Such analysis would help to identify opportunities and efficiency improvements that may provide room for manoeuvre and facilitate sustainable access to medicines.

## **2. Practical steps to develop an international/national tender for new medicines for hospitals and the use of various procurement tools as contractual modalities**

With an analytical approach to procurement of medicines, procurement experts can benefit from collaboration with other countries' experts. Some countries in Europe face challenges owing to their size, language and geographical position, but some of these challenges could be overcome and this should be explored further by strengthening subregional collaboration.

Depending on the products, different tender procedures can be considered. Price should not be the only criterion used to award a supplier a contract: supply security and the concept of a healthy market should also be considered. Countries may also wish to consider further analogue competition, as this has proved useful. Developing specific procurement strategies can be helpful in obtaining efficient results; it was suggested that there should be more focus on joint development of procurement strategies for specific priority medicines to facilitate fair pricing and sustainable access to new high-price medicines.



### **3. Stakeholder analysis before moving to centralized procurement: exploring possible partnerships, benefits and challenges. How to develop strategies that involve partners, inform stakeholders and prepare for any negative reactions.**

Many stakeholders have a role in the procurement process and the power and influence those groups have varies depending on the country. It is essential, however, to conduct a stakeholder analysis when a country decides to move from decentralized to centralized procurement. The potential benefits of voluntary centralized procurement are many, including enhancement of the strategic procurement capacity. Nevertheless, planning is very important and stakeholder analysis is essential to elucidate challenges and opportunities.

### **4. How can improved transparency (nationally as well as through international cooperation) support strategic procurement?**

Price transparency could have benefits for many countries and seems relevant for public procurement of medicines. Sharing non-price information is also important to increase transparency. Countries in Europe are willing to enhance national and international cooperation; increasing transparency is an important commitment to good governance and will be an important element in future work on fair pricing.

### **5. Prerequisites for preferred contracts with supplier to ensure value for money in the outpatient sector**

Price should not be the only criterion to award a supplier a contract: many other technical requirements should be taken into consideration. Having more than one supplier is essential for a healthy market, and use of separate contracts for distribution of medicines is a relevant tool to consider. To ensure supply, contracts should include guarantees. Different contract modalities are available and should be used according to the specific situation.

## Conclusions from the consultation and next steps

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During the consultation, a number of countries and partners presented their experiences with increasing collaboration in the area of procurement. Their experiences spanned from sharing information on prices and HTA, to joint negotiations, all the way to joint procurement of medicines and vaccines (see Fig. 4). Practical aspects of increasing collaboration – in particular challenges and opportunities, analysis of spending on medicines in hospitals and introduction of preferred supplier contracts in the outpatient sector – were the focus of group work. This section summarizes the main conclusions from these discussions.

Efforts to improve procurement should fit into the overall objective of developing a healthy and inclusive (of patients, clinicians and industry) market that delivers results for patients. Participants stressed that price should not be the main focus of collaboration; instead, the ultimate goal should be treating more patients with cost-effective medicines that are also affordable. The business proposal for industry is therefore lower prices in exchange for higher volumes. This means that increased use of generics and biosimilars can free up funds to treat more patients. Norway illustrated this with the example of biosimilar infliximab for rheumatoid arthritis (53). Not only were more patients treated but savings on total expenditure on this medicine were also generated. The successful switch to a biosimilar was

achieved by working closely with clinicians and patients. Other issues that need to be taken into account beyond prices are, for example, environmental issues and additional expenses on top of the price offered (such as packaging, transportation, labelling).

All presentations highlighted very clearly the need for thorough market analysis. A sound knowledge of the product and the market is required to obtain good procurement outcomes. A sound procurement strategy that takes into account the product lifecycle (Figs. 1–3) is also needed.

Intellectual property issues were an important topic of discussion – in particular the negative impact of secondary patents and evergreening on prices and access. For example, GLIVEC® is off-patent in Cyprus (since 2013) for the treatment of chronic myeloid leukaemia and the generic costs €117.6 per month. There is a secondary patent (until 2020) for the use of GLIVEC® for the treatment of gastrointestinal stromal tumours, and the cost of the originator medicine is €2168.4 per month.

The issue of limited use of compulsory licensing in the WHO European Region was raised. Professional groups, academics and civil society groups have called for its use to increase access to direct antiviral medicines in Italy (54). Compulsory licensing is a legal instrument but no country in the Region has yet taken concrete steps in this direction for hepatitis C, probably for fear of retaliation from industry. Concerns about undue pressure from governments and the private sector on countries wishing to implement the Trade-related Aspects of Intellectual Property Rights (TRIPS) Agreement flexibilities including compulsory licensing were raised in the report of the United Nations Secretary-General's High-level Panel on Access to Medicines (11). The Panel recommended that such instances should be reported to the World Trade Organization (WTO) and that punitive measures should be undertaken against offending WTO members. Undue pressure and limited capacity to implement compulsory licensing were discussed well before the release of the High-level Panel report. In this context, authors have suggested that increased cooperation between countries may facilitate increased use of compulsory licensing (41).

The issue of evergreening discussed during the consultation was also highlighted in the United Nations High-level Panel report, which recognized the issue of secondary patents granted for minor but important changes as a barrier to generic or competitor entry (11). The Panel recommended that WTO members make full use of the provisions in Article 27 of the TRIPS Agreement by adopting and applying rigorous definitions of inventions and patentability that prevent evergreening and ensure that patents are only awarded for genuine innovations.

Price transparency was a central topic in most discussions. Countries tend to be willing to share their "real prices" (net of discounts) in the hope of obtaining better ones through collaboration, but political pressures may prevent such disclosure? Further, the possibility exists that countries with large populations that therefore have high bargaining power with industry may think they are better off on their own. Initiatives like Euripid already exist in the EU to share prices of medicines; this gives access to price information to participating countries and collaboration initiatives like Beneluxa. It is important to make increased use of existing tools. In this respect, the United Nations High-level Panel recommended building on existing WHO pricing-based webpages, such as the Global Price Reporting Mechanism (55) and V3P (56), to establish and maintain an international database of prices of on-patent and off-patent medicines including biosimilars, covering both public and private sectors in all countries where a product is registered (11). In the end, however, it is not only about making more information available but rather about ensuring that the information is used in a meaningful way.

Participants generally agreed on the need for increased collaboration; however, collaboration needs to be targeted to areas where there is mutual benefit and is best started through pilots. Information sharing (horizon scanning, HTA, prices) was suggested as a starting-point, thereafter moving gradually

to closer forms of collaboration such as price negotiation or even joint procurement. When undertaking joint procurement it is best to start with well developed pilots; these also contribute to documenting the impact of voluntary collaborative procurement.

In the end prescribing is in the hands of clinicians: national procurement experts need to engage with them when making procurement decisions and find effective ways to communicate to ensure that cost-effective medicines are prescribed and used in a responsible manner. Engagement with clinicians and patients is particularly important to increase use of biosimilars and introduce analogue substitution. Another partner with whom better dialogue is needed is industry. Despite many conflicting objectives, public health bodies and industry share the common aim of ensuring access. It is also important to communicate with industry to know which products are about to enter or exit the market.

Finally, setting up a procurement practitioners' network was suggested as an overall future activity to facilitate exchange of information and experience in procurement of medicines, as established by UNICEF for vaccine procurement.

## Next steps

The strategic procurement workshop was the first of its kind organized by the WHO Regional Office for Europe to discuss the challenges of procuring pharmaceuticals in the Region. Voluntary collaboration on public procurement of high-price medicines and other relevant products is relatively new in Europe; it was confirmed that interest is growing in developing and expanding collaboration in areas of mutual benefit.

Creation of a strategic procurement working group – a medicines procurement practitioner's forum for the European Region – seems a natural next step. The Regional Office will organize a smaller technical meeting in 2017 to ascertain country interest and willingness to continue this collaboration and to develop the terms of reference for a working group to enhance country collaboration. In addition, WHO will convene a global dialogue among relevant stakeholders to explore strategies for establishing fair prices for essential medicines. WHO, in consultation with an advisory group, will organize a two-day public forum in spring 2017, along with a series of academic landscape analyses to frame the discussions of the forum.

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# ANNEXES

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## Annex 1

## Glossary

Access	<p>The patient's ability to obtain medical care, including medicines, and a measure of the proportion of a population that reaches appropriate health services, including medication.</p> <p>Ease of access is determined by such components as the availability of medical services and their acceptability to the patient, the location of health care facilities, transportation, hours of operation and cost of care.</p> <p>Barriers to access can be financial (insufficient monetary resources), geographical (distance to providers), organizational (lack of available providers) and sociological (such as discrimination or language barriers). Efforts to improve access often focus on providing or improving health coverage.</p>
Advance purchase agreement (APA)	<p>A contract, usually for multiple years, between a manufacturer and a third party such as an international donor agency.</p> <p>The goal of an APA is to create market stability for the buyer (product availability will be guaranteed) and the manufacturer (there will be an assured market for the product in an agreed quantity and price). The creation of APAs is intended to increase incentives for the development and production of medicines for diseases that may not otherwise be commercially attractive.</p>
Affordability	<p>The extent to which medicines and further health care products are available to the people who need them at a price they/their health system can pay (1).</p>
Analogous substitution	<p>Dispensation of a medicine (often <b>generic</b>) by the pharmacist with a different active ingredient (or combination product) but the same therapeutic effect instead of the product prescribed by the physician (2).</p>
Anatomical, Therapeutic, Chemical (ATC) classification	<p>A classification system of medicines where the active ingredients are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties (3).</p>
Biological products	<p>Any virus, therapeutic serum, toxin, antitoxin, hormone or protein, including monoclonal antibodies or similar products used to diagnose, prevent, treat or cure a disease or condition (4).</p>
Biosimilar medicines	<p>A biologic product sufficiently similar in quality, safety and efficacy to an already licensed and market-approved biologic product that is shown to have no clinically meaningful differences from the original biologic product (4).</p>



Commitment contract	An agreement with a company to deliver (goods or services) on mutually agreed and binding terms.
Compulsory licensing	Undertaken when a government allows someone else to produce the patented product or process without the consent of the <b>patent</b> owner. It is one of the flexibilities on <b>patent</b> protection included in the World Trade Organization's agreement on intellectual property — the Trade-related Aspects of Intellectual Property Rights (TRIPS) Agreement (5).
Cost–effectiveness analysis (CEA)	An economic analysis that assesses both the costs and the effects of a health intervention. Costs are measured in monetary units. Effects are measured in units of outcomes experienced such as life-years gained, <b>quality-adjusted life-years</b> gained or cases of disease prevented. Whether the outcome of an analysis is cost-effective depends on the cost–effectiveness threshold value. CEA can identify the alternative that, for a given output level, minimizes the actual value of costs or, for a given cost, maximizes the outcome level (2).
Differential pricing	The strategy of selling the same product to different customers at different prices. In the case of (reimbursable) medicine prices these would vary among countries according to their ability to pay. It was not introduced in European countries due to the widespread practice of <b>external price referencing</b> and the existence of parallel trade (2).
Discount	A price reduction granted to specified purchasers under specific conditions prior to purchase (2).
Economics, health economics	The study of how scarce resources are allocated among alternative uses for the care of sickness and the promotion, maintenance and improvement of health, including the study of how health care and health-related services, their costs and benefits and health itself are distributed among individuals and groups in society.
Electronic procurement (e-procurement)	An Internet-based tendering tool to conduct procurement. E-procurement occurs when the activities of the purchasing process are conducted electronically, typically over the Internet, to shorten the cycle time and lower the transaction costs of the acquisition process. It increases efficiency and improves transparency. This goes beyond simply moving to electronic tools; it rethinks various pre-award and post-award phases with the aim of making them simpler for businesses to participate in and for the public sector to manage. It also allows for the integration of data-based approaches at various stages of the procurement process. Several tools are available on the market (6).
Estimated quantity contract	A contract in which the tender quantity is an estimate rather than a firm order.

Evergreening	The process of making slight modifications to existing medicines that are patentable but do not represent a meaningful therapeutic advancement (7). By patenting peripheral aspects of drugs such as their coating or normal metabolites, brand manufacturer can extend the <b>patent</b> lifetime of existing medicines (8).
External price referencing	The practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country (2).
Fixed-quantity contract	A contract that specifies guaranteed quantities (with a small variation sometimes allowed) and delivery either in one large shipment or smaller, separate shipments over the life of the contract.
Forecasting	The process of estimating pharmaceutical needs for the next purchasing order.
Framework agreement	An agreement between two parties that recognizes that the parties have not come to a final agreement on all matters relevant to the relationship between them, but have come to agreement on enough matters to move forward with the relationship, with further details to be agreed in the future. It is intended to provide a reliable framework for expenditure over time. For example, a framework agreement may define how prices of medicines are set and specify <b>rebate</b> arrangements and price reductions for off- <b>patent</b> medicines when competitors enter the market and the like.
Generic product (medicine)	<p>A pharmaceutical product (medicine) that has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicine, and whose bioequivalence with the reference medicine has been demonstrated by appropriate bioavailability studies. According to European Union legislation, different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorized active substance must be supplied by the applicant.</p> <p>The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form.</p> <p>Generics can be classified as branded (with a specific “invented” trade name) and unbranded (using the international nonproprietary name and the name of the company).</p> <p>This definition refers to European legislation. It should be noted, however, that a variety of different, sometimes overlapping, definitions of the term “generics” are in use owing to differences in the requirements for registration of generics between countries the world over. These differences especially relate to the degree and proof of therapeutic equivalence and the fact that they can be sold as branded or unbranded.</p> <p>WHO defines generics as multisource pharmaceutical products that are therapeutically equivalent and interchangeable, not taking into consideration whether or not the “originator” molecule is, or was, under <b>patent</b> protection (2).</p>

Global Price Reporting Mechanism	A database maintained by WHO recording international transactions of HIV, tuberculosis and malaria commodities purchased by national programmes in low- and middle-income countries (9).
Health outcome-based agreement	A performance-based risk-sharing arrangement where <b>reimbursement</b> for specific products is tied by an agreed formula to a measure of clinical outcomes in the "real world". The manufacturer provides <b>rebates</b> , refunds or price reductions if the product fails to meet the agreed outcome targets.
Health technology assessment (HTA)	Health technology is the application of scientific knowledge in health care and prevention. HTA is a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner. Its aim is to inform the formulation of safe, effective health policies that are patient-focused and seek to achieve best value (10).
Healthy market	A market in which high-quality products can be readily procured at a fair and competitive price from a range of suppliers (11).
High-cost/high-price/premium-price medicines	This concept has not yet been clearly defined in the literature. It is generally used, however, when referring to on- <b>patent</b> medicines for the treatment of cancer; biopharmaceuticals for chronic conditions like rheumatoid arthritis and psoriasis; and any other medicinal products which, if not covered by mandatory health insurance, have a cost likely to preclude <b>access</b> to most patients.
Horizon scanning	<p>The systematic identification of health technologies that are emerging, new or becoming obsolete, and that have the potential to effect health, health services and/or society.</p> <p>An emerging health technology in this context is one that has not yet been adopted within the health care system. It could be a pharmaceutical in Phase II or III of clinical trials or pre-launch stage, or a medical device in the pre-marketing stage.</p> <p>A new health technology is one that is in the launch, early post-marketing or early diffusion stages.</p> <p>Horizon scanning systems (such as early awareness and alert systems) aim to support decision-making and the adoption and use of innovative technologies to the benefit of patients and health services (2).</p>
Innovative medicines	A common definition is currently lacking, but from a public health perspective, the level of innovativeness of a medicine is primarily defined by the benefits the medicine generates for patients. These can be in the therapeutic, clinical or quality of life domains, but also in the socioeconomic domain (12).
Inpatient/hospital care	Care of patients whose condition requires admission to a hospital (2).

Joint procurement	The procurement of certain products or services done by a single purchasing body for several health care providers (such as hospitals, regions or countries) (2).
Managed entry agreement (MEA)	An arrangement between a manufacturer and payer/provider that enables <b>access</b> to (coverage/ <b>reimbursement</b> of) a health technology subject to specified conditions. These arrangements can use a variety of mechanisms to address uncertainty about the performance of technologies or to manage the adoption of technologies in order to maximize their effective use or limit their budget impact. Several types of MEA exist: <b>access</b> with evidence development, conditional coverage, conditional treatment continuation, coverage with evidence development, only in research, only with research, outcome guarantees, patient access schemes, pattern or process care, performance-based agreement, performance-based health outcome reimbursement schemes, performance-linked reimbursement, price-volume agreements and risk-sharing schemes (13, 14).
Monopoly	A market situation in which there is only one supplier for a specific product. This supplier has high market power over buyers (15).
Orphan medicinal product (OMP)	A product intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating. The prevalence of the condition in the European Union must not be more than 5 in 10 000 or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development. No satisfactory method of diagnosis, prevention or treatment of the condition concerned can be authorized or, if such a method exists, the medicine must be of significant benefit to those affected by the condition (16).
Outpatient care	Comprises medical and paramedical services delivered to outpatients. Outpatient (ambulatory) care is provided in the outpatient sector as opposed to the hospital sector: hospital outpatient departments are usually not part of the outpatient sector. It should be noted that the term "outpatient" used in the Organisation for Economic Co-operation and Development System of Health Accounts has a wider meaning compared to some national reporting systems where this term is limited to care in outpatient wards of hospitals. In that System, all visitors to ambulatory care facilities that are not day cases or overnight cases are considered outpatients.
Patent	A title granted by public authorities conferring a temporary <b>monopoly</b> for the exploitation of an invention upon the person who reveals it, furnishes a sufficiently clear and full description of it and claims this monopoly (17).
Pooled procurement	A process through which a buyer pulls together demand to increase the total quantity of a specific product to include in a tender, in order to benefit from better procurement conditions and economy of scale. Procurement is done by one office on behalf of a group of health facilities, health systems or countries. Group members agree to purchase certain medicines exclusively through the group (18).

Prequalification by WHO	<p>Aims to ensure that diagnostics, medicines, vaccines and immunization-related equipment and devices for high-burden diseases meet global standards of quality, safety and efficacy, to optimize use of health resources and improve health outcomes.</p> <p>The prequalification process consists of a transparent, scientifically sound assessment, which includes dossier review, consistency testing or performance evaluation and site visits to manufacturers. This information, in conjunction with other procurement criteria, is used by United Nations and other procurement agencies to make purchasing decisions regarding diagnostics, medicines and/or vaccines (19).</p>
Prequalification of suppliers	<p>A process through which the buyer develops a list of registered suppliers based on past performance references from previous clients and documentation of product quality. Only those registered suppliers may participate in tenders. When prequalification works well, substandard suppliers are kept out of the tender process.</p>
Pricing	<p>The act of setting a price for a medicine (12).</p>
Product lifecycle	<p>An important concept in marketing, which describes the stages a product goes through from development, regulatory processes, being superseded by new products and in some cases formal removal from the market. Not all products reach this final stage. Some continue to grow and others rise and fall. The four stages in the product lifecycle are introduction, growth, maturity and decline.</p>
Purchasing power parity (PPP)	<p>Spatial deflators and currency converters, which eliminate the effects of the differences in price levels between countries, thus allowing volume comparisons of gross domestic product (GDP) components and comparisons of price levels.</p> <p>PPPs are calculated in three stages: first for individual products, then for groups of products or basic headings and, finally, for groups of basic headings or aggregates.</p> <p>The PPPs for basic headings are unweighted averages of the PPPs for individual products. The PPPs for aggregates are weighted averages of the PPPs for basic headings (the weights used are the expenditure on the basic headings). PPPs at all stages are price-relative. They show how many units of currency A need to be spent in country A to obtain the same volume of a product or a basic heading or an aggregate that X units of currency B purchases in country B.</p> <p>In the case of a single product, "same volume" means an identical volume, but in the case of the complex assortment of goods and services that make up an aggregate such as GDP, "same volume" does not mean an identical basket of goods and services. The composition of the basket will vary between countries according to their economic, social and cultural differences, but each basket will provide equivalent satisfaction or utility (2).</p>

Quality-adjusted life-year (QALY)	A generic measure of disease burden, including both the quality and the quantity of life lived. It is used in economic evaluation to assess the value for money of medical interventions. One QALY equates to one year in perfect health (2).
Ranking suppliers	Part of the monitoring and evaluation of supplier performance. After a contract is awarded, monitoring supplier performance provides the basis for decisions regarding future purchases.
Rebate	A payment made to the purchaser after the transaction has occurred. Purchasers (hospitals or pharmacies) receive a bulk refund from a wholesaler, based on sales of a particular product or total purchases from that wholesaler or manufacturer over a particular period of time (2).
Reimbursement	Coverage of the cost by a third-party payer (such as social health insurance or the national health service).
Restricted tender	A procurement procedure in which participation in bidding is limited to suppliers that meet certain prerequisites (via <b>prequalification</b> ) or have previously registered as suppliers.
Shelf-life	The length of time a material may be stored without affecting its usability, safety, purity or potency (20).
Staircase agreement	An agreement in which the final unit price for specific products will vary depending on the total quantity procured (the supplier will give a discount depending on the total quantity).
Strategic procurement	The exercise of improving efficiency when conducting procurement. It includes, for example, minimizing low-value repetitive purchases, increasing the benefit of economies of scale and reducing transaction and transport costs (21).

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## Annex 2

# Procurement features

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## Procurement methods

Different types of procurement method can be ascribed to four main groups: open tender, restricted tender, competitive negotiation and direct procurement (1). All can be used for multisource and single-source products under different conditions (apart from direct procurement, which makes sense only for single-source products since it does not compare the prices of different suppliers).

In an **open tender** bids are invited from any supplier representative, subject to the terms and conditions specified in the tender document. All suppliers interested in the tender may bid.

In a **restricted tender** interested suppliers need to be approved in advance – for example, through a formal prequalification process that takes into account adherence to good manufacturing practices, past supplier performance, financial viability and similar. The process of prequalification is often open to any supplier. A reverse auction is a two-step variation of a restricted tender, in which the lowest price offered 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 seldom been used for medicines.

In a **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. Several procurement agencies use this method. Examples of application of this method are the negotiation of reduced prices for antiretrovirals conducted by the United Nations Children's Fund (UNICEF) and the Clinton Foundation. International or local shopping is based on the same principle, but negotiation is not permitted.

**Direct procurement** deals with a single supplier (for example, with single-source products) and procures at list prices or negotiated prices. In general, single-source products may be procured via negotiated procurement, direct procurement or tendering of the single-source product and therapeutic substitutes in order to create a competitive environment.

## Global or regional pooled procurement initiatives

The methods described above can be applied at the local, regional and global levels. For certain products countries may decide to procure through a global or regional pooled procurement initiative; United Nations agencies like UNICEF have long conducted pooled procurement for countries. More recently, new global procurement groups have been created, often for specific products (such as the Global Drug Facility (GDF)). Regional procurement initiatives have focused on non-European countries in the past and include, for example, the pooled procurement service of the Organisation of Eastern Caribbean States (2), the Gulf Cooperation Council's group purchasing programme (3) and the Pan American Health Organization's regional programmes for vaccines and antiretroviral procurement (4, 5).

## Levels of collaboration in procurement

The extent of collaboration can vary from **informed buying** (through which participating countries share information on prices and suppliers) to **coordinated informed buying** (through which participating countries also conduct joint market research) and **group contracting** (through which countries also jointly negotiate prices, select suppliers and agree from whom to buy) (1). In all these three collaborative models countries conduct their own procurement individually. In a **central contracting and procurement** model, participating countries conduct joint tenders through a central buying unit.

Possible advantages of these collaboration models include the following. Through **informed buying**, increased transparency on prices can strengthen negotiating power and elicit reductions in prices. Information on prices or supplier performance can be shared through collaboratively established databases in the region (or among the countries concerned). Collaboration between countries can involve sharing strategic plans – business models and resource mobilization – or transferring technical capacity in efficient procurement practices, through study tours to countries with well established procurement systems or regional training on national forecasting and quantification, and negotiating strategies (6).

In addition to the possible advantages of informed buying, **coordinated informed buying** can curtail administrative costs of market research as well as costs of information gathering and monitoring of prices and supplier performance (7). **Group contracting** is the model selected as the regional pooled procurement strategy by the Southern African Development Community and Gulf Cooperation Council. It can lower operating costs and administrative burdens, as well as improving quality assurance. Economies of scale are expected when involving large countries, which are capable of negotiating lower prices independently (8). **Central contracting and procurement** – which has been employed as the model for GDF, the Pan American Health Organization's revolving fund for vaccine procurement and the pharmaceutical procurement services of the United Nations Population Fund and the Organisation of Eastern Caribbean States – can be considerably beneficial in resource-constrained settings and reduce the potential for corruption (9).

## Procurement planning

### **Forecasting and quantification**

After medicines to be procured have been selected, a choice which should be made based on the national essential medicines list or hospital formularies. Further, before the call for bids is launched, the quantity of medicines to be procured must be estimated. Two main methods are used to forecast needs: one based on past consumption data and the other based on morbidity data. The best outcome is usually obtained when the two data sources are combined to generate a final estimate of needs for a particular time period. Once the quantity needed has been established, it needs to be costed and the forecasted expenditure compared with the available funds before a supply plan is developed (10).

### **Analysis of utilization**

Analysis of utilization data, including price and expenditure data, can help identify levers for creating efficiencies and thus generate savings. The information generated is particularly valuable to drug therapeutic committees.

### **ABC analysis**

In this analysis, products are classified according to their value (expenditure) for the respective buyer in three categories:

- A – those few items accounting for 75–80% of the total value;
- B – those items that take up the next 15–20%;
- C – the bulk of items, which only account for the remaining 5–10% of the total value.

Typically, category A items constitute 10–20% of all items, with category B items constituting another 10–20% and the remaining 60–80% in category C (11).

Once the high-volume products have been identified, it is important to check whether lower-cost alternatives are available in the market. Alternatively, it is possible to consider opportunities for therapeutic substitution or to try to negotiate lower prices with suppliers (11). ABC analysis can also support analysis of consumption vs public health needs and possible poor-quality use of medicines.

### **Therapeutic category analysis**

This analysis builds on the ABC analysis by looking at consumption and spending at therapeutic class level instead of international nonproprietary name level.

### **Vital, essential and nonessential (VEN) analysis**

In a VEN analysis, medicines are classified as vital (V), essential (E) and nonessential (N). Vital medicines are potentially life-saving or crucial to providing basic health services; essential medicines are effective against less severe but significant forms of disease, but not absolutely vital to providing basic health care. Nonessential medicines are used for minor or self-limited illnesses; these may or may not be formulary items and efficacious, but they are the least important items stocked (11).

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## Annex 3

# Agenda of the consultation with member states in the WHO European Region

### DAY 1: Thursday 22 September 2016

OPENING AND WELCOME: HANS KLUGE, DIRECTOR, DIVISION OF HEALTH SYSTEMS AND PUBLIC HEALTH (DSP) AND HANNE BAK PEDERSEN, PROGRAMME MANAGER, HEALTH TECHNOLOGIES AND PHARMACEUTICALS (HTP), DSP, WHO REGIONAL OFFICE FOR EUROPE

#### Part 1: overview of different approaches to increase efficiency in procurement

**Aim: to present an overview of opportunities and challenges faced by countries regarding access to new medicines**

**Chair:** Hanne Bak Pedersen (HTP, DSP)

- Challenges and opportunities in improving access to medicines through efficient public procurement in the WHO European Region – general overview including results from the strategic procurement survey in Europe 2016 (Panos Kanavos and Alessandra Ferrario, London School of Economics and Political Science – LSE Health)
- Overview of access to cancer medicines in Europe (Sabine Vogler, Austrian Public Health Institute)
- Increasing efficiency in public procurement of medicines – addressing operational waste (Karolina Socha and Agnes Couffinhal, OECD Health)
- Q&A and discussion

#### Part 2: sharing country experiences so far on public procurement of new medicines

**Aim: to share best practices promoting strategic procurement**

**Chair:** Panos Kanavos (LSE Health)

- Increasing efficiency in procurement in Norway: biosimilars procurement (Torfinn Aanes, LIS, the Norwegian drug procurement agency)
- France: procurement strategies in Europe's biggest hospital (Claire Biot, Greater Paris University Hospitals, France)
- Procurement reform in Serbia (Biljana Čukanović, Ministry of Health, Serbia)
- Q&A and discussion

#### Part 3: group work – how to increase efficiency in procurement (five different topics addressed in group work sessions)

**Aim: to review challenges and barriers faced by countries when procuring new medicines and prepare suggestions for action**

**Chair:** Tifenn Humbert (HTP, DSP)

Cont.

- Introduction to group work: which measures should be taken to improve procurement of new medicines in European Union (EU) and non-EU countries?
- Group 1. Analysing spending on medicines in hospitals – what can be achieved? How can this information be used proactively in developing specific approaches to procurement for specific categories of medicines?  
**Facilitator:** Dorte Bartels, Amgros, Denmark
- Group 2. Practical steps to develop an international/national tender for new medicines for hospitals and the use of various procurement tools as contractual modalities.  
**Facilitator:** Karl Farrugia and Alison Anastasi, Malta
- Group 3. Stakeholder analysis before moving to centralized procurement: exploring possible partnerships, benefits and challenges. How to develop strategies that involve partners, inform stakeholders and prepare for any negative reactions.  
**Facilitator:** Kevan Wind, United Kingdom
- Group 4. How can improved transparency (nationally as well as through international cooperation) support strategic procurement?  
**Facilitator:** Sabine Vogler, Austria
- Group 5. Prerequisites for preferred contracts with suppliers to ensure value for money in the outpatient sector.  
**Facilitator:** Ad Schuman, Netherlands
- Presentations from group work

## DAY 2: Friday 23 September 2016

### **Part 4: network of information exchange – sharing experiences in setting up a platform to exchange information**

**Aim: to identify future directions to increase access to new medicines**

**Chair:** Flemming Sonne (Amgros, Denmark)

- Sharing experiences from vaccine procurement – United Nations Children’s Fund (UNICEF)/No man is an island – Strategies to improve knowledge translation and exchange in vaccine procurement (Heather Deehan, UNICEF Supply Division)
- Regional report reviewing vaccine pricing (Oleg Benes, WHO Regional Office for Europe)
- Discussion: can Vaccine Procurement Practitioners Network experiences be used in expanding to medicines? And how?

### **Part 5: joint procurement – challenges and success**

**Aim: to review experiences from collaboration and identify future directions**

**Chair:** Alessandra Ferrario, LSE Health

- Belgium, Netherlands, Luxemburg and Austria/pilot project (Francis Arickx, National Institute for Health and Disability Insurance, Belgium)
- Lessons learnt from the joint procurement for vaccines in Baltic countries (Andris Lobovs, National Health Service, Republic of Latvia)
- EU joint procurement initiative for influenza vaccine: success and challenges (Jean Luc Sion, European Commission)
- Scotland: joint procurement with England for recombinant factor VIII and IX – how aggregating volumes could lead to prices reduction (Lindsay McClure, Pharmaceutical Adviser, National Health Service, United Kingdom)

### **Part 5 continued: joint procurement – challenges and success**

**Aim: to review experiences from collaboration and identify future directions**

**Chair:** Panos Kanavos, LSE Health

- Introduction to WHO fair pricing initiative (Gilles Forte, WHO headquarters/Health Systems and Innovation /Essential Medicines and Products/ Public Health, Innovation and Intellectual Property)
- Panel discussion: new approaches and new partnerships; innovative solutions to access new medicines; proposals for action.  
Panellists: Vinzent Rest (Austria); Helena Panayiotopoulou (Cyprus); Flemming Sonne (Denmark); Claire Biot (France); Botagos Zhakselekova (Kazakhstan) ; Ing Karl Farrugia (Malta); Oyvind Melien (Norway); Liliana Iaquan (Republic of Moldova); Jurij Furst (Slovenia); Jean Luc Sion (European Commission)

Conclusions and next steps (Hanne Bak Pedersen, HTP, DSP)

## Annex 4

# Survey of public procurement practices in the WHO European Region

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## Methods

A survey on public procurement methods, with specific focus on tendering, was developed and finalized in consultation with academic partners. The survey included 21 questions: 19 with multiple choice answers (some with the option to complement a yes/no answer with text) and two open-ended questions. Most questions were objective, as the same response was expected among respondents from the same country (for example, “Do you use tendering in the ambulatory sector?”), while some were subjective, since different answers could apply among respondents from the same country (for example, “What are the biggest challenges in procurement?”).

The survey was uploaded on the software Qualtrics® and distributed electronically to the 53 Member States in the WHO European Region via a link to the online survey in English and Russian. More than one respondent per country was invited to provide complementary views on procurement, as it is often fragmented between different actors within the country. Invitees included WHO Regional Office for Europe regular contact partners for pharmaceutical matters such as national procurement agencies, ministries of health and United Nations agencies, and members of the Competent Authorities Responsible for Pricing and Reimbursement and the Pharmaceutical Pricing and Reimbursement Information network. Responses from countries with more than one respondent were compared; if discrepancies arose in the responses to objective questions, respondents were contacted to clarify. Only one valid answer per country was included in the analysis for objective questions, while more than one response per country was included in the analysis for subjective questions. Not all countries replied to all questions: the denominator for the percentages in the following figures thus varies and is always stated. Two countries (Czechia and Spain) provided some information after the survey was closed. This could not be included in the main findings reported in this annex but is reflected in Tables 2 and 3 in the main body of this report.

## Findings

Of the 53 Member States in the WHO European Region, 39 replied to the survey (74%). In nine countries there was more than one respondent.

### **General information on procurement of medicines**

Thirty-seven countries<sup>1</sup> reported using public procurement through tenders to purchase medicines – at the international level only (25), at both the national and international levels (10) or at the national level only (2). This happens mostly in both the hospital and ambulatory sectors (30), but in some countries in the hospital sector only (7). No country conducts tenders in the ambulatory sector only.

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<sup>1</sup> Germany and the Netherlands did not answer this question.

### **Ambulatory sector**

Of the 30 countries reporting that they conduct procurement through tenders in the ambulatory sector, 17 do it for all products, five for vaccines only, three for off-patent medicines and vaccines, two for on-patent medicines and vaccines, two for both off-patent and on-patent medicines and one for on-patent medicines only.

Among respondents, 11 countries also procure other products for the ambulatory sector. These include serums (Republika Srpska, Bosnia and Herzegovina), peritoneal dialysis medicines and devices and vision correction devices for children (Latvia), biosimilars (Lithuania), surgical and medical devices (Malta) and specific products like nutritional supplements, wound dressings and insulin pumps (United Kingdom, excluding Scotland). Belarus, Kyrgyzstan, Iceland, the Russian Federation and Ukraine replied “yes” but did not specify the products. Scotland (United Kingdom) specified that it has rebate arrangements in place for a number of branded medicines; these are commercial agreements that are separate from the tender process.

### **Hospital sector**

Overall, 37 countries reported conducting procurement through tenders in the hospital sector.<sup>2</sup> Of these, 36 provided information on which hospital products they tender for:<sup>3</sup> 25 for all products, eight for off- and on-patent products, two for off-patent products and vaccines and one for in-patent products only.

Ten countries also procure other products used in hospitals. These include medical devices (Finland, Malta and Ukraine), products in the national formulary/reimbursement list (Belarus, the Russian Federation, Turkey), serums (Latvia and Republika Srpska, Bosnia and Herzegovina), medical gases, certain unlicensed medicines (unlicensed imports, pre-compounded chemotherapy infusions, compounded parenteral nutrition), IV fluids and plasma products (Scotland, United Kingdom) and dose-banded chemotherapy products and nitric oxide (United Kingdom, excluding Scotland).

### **Discounts and transparency**

Only seven countries (of the 35 responding) reported that they declare publicly the discounts offered by manufacturers or wholesalers to hospitals. These were Belarus, Belgium, Cyprus, Denmark, Kazakhstan, Poland and the Russian Federation.

A maximum level of discounts offered by manufacturers or wholesalers to hospitals is set in three countries (of the eight responding): Cyprus, Hungary and Kazakhstan. In Cyprus the maximum level of discounts offered by manufacturers or wholesalers to hospitals is set in the contract. In Kazakhstan, pre-payment is the main reason a discount may be offered: the discount increases with the level of pre-payment.

In Italy, discounts offered to hospitals are generally published in the *Official Journal (Gazzetta Ufficiale)*, with the exception of confidential managed entry agreements.

Of the 36 responding countries, 25 reported publishing their tender results in the public domain. In terms of how transparency should translate into greater access, the Republic of Moldova responded that transparency was particularly important in tendering procedures and could increase the number of bidders: if there is no transparency, manufacturers may not be interested in participating in tenders due to uncertainty about the outcome.

For Kyrgyzstan, access to pricing information might result in companies supplying the same product for lower price. Pharmaceutical procurement is largely decentralized in Kyrgyzstan, except for insulin and

<sup>2</sup> Germany and the Netherlands did not answer this question.

<sup>3</sup> Azerbaijan did not give this information.



vaccines (the latter are procured through Gavi, the Vaccine Alliance). Increased transparency allows both the purchaser and the supplier to compare prices on the market and for the purchaser to shop around. Not only do prices need to be transparent but the tendering procedures also need to ensure that the company providing the best quality products at the most cost-effective price will win the tender.

Ukraine's experience shows how political commitment and adequate information technologies are necessary prerequisites to increase transparency. Transparency in the procurement process was a legal requirement in Ukraine from 2005, but the way the information technology platform was built made it very difficult to collect, unify and analyse data. These weaknesses in the system failed to simplify the procurement process. In 2014, therefore, the Ukrainian government started implementing a new tendering system called ProZoro. From 2015, with the support of high-level politicians and authorities, it was gradually made the mandatory platform for public procurement. It includes an analytical component that facilitates analysis of bids, adjudication decisions, awards and tender participation patterns.

### **Procurement modalities**

In the majority of countries (27 of the 36 responding<sup>4</sup>), lowest price is one of the award criteria, but not the sole criterion. Others include quality (25), ability to supply a share of the market (16) and enhanced competition (13). The 10 factors listed as "other" were:

- other terms of the tender documents, such as delivery time, shelf-life and so on (Cyprus);
- special criteria applicable for medical devices (Denmark);
- priority rights for domestic manufacturers (Kazakhstan);
- delivery time and registration (Malta);
- expiry date (Poland);
- cost-effectiveness (Norway);
- compliance with the required delivery dates, specifications and registration at the national regulatory authority (Kyrgyzstan);
- distribution (Romania);
- business continuity/resilience (Scotland);
- provision of associated services (Scotland).

Further, Scotland (United Kingdom) previously awarded contracts entirely on the basis of price, but the regulations have recently changed to ensure that other criteria are taken into consideration.

The majority of countries (22 of the 32 responding<sup>5</sup>) reported awarding the entire market to the lowest bidder. Only six countries responded that they shared the market between bidders offering the two or three lowest prices. Four countries did not respond to the question.

The use of both approaches (one winner vs multiple winners), depending on the product tendered, is likely to explain why five countries replied "no" to both options ("The bidder offering the lowest price wins the entire contract" and "The bidders offering the two or three lowest prices are contracted").

Some countries provided additional details on how the market is shared. In Denmark and Slovenia, the number of contracts depends on the product tendered. In England (United Kingdom), a bid can only win part of the overall market where there is more than one bid.

<sup>4</sup> Azerbaijan, Germany and the Netherlands did not answer this question.

<sup>5</sup> Azerbaijan, Georgia, Germany, Iceland, the Netherlands, Romania and Slovenia did not answer this question.



Only four non-European Union (EU) countries (Armenia, Belarus, Kyrgyzstan and the Russian Federation) of the 32 responding stated that they may give preferential treatment to manufacturers prepared to produce locally as an incentive to encourage local manufacturing. This is because EU regulations prohibit stating a preference for a national producer. In the Russian Federation, if at least two manufacturers are from the Eurasia region, manufacturers from other countries are not allowed to bid. Market sharing could be achieved, for example, by splitting a contract into numerous smaller lots rather than having one large sole supplier. Whether this is feasible or an appropriate strategy depends on the context of the market. In Turkey, supporting local manufacturers through the tendering system is under discussion in the medical devices sector, but not yet in pharmaceuticals.

A mechanism to centralize the procurement of high-price on-patent medicines exists in 27 countries (of the 36 responding<sup>6</sup>). Orders are merged at the national level (18), the regional/state level (2), the hospital level (2) or through joint procurement with other jurisdictions (1). In this last case, there are examples where Scotland joins an English procurement exercise if it is believed that aggregating their volumes across the United Kingdom will lead to better pricing in the world market – for example, for plasma products. A partnership agreement between Baltic States exists, but this mechanism has not been used so far to centralize the procurement of high-cost medicines.

Tendering with fixed quantities is the most commonly used mechanism for public procurement (in 21 countries of the 34 responding), followed by framework agreements (6) and others (3). Only Denmark reported using staircase tendering with volume discounts for some new products. According to the literature,<sup>7</sup> however, this modality is also used in Italy for sofosbuvir for the treatment of hepatitis C.

Among other modalities, Malta uses negotiations when medicine is patented, and package deals in addition to fixed volume tendering. Further, e-auctioning is being piloted for generics. In Scotland (United Kingdom), framework agreements are the standard approach but on occasion commitment contracts are employed, depending on the circumstances. Influenza vaccine is an example of a commitment approach, where the vaccine is manufactured to order.

In Ukrainian public procurement law the following tools are envisaged to be used by tender committees: open tenders (standard procedure), competitive dialogue (applicable to works and services), negotiations (allowed to be used in exceptional circumstances when there is no competition on the market) and framework contracts. Despite available tools to diversify procurement strategies, in practice negotiation is used only as a last resort after an open tender has failed three times. This situation leads to a loss of time, and is perceived to be one of the major factors causing stock-outs and, potentially, treatment interruption.

### **Good procurement and key challenges**

The survey responses highlighted a number of positive features and key challenges for procurement (Fig. A4.1 and Fig. A4.2), many of which were backed up by information gained from the literature review.

The survey and literature review highlighted the fact that issues of fragmentation of procurement responsibilities may lead to a less efficient procurement outcome. Austria, for example, mentioned that the absence of joint procurement between hospitals (most hospitals procure individually) and inpatient and outpatient sectors (which also do not share procurement) is a missed opportunity to increase bargaining power.

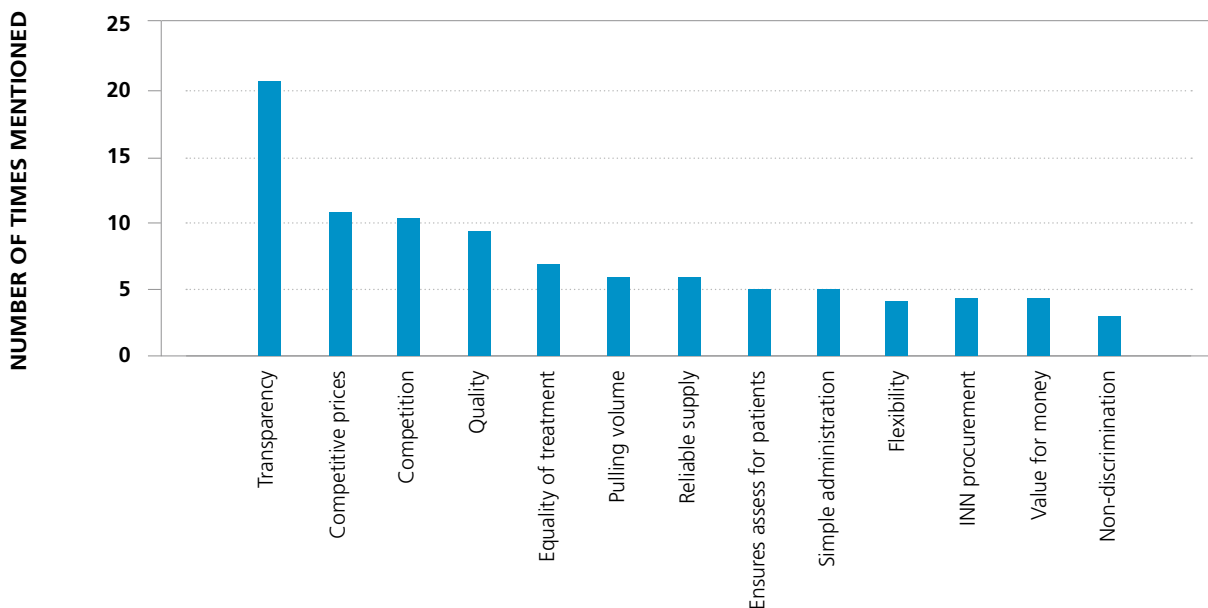
<sup>6</sup> Azerbaijan, Germany and the Netherlands did not answer this question.

<sup>7</sup> Messori A. Evolocumab and alirocumab: exploring original procurement models to manage the reimbursement of these innovative treatments. *Int J Clin Pharmacol Ther.* 2016;Apr 27 [Epub ahead of print].

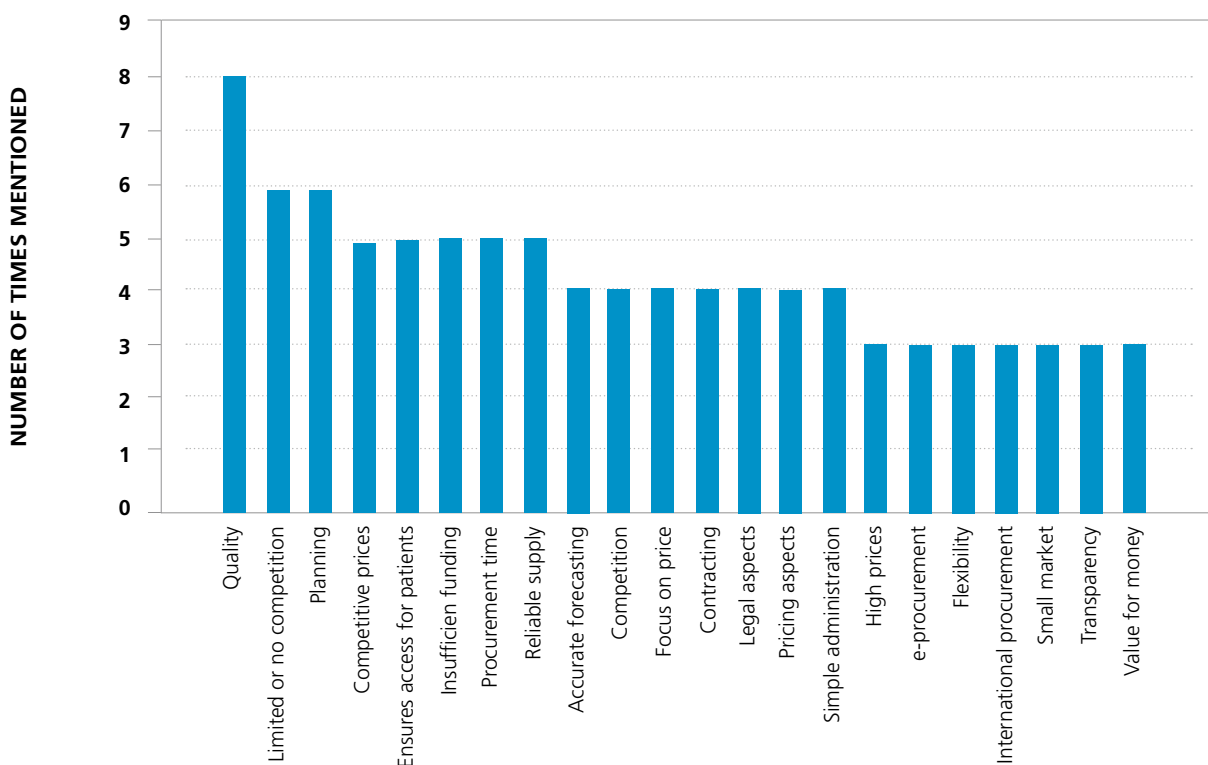
In Estonia, a country of 1.3 million inhabitants, each hospital conducts its own tender processes. Procurement responsibilities are further fragmented, with the Ministry of Social Affairs responsible for the procurement of vaccines, tuberculosis (TB) and HIV/AIDS medicines, the National Institute of Health Development responsible for methadone procurement and the Health Board responsible for the procurement of antidotes.

In Ukraine fragmentation of the procurement cycle is an important issue. At the national level over 17 governmental entities were reported to be responsible for conducting procurement of health commodities. At the subnational level, health care facilities managing tenders in the public sector are estimated to include

**Fig. A4.1** | Features of good procurement mentioned more than three times



**Fig. A4.2** | Procurement challenges mentioned more than three times



several thousand entities. As a result, the country cannot achieve economies of scale; it grapples with transparency issues and the ability to monitor public tenders. To address this, in 2015 the Ministry of Health delegated the procurement function to international organizations, such as the United Nations Development Programme, the United Nations Children’s Fund (UNICEF) and Crown Agents (a private procurement entity), and initiated concept development to establish an independent health commodity procurement agency.

Challenges in human resource capacity to conduct procurement were mentioned in both the survey and the literature. In the Republic of Moldova, for example, no staff have experience of direct price negotiations with manufacturers. In Kyrgyzstan a lack of professionalization of the procurement function leaves important skills gaps, in particular in relation to quality assurance, development of technical specifications, tendering techniques, forecasting and quantification and bid adjudication, for example. The situation is similar in Ukraine where, due to a lack of public funds, members of the tendering committees established in health care facilities have limited access to professional procurement training. Expertise in forecasting and quantification tools, supplier performance monitoring and managing the procurement lifecycle is reportedly scarce and fragmented.

### **Managed entry agreements**

Of the 38 countries<sup>8</sup> responding, 17 reported using financial managed entry agreements (MEAs), which are mostly (14) confidential. With some exceptions, there was a clear geographical focus of MEA implementation in western Europe vs central and eastern Europe and the central Asian region.

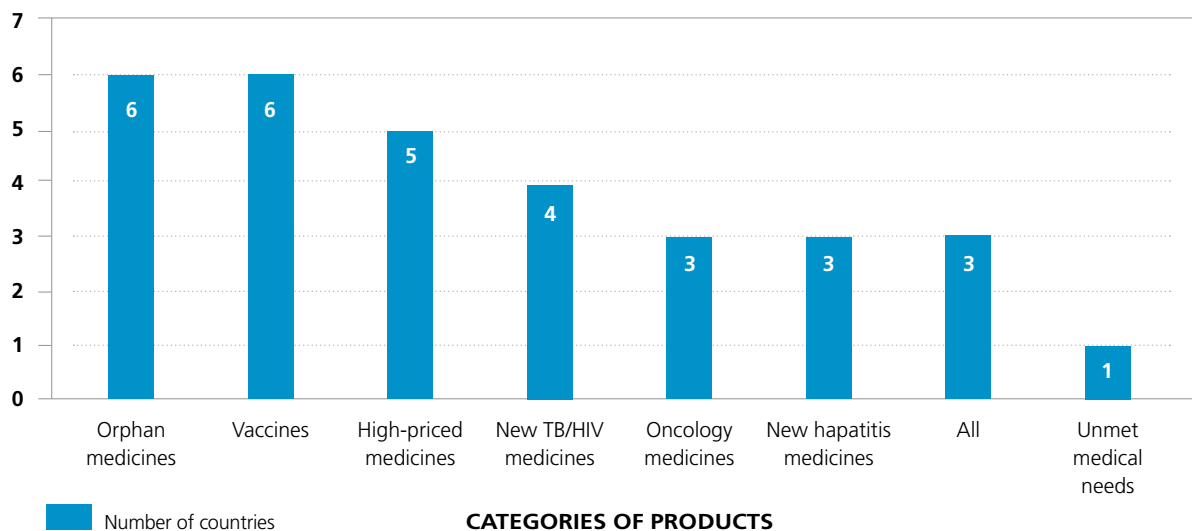
Twelve countries (of the 37 responding<sup>9</sup>) implement health outcome-based agreements, which are mostly (11) confidential. The same geographical trend for financial MEAs holds for health outcome-based agreements.

### **Collaboration**

This section covers the subjective (open) questions of the survey, where respondents could include more answers per country if desired.

Of the 48 respondents, 38 expressed interest in developing collaborations with other countries to conduct strategic procurement of high-price medicines (offering joint tendering, price sharing and so on). Fig. A4.3 shows the products countries were most interested in working on collaboratively.

**Fig. A4.3** | Therapeutic areas and product characteristics of interest for possible collaboration



<sup>8</sup> Azerbaijan did not answer this question.

<sup>9</sup> Azerbaijan and the Netherlands did not answer this question.

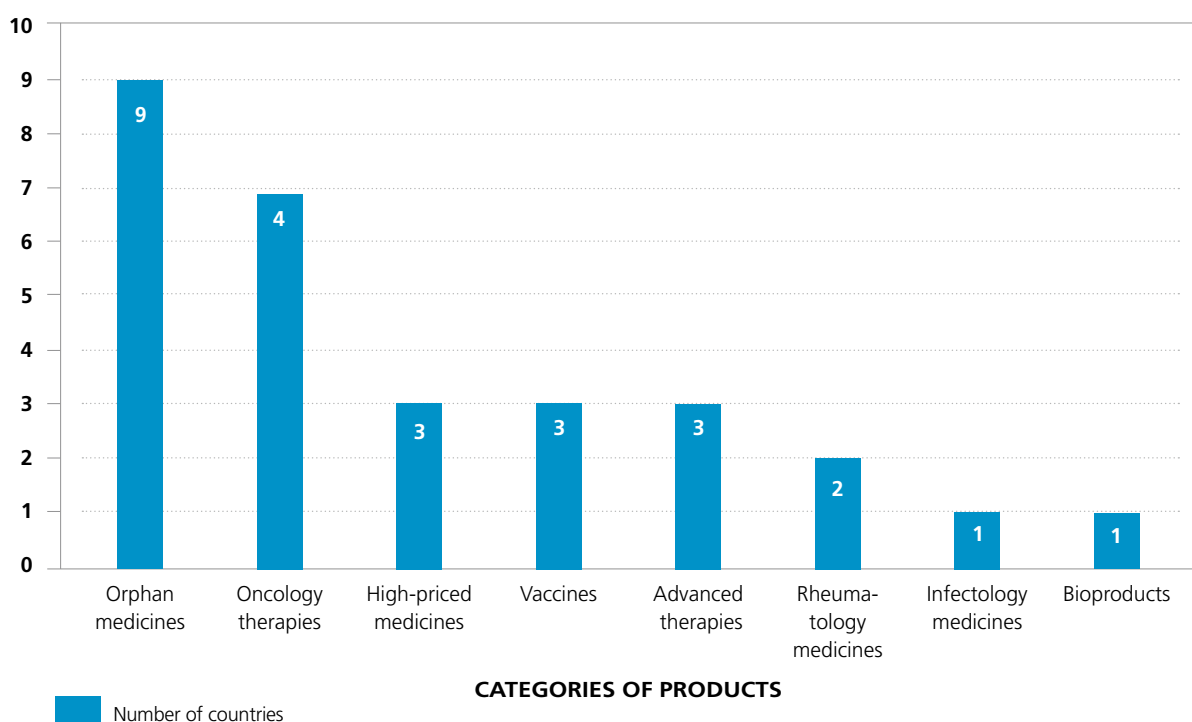
Five respondents also mentioned other products, including medicines used in small quantities (Kazakhstan), medicines and devices that are difficult to source and fund (Malta), disinfectants and medical devices (Republic of Moldova), innovative drugs (Serbia) and cytostatics and biological medicines (Republika Srpska, Bosnia and Herzegovina). Further, three respondents mentioned interest in price sharing (Bosnia and Herzegovina and Cyprus).

Scotland (United Kingdom) expressed interest in exploring the value of such collaboration and testing the concept with a pilot project. A possible area to explore would be products for which aggregating volume would lead to better prices on the world market. This was suggested for hepatitis C, but the respondent thought that a multicountry tender was only likely to lead to better prices under certain circumstances. Confidence needs to be provided to suppliers that a lower price will lead to a higher market share in all countries involved – for example, giving confidence that prescribers will prescribe the product over therapeutic alternatives. It may be difficult to get the necessary clinical buy-in when working across countries, however. The Netherlands would also be keen to collaborate on these topics in general, although not only on specific products.

Among the respondents, 20 thought that such collaboration should take place with whoever is interested, while 17 thought that they should only occur with a limited number of neighbouring countries.

Of the 44 respondents, 24 were interested in pre-commercial procurement (planning procurement of products that are not yet on the market) and suggested the following products and therapeutic areas for a potential pilot project (Fig. A4.4).

**Fig. A4.4** | Products of interest for pre-commercial procurement



Denmark expressed interest in working on new products in the market – especially products where supply problems are likely to arise due to very limited number of suppliers.

Overall, 39 respondents (out of 48) were interested in sharing their public procurement experiences by participating in a WHO consultation on strategic procurement of high-price medicines on 22–23 September 2016 in Copenhagen, with the intention of developing a practitioners' forum on strategic public procurement of new high-price medicines under the umbrella of WHO.

## Annex 5

# Survey questionnaire

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Please provide the following information:

	Please specify:	Comments:
Country (1)		
Date (2)		
Name (3)		
Title (4)		
Employee (5)		
Postal Address (6)		
Tel. No. (7)		
Email (8)		

**Q1. Is public procurement through tenders used in your country to purchase medicines, at any level?**

- No  
 Yes

**Q2. If yes, is this procurement happening**

- at the international level?  
 at the national level?  
 at both levels?

**Q3. If yes, which part of the health sector medicines supply is eligible?**

- Ambulatory care medicines (general practice/primary health care and outpatient hospital care)  
 Inpatient only medicines (hospital)  
 Both

**Q4. If you procure for ambulatory care, which product groups are eligible? (You can tick more than one answer.)**

- Off-patent medicines (generics and biosimilars)  
 On-patent (patented or originator) medicines  
 Vaccines  
 Other (please specify): \_\_\_\_\_

**Q5. If you procure for inpatient care, which product groups are eligible? (You can tick more than one answer.)**

- Off-patent medicines (generics and biosimilars)
- On-patent (patented or originator) medicines
- Vaccines
- Other (please specify): \_\_\_\_\_

**Q6. With regard to inpatient care medicines, at what level is public procurement undertaken?**

- At national level (sickness fund, ministry of health, procurement agency etc.)  
(please specify): \_\_\_\_\_
- At regional/subregional level (hospitals, etc.) (please specify): \_\_\_\_\_
- Both levels (please specify): \_\_\_\_\_

**Q7. Are the discounts offered by manufacturers or wholesalers to hospitals publicly declared?**

- Yes
- No

**Q8. If yes, is a maximum level of discount offered by manufacturers or wholesalers to hospitals set?**

- Yes (please specify and add link if available): \_\_\_\_\_
- No

**Q9. Do you publish the tender results in the public domain?**

- Yes (please specify): \_\_\_\_\_
- No

**Q10. What are the modalities used in your country to procure medicines?**

Modality	Please tick all that apply:	
	YES	NO
1. The lowest price is the only criterion used to award a procurement contract	<input type="checkbox"/>	<input type="checkbox"/>
2. The lowest price is one of the criteria used to award a procurement contract	<input type="checkbox"/>	<input type="checkbox"/>
3. Beyond the lowest price and depending on the type of product, other factors are taken into account. Please tick all of the following that apply.	<input type="checkbox"/>	<input type="checkbox"/>
i) Quality	<input type="checkbox"/>	<input type="checkbox"/>
ii) Ability to supply a share of the market	<input type="checkbox"/>	<input type="checkbox"/>
iii) Enhanced competition	<input type="checkbox"/>	<input type="checkbox"/>
iv) Other (please specify):	<input type="checkbox"/>	<input type="checkbox"/>
4. The bidder offering the lowest price wins the entire contract.	<input type="checkbox"/>	<input type="checkbox"/>
5. The bidders offering the two or three (please specify below) prices are contracted.	<input type="checkbox"/>	<input type="checkbox"/>
6. As an incentive to encourage local manufacturing, preferential treatment may be given to manufacturers who are prepared to produce locally. Please specify other criteria that apply in the award.	<input type="checkbox"/>	<input type="checkbox"/>

**Q11. Is there a mechanism for centralizing procurement of high-price on-patent medicines (examples: monoclonal antibodies, hepatitis C medicines, etc.)?**

- Yes (please specify at which level – national, regional...): \_\_\_\_\_
- No

**Q12. Under what terms and conditions is medicines procurement undertaken?**

- Framework agreement tendering where there is an intent to contract but no binding obligation to purchase
- Tendering for fixed quantity with binding contract
- Staircase tendering with volume discounts
- Other (please specify): \_\_\_\_\_

**Q13. If you are conducting public procurement of medicines, what do you consider a good public procurement policy? Please list three elements/principles that in your opinion define the core of a virtuous public procurement policy.**



**Q14. What do you consider to be the biggest challenges in relation to public procurement of medicines?** Please list up to five challenges in descending order, starting with the most important.

**Q15. Are you using financial managed entry agreements (MEAs) to enable procurement of new medicines?**

- Yes, we use financial MEAs and details of the deal are confidential.
- Yes, we use financial MEAs and details of the deal are publicly available.
- No, we do not use financial MEAs.

**Q16. Are you using health outcome-based MEAs?**

- Yes, we use health outcome-based MEAs and details of the agreement are confidential.
- Yes, we use health outcome-based MEAs and details of the agreement are publicly available.
- No, we do not use health outcome-based MEAs.

**Q17. Would you be interested in developing collaborations with other countries enabling you to conduct strategic procurement of high-price medicines (i.e. offering joint tendering, price sharing, etc.)?**

- Yes (please specify possible eligible products): \_\_\_\_\_
- No

**Q18. If yes, at what level should this take place?**

- Only with a limited number of neighbouring countries
- With whoever is interested

**Q19. Would you be interested in pre-commercial procurement (PCP), meaning planning procurement of products that are not yet on the market?**

- Yes
- No

**Q20. If you are interested in PCP, is there a specific therapeutic area or product group that you would like to recommend for a pilot project?**

- Yes (please specify): \_\_\_\_\_
- No

**Q21. Would you be interested in sharing your experiences by participating in a WHO consultation on strategic procurement of high-price medicines, on 22–23 September 2016 in Copenhagen, with the intention of developing a practitioners' forum on strategic public procurement of new high-price medicines under the umbrella of WHO?**

- Yes
- No

## Annex 6

# Literature review on procurement practices

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## Methods

A literature review on procurement of medicines was conducted using PubMed and Google Scholar (searched on 9 May 2016). Both peer-reviewed and grey literature were included. The following keywords were used.

- **PubMed**

((“tendering” [Title/Abstract] OR “procurement” [Title/Abstract]) AND (“pharmaceuticals” [Title/Abstract] OR “drugs” [Title/Abstract] OR “medicines” [Title/Abstract]))

- **Google Scholar**

(“tendering” OR procurement) AND (“pharmaceuticals” OR “drugs” OR “medicines”) (“rebate contracts” OR “tendering” OR “preference policy” OR “rabattvertäge” OR “rabattvertraege”) AND (“pharmaceuticals” OR “drugs” OR “medicines”)

In addition, the reference lists of the retrieved literature were checked and relevant recent publications by WHO were also included.

No language or geographical restrictions were applied. As the focus was on recent evidence on procurement of medicines (and vaccines), publications older than 2011 or focusing exclusively on medical devices were excluded.

The end-points of interest were assessments of the impact of different procurement practices (tendering, negotiations and so on), experience-sharing about procurement without impact assessments (for example, reviews of procurement methods and their applicability in other countries) and recent changes in procurement practices (such as the European Union (EU) Joint Procurement Agreement, described in detail below).

## Findings

The authors identified 37 relevant publications on public procurement of medicines (2011–2016) after applying the search strategy and inclusion/exclusion criteria. An overview of the study characteristics and their main findings is set out in the following sections. The literature findings are divided into impact assessment studies (using either descriptive or statistical methods), experience-sharing studies without impact assessment and discussion papers on recent changes.

### ***Studies on the impact of different procurement practices***

#### *Overview of studies*

Of the 37 selected publications, 19 analysed the impact of different procurement practices on price, expenditure, volume and availability/supply security (Annexes 7–11) – 15 were single-country studies, three multicountry studies and one focused on an international procurement agent (Table A6.1).

**Table A6.1** | Overview of impact assessment studies found in the literature

	Area or agent covered (number of studies if more than 1)
<b>Single-country studies</b>	<ul style="list-style-type: none"> <li>- WHO Regional Office for Europe: Cyprus, Denmark, Germany, Greece, Italy (n=4), Sweden</li> <li>- WHO Region of the Americas: Brazil (n=2), Chile, Mexico (n=2)</li> <li>- WHO Western Pacific Region: China</li> </ul>
<b>Multicountry studies</b>	<ul style="list-style-type: none"> <li>- WHO Eastern Mediterranean Region: Jordan, Lebanon, Syrian Arab Republic and West Bank and Gaza Strip</li> <li>- WHO Regional Office for Europe: Austria, Netherlands, Norway, Portugal, Slovakia</li> <li>- 37 middle- and low-income countries from different WHO regions</li> </ul>
<b>International procurement agent study</b>	<ul style="list-style-type: none"> <li>- Global Drug Facility</li> </ul>

These studies focused on individual types of medicinal product (on-patent (n=2), off-patent (n=2), vaccines (n=1) or biosimilars (n=1)) or different types of products (on-patent and off-patent (n=5); all medicines procured for hospitals (n=2)). In six studies the types of product procured were not specified.

Most of the studies did not specify the sector for which procurement was conducted (n=9); five studies focused on the hospital sector, three on the ambulatory sector and two on both the hospital and ambulatory sectors.

Four studies focused on one particular therapeutic area, nine on multiple therapeutic areas and six did not specify the therapeutic area (Table A6.2).

**Table A6.2** | Therapeutic areas covered in the impact assessment studies

	Therapeutic areas (number of studies if more than 1)
<b>One therapeutic area</b>	<ul style="list-style-type: none"> <li>- Antiretrovirals (ARVs)</li> <li>- Cardiovascular</li> <li>- Human papillomavirus (HPV)</li> <li>- Tuberculosis (TB)</li> </ul>
<b>Multiple therapeutic areas</b>	<ul style="list-style-type: none"> <li>- HIV/AIDS, TB and malaria</li> <li>- Somatropin, epoetin and filgrastim</li> <li>- Cardiovascular, central nervous system, diabetes</li> <li>- Oncology, rheumatoid arthritis, immunomodulation, anti-inflammatory, neurology – multiple sclerosis, cardiology, blood</li> <li>- Oncology, haematology, infectious diseases, neurology, endocrinology, rheumatology and other clinical specialties</li> <li>- Various (n=4)</li> </ul>
<b>Not specified</b>	<ul style="list-style-type: none"> <li>- Not specified (n=6)</li> </ul>

Of the 19 studies, 15 focused on tendering, either at national or regional levels, including two on preferred supplier policy in the ambulatory sector, one on electronic tendering (e-tendering) and one comparing centralized procurement by the United Nations Relief and Works Agency for Palestine Refugees in the Near East (UNRWA) with local direct procurement prices. Two studies analysed the impact of centralized price negotiations for on-patent medicines in Mexico; one analysed the impact of the Intermunicipal Health Consortium in Brazil; and another modelled different price and volume scenarios of a price-volume agreement for PCSK9 inhibitors in Italy.

Most studies evaluated the impact of procurement against price (n=13), followed by total expenditure on procurement (n=9), volume (n=2), number of bidders (n=2) and stock-outs (n=1).

#### *Overview of study findings*

It is difficult to compare findings on the impact of different procurement methods owing to the diversity of the studies in terms of objectives, geographical and therapeutic focus, study time and methods used to analyse the data, to mention only a few. It is possible, however, to make some general observations. For example, in studies on the impact of procurement on prices (Annex 7), the expectation that high volume is a prerequisite to obtain lower prices was not always the case. Some studies did indeed find that pooling volume contributed to lower prices (1–6), while a study on medicine procurement prices in UNRWA found that competitive prices were obtained even for relatively small-volume orders (7). A study on procurement prices, mostly for ARVs, in emerging markets found that the effect of volume on prices is mainly on originators (8). A study on prices of HPV vaccines in different Italian regions found only a negligible correlation between prices and volumes (9).

The explanation for these variations is probably that other factors influence procurement outcomes beyond volume and can modify the effect of volume on prices. For example, a study in Brazil found that if good buyers (those known to pay on time) are joined in the pool by bad buyers (those known not to pay on time), prices are higher than for a comparable pool of good buyers (4). This higher price was seen as compensation for the risk of delayed payment. Other studies on international procurement agents mentioned the prequalification requirement as crucial to attracting multinational generic suppliers and thus lowering prices (1, 8).

In general, studies (Annex 8) found centralized procurement to be associated with lower expenditure in comparison to pharmacy purchasing prices (10, 11) or forecasted expenditure (12). It is important to note, however, that the introduction of a centralized procurement structure in Cyprus, Denmark and Greece was associated with other reforms in procurement organization, selection of medicines and so on; these are likely to have contributed to lower expenditure.

Two studies investigated the impact of procurement on volume (Annex 9). The study on preferred supplier contracts in Germany found that signing such contract had a positive effect on a brand's own market share and a negative effect on the market shares of competitors, and that the time period between signing the first and the following preferred supplier contracts, at least initially, positively affected the market share gained (13). As time elapsed, the market shares of different suppliers converged. The second study was a simulation of various price–volume combinations for evolocumab and alirocumab, estimating expenditure and the number of patients treated at different pricing levels (14).

One study (Annex 10) assessed the impact of using an e-tendering tool on prices of medicines in Chile. One of its hypotheses was that the price of medicines and medical devices decreased with an increasing number of bidders. Since the Chilecompra electronic platform attracts more suppliers to tender, this leads to indirect savings through more bidders. The study found that greater aggregation of orders led to prices 2.8% lower, and thus that more bidders resulted in lower prices, but also found that the number of bidders failed to increase after 2004, the year use of the electronic platform became mandatory (6).

Finally, a study on the Intermunicipal Health Consortium in Brazil also investigated the impact of aggregating volume across municipalities on stock-outs (Annex 11). It found that the number of items with stock-outs for at least one day decreased by approximately 12% from 2007 to 2008 (the year the Consortium began to be set up) and by 48% from 2009. The number of medicines unavailable for more than 90 days also decreased from 11 in 2007 to three in 2008 and two in 2009 (5).

### ***Experience-sharing studies about procurement without impact assessment***

The literature review identified 13 papers on experience-sharing. Seven publications reviewed procurement experiences in different countries and sectors, while the remaining six addressed specific topics including advance purchase agreements for influenza vaccines, biosimilars, international joint procurement, the application of framework agreements in sub-Saharan Africa and international price comparisons for ARVs and vaccines.

#### *Reviews of country and sector procurement systems*

Of these seven procurement system reviews, three focused on tendering systems at different national and subnational levels, two investigated a variety of procurement methods and two did not specify the procurement methods used. Four reviews focused largely on the WHO European Region – more specifically on EU countries (Belgium, Denmark, England (United Kingdom), Germany, Malta, the Netherlands, Romania and Slovenia) – one focused on India, one on the Islamic Republic of Iran and one covered different low- and middle-income countries across various WHO regions. Three publications looked at the on-patent and off-patent sector, one the off-patent only and three did not specify the sector covered. Two studies covered various therapeutic areas, while five simply did not specify them. The procured products were for the ambulatory and hospital sectors (three studies), ambulatory only (one study), hospital only (one study) or not specified (to studies). The data sources used in these reviews were surveys (two studies), interviews, the literature, the literature combined with interviews, data from the national procurement agency and site visits (one study each).

#### *Study on advance purchase agreements for influenza vaccines*

One case study used vaccine procurement during the 2009 H1N1 pandemic to examine how states procure vaccines and whether the procurement tools available to developing states are likely to secure adequate supplies of influenza vaccines in a future pandemic (15). The main traditional public procurement methods for vaccines identified were procurement directly by the state; vaccine procurement using advance purchase agreements (APAs); donations via international organizations; vaccines procured and administered by international organizations; and interstate donations and sales (rare). The paper argued that APAs are not effective procurement methods for developing states because vaccine supply is dominated by the developed states where APAs are in place. It concludes that despite the introduction of a pandemic influenza preparedness stockpile, to which developing states may have access, demand will be again greater than supply and developing countries will be the least likely to gain timely access for their populations.

#### *Study on biosimilars*

One review examined policy approaches to promoting competition between biosimilar and originator oncology medicines used by seven European countries and the United States of America (USA) (16). Tendering at a hospital, regional or national level is a common practice to procure biological medicines, including biosimilars in the eight countries reviewed, and proved to be very effective at reducing the price for the biosimilar infliximab (at a discount of 69% discount compared with its reference product). Based on the experiences of Belgium and Italy (17, 18), the review concluded that tendering seems to be effective at increasing biosimilar uptake while reducing prices. Confidential deals between manufacturers and hospitals reduce transparency in the market, however; this could give an advantage to the reference product (16). Another aspect to consider is whether the long-term discounts offered by the biosimilar offset the fringe benefits (such as sponsored additional training and clinical research grants) that reference products may offer.

The review of performance of hospitals in England recommended that health care trusts reduce their expenditure on medicines through selection and actively monitoring market developments (19). The report used the example of the biosimilar infliximab which, launched in March 2015, was expected to generate a 40% reduction overall in the costs of this one medicine, saving the National Health Service (NHS) over £60 million per annum. To this end, it recommended that NHS Improvement should regularly publish a list of the top 10 medicines with savings opportunities for trusts to pursue.

*Study on international joint procurement*

One study reviewed the purpose and benefits of pooled procurement mechanisms based on a literature review and interviews with key informants (20). It identified the following benefits for pooled procurement:

- reductions in unit prices;
- improved quality assurance;
- reduction or elimination of procurement corruption;
- rationalized choice through better informed selection and standardization;
- reduction of operating costs and administrative burden;
- increased equity between members of the pool;
- stronger role of the host institutions (regional or international) administering the system; and
- increased access to essential medicines.

It concluded that developing countries can benefit from being part of a pooled procurement mechanism through lower prices, quality assurance and less potential for corruption.

*Study on framework agreements*

Despite the widespread use of framework agreements in high-income countries and multilateral organizations, their use for the procurement of health commodities has been rather limited in sub-Saharan Africa (21). Based on the experience with framework agreements in the USA, this paper discussed the feasibility of their implementation in sub-Saharan Africa, identifying key enablers: a legal basis and technical capacity to develop and manage long-term contracts. The authors envisaged that implementation of these agreements would improve supply security and reduce costs.

*Studies on international price comparisons*

Two relevant studies were identified – one on procurement prices for ARVs in Latin America and the Caribbean and one on vaccine prices and procurement in the WHO European Region.

The study on ARVs used 2008 public procurement data reported to the WHO Global Price Reporting Mechanism to develop regional and global price benchmarks (22). The authors found large price variations for first- and second-line ARV combinations between countries in Latin America and the Caribbean. It was estimated that if the price of ARV medicines procured in many countries were closer to the lowest regional generic price, these countries could treat between 1.17 and 3.8 times more patients. For all second-line combinations, prices closer to the lowest regional innovator or to the global median transaction price for lower-middle-income countries would lead to an even greater number of patients treated (nearly five times more). The study concluded with a call for greater transparency in the prices of medicines and the development of a regional, publicly available database for sharing prices in the region.

The WHO Regional Office for Europe vaccine pricing report found that vaccine pricing information was generally widely available in countries of different income groups. The key issue was its limited accessibility to the public. Interestingly, few legal restrictions exist on making this information publicly available, thus providing an opportunity to increase vaccine pricing transparency (23).

***Theme relevant to all 37 studies***

The importance of comparing prices within and across national boundaries was emphasized in the literature. The English NHS hospital performance report suggests that new purchasing price index should be introduced and used to monitor performance and hold trusts accountable (19). A price list observatory was established during the procurement reform process in Greece to compare prices across hospitals nationally (12). At the time of writing, it was envisaged that foreign health care institutions might also be included in the future.

### **Key challenges in public procurement**

A number of key challenges relating to public procurement of medicines were identified in the literature (Annexes 12 and 13) and in two case studies (Annex 15). The most frequently cited were issues related to:

- the supply chain (shortages, mark-ups and taxes, reliable supply and data);
- legal aspects, including a clear legal framework to enable the implementation of different procurement methods and facilitate the participation of national and international bidders;
- limited competition due to over-reliance on single-source suppliers, with preferences for local suppliers and distributors;
- pricing aspects (discounts granted to hospital vs ambulatory medicines, difficulties in obtaining competitive prices for innovative medicines, lack of inclusion of value aspects in pricing and reimbursement decisions);
- limited human resource capacity to conduct procurement (particularly when it comes to skills and experience, rather than numbers);
- tender award criteria – in particular the strong focus on lowest price above other criteria, including quality; and
- monitoring the performance of suppliers and the procurement body and clinicians' prescribing choices.

### **Key enabling factors**

A number of enabling factors, found to improve procurement outcomes (lower prices and increased availability), were identified (Annex 14). It is important to note that the evidence on a particular factor often comes from a limited number of settings; as such, they are very context-specific. Examples include:

- establishment of a centralized body to negotiate prices of on-patent medicines in Mexico (24, 25);
- pooling volume at different levels (various studies in different countries including Brazil, Cyprus, Denmark, Greece and Italy) (4, 5, 10–12);
- a dedicated procurement body to reduce fragmentation of procurement responsibility within the health care system, free clinical staff of procurement duties, train and maintain a limited number of professionals focusing exclusively on procurement and therefore highly skilled workers (Denmark) (10);
- use of framework agreements in Denmark, Greece and the USA (10, 12, 21); and
- procurement via international procurement bodies like the Global Drug Facility (GDF) and UNRWA (1, 7).

### **Recent changes in procurement practices**

The following section reviews recent changes in procurement in the WHO European Region identified through the literature review (more changes at the country level are likely to have taken place in recent years or to be ongoing, so this is most likely a partial list).

#### *EU directive transposition*

In February 2014 the EU adopted a legislative package on public procurement that aimed at in-depth modernization of public procurement. This included Directive 2014/24/EU on public procurement, Directive 2014/25/EU on procurement by entities operating in the water, energy, transport and postal services sectors and Directive 2014/23/EU on the award of concession contracts (26). Member States were expected to implement the new directives into their own national legislation by 18 April 2016.

#### *Joint Procurement Agreement to Procure Medical Countermeasures*

The aim of the Joint Procurement Agreement is to enable more equitable access to medical countermeasures for the Member States involved, to help them meet their citizens' needs and obtain more balanced contractual conditions (27). The legal basis for the Agreement was laid down in Article 5 of Decision 1082/2013/EU, which states:



The institutions of the Union and any Member States which so desire may engage in a joint procurement procedure ... with a view to the advance purchase of medical countermeasures for serious cross-border threats to health.

Debate took place as to whether Directive 2014/24/EU on public procurement could be used for high-price medicines but the European Commission clarified that this was not its aim (28).

Medical countermeasures are defined as “any medicines, medical devices, other goods or services that are aimed at combating serious cross-border threats to health” (27). Serious cross-border threats to health are life-threatening or otherwise serious hazards to health of biological, chemical, environmental or unknown origin, which spread or entail a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at the EU level to ensure a high level of human health protection. These include:

- threats of biological origin, consisting of:
  - communicable diseases;
  - antimicrobial resistance and health care-associated infections related to communicable diseases;
  - biotoxins or other harmful biological agents not related to communicable diseases;
- threats of chemical origin;
- threats of environmental origin;
- threats of unknown origin;
- events that may constitute public health emergencies of international concern under the International Health Regulations (IHR), provided they fall into one of the categories of threats set out above.

Examples of medical countermeasures that could be procured in common under the Joint Procurement Agreement are laboratory tests, diagnostic tools/kits for seasonal or pandemic influenza, influenza vaccines, antivirals, decontamination products, masks and personal protective equipment or other goods and services depending on the need triggered by a serious cross-border threat to health.

The Joint Procurement Agreement enables EU Member States to purchase medical countermeasures for different categories of threat, provided that they can be considered cross-border threats within the meaning of Article 3(g) and in line with the objectives of Decision 1082/2013/EU. Member States participating Agreement will decide, on a voluntary basis and as deemed appropriate by each of them, for which medical countermeasures they would like the Commission to analyse the feasibility of a specific procurement procedure. The Agreement sets the minimum number of contracting parties to launch a specific procurement procedure at five, including the Commission (Article 13(1)), which means that a procedure could be launched once four Member States agree to do so.



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## Annex 7

# Studies on the impact of tendering on prices

Country (reference)	Products procured	Therapeutic area	Sector	Study objective
37 middle- and low-income countries (1)	On-patent and off-patent	HIV/AIDS, tuberculosis (TB) and malaria	Ambulatory	To analyse determinants of ex-manufacturer prices for originator and generic drugs across countries
Sweden (2)	Off-patent	Not specified	Ambulatory	To study: 1) how the lowest bidder's market share affects the average price directly and indirectly and 2) the effect of the number of firms on the average price
Italy (3)	Biosimilars	Somatropin (H01AC01), epoetin and filgrastim (L03AA02)	Ambulatory and hospital	To assess the awarded prices achieved by the regional tenders for biosimilars in Italy
Cyprus (4)	On-patent and off-patent	Various	Ambulatory and hospital	To assess the financial benefit of tendering and evaluate its operational framework
Austria, the Netherlands, Norway, Portugal and Slovakia (5)	On-patent and off-patent	Oncology, rheumatoid arthritis, immunomodulation, anti-inflammatory, neurology – multiple sclerosis, cardiology, blood	Hospital	To survey price reductions such as discounts and rebates granted for medicines used in hospitals
Chile (6)	Mostly off-patent medicines, medical devices	Various	Hospital	To investigate the effect of electronic tendering on the price paid by the public sector for pharmaceuticals and medical devices in Chile
Italy (7)	Not specified	Not specified	Hospital	To test which tender systems (centralized, decentralized or hybrid) perform better

Method	Study period	Comparison	Impact on price
Regression analysis	Jan 2004 – Jun 2008	Tendered vs retail prices	Tendered procurement lowers originator and generic prices by 42% and 34%, compared with their respective retail prices; this procurement effect cannot be explained by volume.
Regression analysis	2006–2011	1) Increases in the lowest bidder's market share in the short and long terms; 2) the effect over time	1) Increasing the lowest-priced product's market share results in significant short-term savings, whereas the long-term effect is statistically insignificant and close to zero. 2) A 1% reduction in the number of firms raises prices by approximately 1% in the long term. This corresponds, for example, to prices falling by approximately 33% when the number of firms rises from two to three.
Regression analysis	2008–2012	Time (years), originator, biosimilar, other	While the price of somatropin stayed steady, those of filgrastim and epoetin dropped steeply over time. The mean number of competitors was lowest for somatropin and highest for filgrastim. One additional competitor was associated with about a 10% reduction in the price on average. The benefits of having many competitors did not fade with increasing numbers of companies.
Descriptive analysis	2011	Tendered vs pharmacy procurement prices (wholesale)	A 39.39% mean price reduction was achieved with the tendering system. Generics demonstrated the greatest reduction in mean price (62.97%); branded products reached 25.99% and the top 20 products achieved 23% mean price reduction.
Descriptive analysis	Sep 2009 – Mar 2010	Centralized tender prices vs decentralized procurement prices	Price reductions for medicines procured by central tendering tended to be higher than those obtained in decentralized procurement.
Regression analysis	2001–2006	Before and after the Chilecompra electronic platform was implemented	The empirical results support the volume effect: greater aggregation of purchases led to 2.8% lower prices. The evidence does not support the other indirect channels. More bidders resulted in lower prices, but the number of bidders failed to increase after 2004, the year use of Chilecompra became obligatory.
Regression analysis	2009–2012	Price paid by different tender methods	Centralized and hybrid procurers paid lower prices than decentralized units. The average cost saving was about 20% for centralized agencies and around 9% for hybrid procurers.

Contd

Country (reference)	Products procured	Therapeutic area	Sector	Study objective
Mexico (8)	On-patent and off-patent	Antiretrovirals (ARVs)	Not specified	To assess the immediate impact of the creation of the Mexican Commission for Price Negotiation on ARV prices and expenditures
Brazil (9)	Not specified	Not specified	Not specified	To evaluate the impact of the Intermunicipal Health Consortium on budget and shortages of medicines for the basic pharmaceutical assistance component in Indaial municipality, southern Brazil
China (10)	Not specified	Not specified	Not specified	To review the impact of reform of the essential medicines system in China
Brazil (11)	Not specified	Not specified	Not specified	To analyse empirically whether prices paid by buyers increase or reduce when they are joined by other buyers in procurement pools
Jordan, Lebanon, Syrian Arab Republic, West Bank and Gaza Strip (12)	Not specified	Various	Not specified	To assess the United Nations Relief and Works Agency for Palestine Refugees in the Near East (UNRWA)'s medicine procurement prices to see if savings could be possible
Italy (13)	Vaccines	Human papillomavirus (HPV)	Not specified	To examine the correlation between prices, timing of tenders and volumes purchased

Method	Study period	Comparison	Impact on price
Descriptive analysis	2004–2009	1) price variation before and after the creation of the Commission; 2) Mexican ARV prices and international procurement prices; 3) Mexican ARV expenditure and international procurement expenditure	Prices for ARVs dropped by an average of 38% after the first round of negotiations, indicating that the interinstitutional Commission was successful in price negotiations. When compared with other upper-middle-income countries, however, Mexico continues to pay an average of six times more for ARVs.
Descriptive analysis	2007–2009	Price, expenditure and stock-outs in 2007 (without Consortium), 2008 (mixed) and 2009 (with Consortium)	Per unit prices paid in 2008 for the procurement of medicines, already under the influence of the Consortium, were systematically lower than in 2007 (63% of items). Per unit prices in 2009, with medicine procurement by Consortium, decreased in comparison to the 2007 price for 76% of items.
Descriptive analysis	n/a	Before and after the reform	Pooling volume at a provincial level, streamlining of supply chains and the introduction of a government-led bidding platform at the regional level have resulted in reductions in medicine prices. The government reported that the price of essential medicines dropped on average by 16.9% between 2009 and 2011. Independent small-scale studies demonstrated even larger reductions in medicine prices. A decline in the average cost per prescription from 45 to 27 Yuan in Hubei province was reported.
Regression analysis	2004–2009	Pooled procurement vs individual procurement by public bodies	Prices paid by public bodies in Brazil are lower when they buy through pooled procurement than individually. On the other hand, federal agencies (i.e. good payers) pay higher prices for products when they are joined by state agencies (i.e. bad payers) in a pool.
Descriptive analysis	2010	Prices achieved by different procurement bodies (UNRWA, Management Sciences for Health, Jordan's Joint Procurement Department, the Gulf Cooperation Council, IDA Foundation) and levels (central tender vs local procurement)	Central procurement prices did not differ markedly from reference prices: median ratios of UNRWA prices to Management Sciences for Health's international drug price indicator guide, Jordan's Joint Procurement Department, the Gulf Cooperation Council, and IDA Foundation bulk packs were 0.99, 1.00, 0.98 and 1.12, respectively. Local procurement was generally less cost-effective than central tender procurement, with notable differences across fields and medicines.
Regression analysis	2007–2009	Procurement prices of two HPV vaccines: a quadrivalent (Gardasil, Sanofi-Pasteur MSD), and a bivalent (Cervarix, SKF)	The study found a strong relationship between prices and timing of tenders, but only a negligible correlation between prices and volumes ( $R^2 = 0.08$ ), showing that lower prices were not related to stronger purchasing powers in bigger regions. A closer look at the price patterns for the two vaccines separately revealed that the quadrivalent vaccine, initially more expensive than the bivalent one, became the cheaper after two years of tendering.

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## Annex 8

# Studies on the impact of tendering on expenditure

Country (reference)	Products procured	Therapeutic area	Sector	Study objective
Mexico (1)	On-patent and off-patent	Antiretrovirals (ARVs)	Not specified	To assess the immediate impact of the creation of the Mexican Commission for Price Negotiation on ARV prices and expenditures
Brazil (2)	Not specified	Not specified	Not specified	To evaluate the impact of the Intermunicipal Health Consortium on budget and shortages of medicines in the Indaial municipality in southern Brazil
Denmark (3)	Various	Various	Hospital	To present the Danish experience with centralized procurement
Mexico (4)	On-patent	Oncology, haematology, infectious diseases, neurology, endocrinology, rheumatology and other clinical specialties	Not specified	To discuss achievements and challenges in negotiating prices for patented by the new central body in Mexico
Greece (5)	Medical devices and pharmaceuticals	Not specified	Hospital	To present the procurement practices and policies set forth by the Health Procurement Committee and the first measurable outcomes, in terms of cost savings, resulting from these policies

Method	Study period	Comparison	Impact on expenditure
Descriptive analysis	2004–2009	1) price variation before and after the creation of the Commission; 2) Mexican ARV prices and international procurement prices; 3) Mexican ARV expenditure and international procurement expenditure	Prices for ARVs dropped by an average of 38% after the first round of negotiations, indicating that the interinstitutional Commission was successful in price negotiations. When compared with other upper-middle-income countries, however, Mexico continues to pay an average of six times more for ARVs.
Descriptive analysis	2007–2009	Price, expenditure and stock-outs in 2007 (without Consortium), 2008 (mixed) and 2009 (with Consortium)	Total expenditure decreased by 33% when comparing procurement by the Intermunicipal Health Consortium (2009) to municipal procurement (2007), and by 18% when compared to the average expenditure of the 2009 health prices database from the Ministry of Health.
Descriptive analysis	2008–2015	Expenditure at tender prices vs expenditure at retail prices	By investing in and combining a centralized structure (Amgros) and the establishment of the Danish Council for the Use of Expensive Hospital Medicines, which assesses the clinical costs and benefits of expensive medicines and helps guide the selection of medicines by Amgros and clinicians, the Danish Government saved approximately €314 million in 2015.
Descriptive analysis	2008–2011	reference to the preceding year	According to the annual reports by the Coordinating Commission for Negotiating the Price of Medicines and other Health Inputs, the accumulated direct savings (e.g. price reductions resulting from the negotiation) over 2008–2011 reached a total of US\$ 355 million.
Descriptive analysis	2010–2011	Difference between estimated budget and actual contract prices	In 2010 implementation of the Health Services Procurement Programme resulted in savings of approximately €180 million, i.e. the difference between estimated budget and actual contract prices. The Health Procurement Committee performed the first tender for hospital drugs in July 2011 using the e-procurement method, and specifically for four active substances on behalf of three hospitals with a total budget exceeding Euro 2 million. The e-auction process resulted in annual economic savings of 80%. On an even larger scale, the second e-tender for hospital drugs conducted in November 2011 involved 23 active substances on behalf of all Greek Hospitals with a total budget exceeding Euro 80 million. In this case the e-auction process resulted in substantially lower prices which are estimated at 57%.

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Country (reference)	Products procured	Therapeutic area	Sector	Study objective
n/a (6)	Not specified	Tuberculosis (TB)	Not specified	To review the contribution of the Global Drug Facility (GDF) in reducing the price of multidrug-resistant (MDR) TB treatment
Italy (7)	On-patent	Cardiovascular	Not specified	To model different price–volume scenarios for the procurement of evolocumab and alirocumab (PCSK9 inhibitors)
Cyprus (8)	On-patent and off-patent	Various	Ambulatory and hospital	To assess the financial benefit from tendering and to evaluate its operational framework
Chile (9)	Mostly off-patent medicines, medical devices	Various	Hospital	To investigate the effect of electronic tendering on the price paid by the public sector for pharmaceuticals and medical devices in Chile

Method	Study period	Comparison	Impact on expenditure
Descriptive analysis	2011–2013	Cost of treating a patient for 24 months in different years	There was a significant reduction in the overall cost of treatment. Between 2011 and 2013 the cost of the longest (24-month) treatment course and most expensive regimen for treating MDR-TB in one patient decreased by up to 26%: from US\$ 7890 to US\$ 5822.
Simulations	2016	Different price-halving populations (PHPs)	In nine price–volume simulations (testing three values of PHP at 25 000, 50 000 or 100 000 patients), the total national expenditure varied from €204 million to €721 million. In the least expensive scenario (PHP = 25 000 patients), the expenditure ranged from €204 million to €338 million, while the average treatment cost per year was €3382. At more than 100 000 treated patients, the treatment cost fell to €626. On the other hand, the scenarios based on PHP = 50 000 and PHP = 100 000 patients were very unlikely to be acceptable for national health systems.
Descriptive analysis	2011	Tendered vs pharmacy procurement prices (wholesale)	A 60.6% reduction in expenditure was achieved with the tendering system. Generics demonstrated the greatest reduction in expenditure (94.8%); branded products reached 33.4% and the top 20 products achieved 29% expenditure reduction.
Regression analysis	2001–2006	Before and after the Chilecompra electronic platform was implemented	In 2006, US\$ 65 million in drugs and US\$ 37 million in medical devices were tendered over Chilecompra. Using only the direct effect of e-tendering on price the authors found savings of US\$ 8.7 million.

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## Annex 9

# Studies on the impact of tendering on volume

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Country (reference)	Products procured	Therapeutic area	Sector	Study objective
Germany (1)	Off-patent	Cardiovascular, central nervous system, diabetes	Ambulatory	1) To quantify the effect of signing preferred supplier contracts on market shares at the brand level; 2) to analyse whether branded generic and original manufacturers – neither usually signing preferred supplier contracts – are to some extent able to shield their sales against other competitors that sign preferred supplier contracts; and 3) to evaluate whether the sequence of contracting (such as being the first mover effects market shares in post-patent drug markets
Brazil (2)	On-patent	Cardiovascular	Not specified	To model different price–volume scenarios for the procurement of evolocumab and alirocumab (PCSK9 inhibitors)

Method	Study period	Comparison	Impact on volume
Hierarchical market share attraction model	January 2007 – July 2009	Comparison of market shares between original manufacturers, branded generics and unbranded generics over time	<p>1) Signing a preferred supplier contract has a positive effect on a brand's own market share and a negative effect on the market shares of competitors.</p> <p>2) The original manufacturers are unable to exploit successfully physicians' accumulated stock of drug knowledge after generic entry.</p> <p>3) The time period between signing the first and following preferred supplier contracts positively affects market share gained, although curves converge with time.</p>
Simulations	2016	Different price-halving populations (PHPs)	In nine price–volume simulations (testing three values of PHP at 25 000, 50 000 or 100 000 patients), the total national expenditure varied from €204 million to €721 million. In the least expensive scenario (PHP = 25 000 patients), the expenditure ranged from €204 million to €338 million while the average treatment cost per year was €3382. At more than 100 000 treated patients, the treatment cost fell to €626. On the other hand, the scenarios based on PHP = 50 000 and PHP = 100 000 patients were very unlikely to be acceptable for national health systems.

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## Annex 10

# Study on the impact of tendering on the number of bidders

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Country (reference)	Products procured	Therapeutic area	Sector	Study objective
Chile (1)	Mostly off-patent medicines, medical devices	Various	Hospital	To investigate the effect of electronic tendering on the price paid by the public sector for pharmaceuticals and medical devices in Chile



Method	Study period	Comparison	Impact on the number of bidders
Regression analysis	2001–2006	Impact assessment	More bidders resulted in lower prices, but the number of bidders failed to increase after 2004, the year use of the Chilecompra electronic platform became mandatory.

## Annex 10 reference

1. Raventós P, Zolezzi S. Electronic tendering of pharmaceuticals and medical devices in Chile. *J Bus Res.* 2015;68.

## Annex 11

# Study on the impact of tendering on stock-outs

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Country (reference)	Products procured	Therapeutic area	Sector	Study objective
Brazil (1)	Not specified	Not specified	Not specified	To evaluate the impact of the Intermunicipal Health Consortium on the budget and shortage of medicines for the basic pharmaceutical assistance component in Indaial municipality, southern Brazil

Method	Study period	Type of study	Comparison	Impact on stock-outs
Descriptive analysis	2007–2009	Impact assessment	Price, expenditure and stock-outs in 2007 (without Consortium), 2008 (mixed) and 2009 (with Consortium)	The number of items with stock-outs for at least one day decreased by approximately 12.0% in 2008 in relation to 2007, and by 48.0% in 2009 in relation to 2007. The number of medicines unavailable for more than 90 days was 11 (2007), three (2008) and two (2009).

## Annex 11 reference

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## Annex 12

# Findings from studies reviewing countries' public procurement systems

Country (reference)	Products procured	Therapeutic area	Sector	Study objective
Survey conducted in 19 European countries, of which the following seven responded as having experience with tendering in the ambulatory sector: Belgium, Denmark, Germany, Malta, the Netherlands, Romania and Slovenia (1)	Off-patent	Not specified	Ambulatory	To explore the status (in 2010) of tendering programmes for outpatient pharmaceuticals in the European countries and how these operate
Survey conducted in 31 European countries (2)	Biosimilars	Various	Ambulatory and hospital	To describe pricing and reimbursement policies for off-patent biologicals (data collected between September 2013 and March 2014)
Denmark (3)	On-patent and off-patent	Various	Ambulatory and hospital	To describe the market for hospital pharmaceuticals in Denmark – both its organization and market characteristics and the relative contribution of price and volume to expenditure growth in the hospital and retail sector
England, United Kingdom (4)	Not specified	Not specified	Hospital	To assess operational productivity and performance in English National Health Service acute hospitals

Data source	Findings
Survey	<p>Tendering was more popular in countries with a mature (54%) than a developing generic medicines market (12.5%), among the 19 respondents. A legal basis, criteria to grant the tender, the number of winners and the duration of the tender were among the minimum criteria to issue the tender. All countries had the same objective for installing a tendering procedure; namely, to create savings in the health care budget by obtaining lower prices for pharmaceuticals. This objective was reached in Denmark and the Netherlands. In Germany the effect on the budget was unclear. Romania and Slovenia had variable outcomes and the objectives were not always reached. In Belgium savings for simvastatin were not achieved (the response did not specify whether they were met for other medicines, although singling out simvastatin seems to imply they were).</p>
Survey	<p>24 countries conducted tenders for biologics; 13 at ATC-5 level only (substance level), nine at ATC-4 level (therapeutic class) and two at both levels.</p> <p>No responding country required substitution of patients on treatment at the time of the survey. Nearly two thirds of the countries had either laws or guidelines in place to prohibit substitution of biological medicines. In 12 countries it was possible for patients on a given treatment to be changed to a different product as a result of tender outcomes. While prescribing by international nonproprietary name was mandatory or recommended in 13 of 31 countries, the majority of countries had introduced mechanisms to exempt biological medicines from such prescribing.</p>
Amgros	<p>The market for hospital pharmaceuticals is more concentrated and the market share of generics and parallel imports is significantly lower than in the retail sector. While the price increase for pharmaceuticals was larger in the hospital than the retail sector, the majority of expenditure growth was due to an increase in utilization, reflecting increased hospital activity, and introduction of new substances in the hospital sector.</p>
Site visits to hospitals	<p>Many areas where efficiencies could be generated in procurement were identified – in particular, the need to increase use of e-tools and pool procurement to generate savings.</p>

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Country (reference)	Products procured	Therapeutic area	Sector	Study objective
European Union (5)	On-patent and off-patent	Not specified	Ambulatory and hospital	To provide an overview of the applicability of public procurement legislation in the health care sector, and more specifically the challenges it sets to the pharmaceutical industry
India (6)	Not specified	Not specified	Ambulatory and hospital	To perform an initial qualitative comparison of the different procurement models in India to frame questions for future research in this area; to capture the finer differences between the state models through 53 process and price parameters to determine their functional efficiencies
Iran (Islamic Republic of) (7)	Not specified	Not specified	Not specified	To review the current methods of pharmaceutical purchasing by Iranian insurance organizations within the World Bank conceptual framework model, and to make recommendations on applicable purchasing strategies to increase access to medicines
Various (8)	On-patent and off-patent	Various	Not specified	To review current status, past achievements and future challenges in procurement of medicines in low- and middle-income countries
WHO European Region (9)	Vaccines			To present data submitted by Member States in the WHO European Region through the WHO/UNICEF Joint Reporting Form for 2013

Data source	Findings
Survey	Despite a deep harmonization of the rules on public contracts throughout the European Union, the practical implementation of those rules varies among Member States.
Interviews	The analysis indicated that autonomous procurement organizations were more efficient in relation to payments to suppliers, had relatively lower drug procurement prices and managed their inventory more scientifically.
Literature and interviews	Purchasers face many structural, financing, payment, delivery and service procurement and purchasing challenges. There is a need to shift from passive purchasing of medicines to a strategic method in order to increase access to essential medicines.
Literature	While new funding, procurement and pricing mechanisms implemented by multilateral agencies and donors have improved public sector access to medicines, significant systemic and operational challenges still exist in national-level public sector health care procurement. Addressing these challenges will require strong commitment at the national government level, and continued multilateral agency and donor engagement and support, including capacity-building that is harmonized and conducted on a system-wide basis.
Survey	Of the 53 Member States in the WHO European Region, 29 from all income groups participated in the survey. Countries reported using different procurement methods. At the national level, procurement via a government agency was the most common method used in the 16 responding high-income countries (HIC) (16/16), followed by the six upper-middle-income countries (UMIC) (5/6), the five lower-middle-income countries (LMIC) (2/5) and the two low-income countries (LIC) (1/2). International procurement agencies were mostly used in LMIC (5/5) and LIC (2/2), followed by UMIC (1/6), but were not used in HIC. Use of other procurement mechanisms was reported in LIC (2/2), some LMIC (2/5), HIC (2/16) and UMIC (1/6).

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## Annex 13

# Summary of the key challenges identified in the literature

Challenge	Quotation from the literature review
<b>Award criteria</b>	
<ul style="list-style-type: none"> <li>• Price only</li> </ul>	Authorities place the strongest emphasis on obtaining the lowest possible price (1).
	Price vs quality challenges can be an issue if the sole criterion of the tender award is the lowest price (2).
	The lack of an integrated health care system has also resulted in the inability to establish an effective health technology assessment mechanism in Greece. In absence of a formal health technology assessment structure, procurement and reimbursement is currently based mainly on their price rather than value (3).
	Although tendered contracts can achieve large price discounts, important caveats do exist. Confidential and multifaceted deals between manufacturers and hospitals do not contribute to transparency in the market, which might favour the manufacturers of originator products. For example, Belgium is finding that tendered contracts with fringe benefits, such as sponsored additional training and clinical research grants, between manufacturers of branded biological drugs and hospitals result in deals that cannot be matched by biosimilar developers (4).
<ul style="list-style-type: none"> <li>• Single winner</li> </ul>	The winner-takes-all type of tender can have direct impact on the market. By limiting the number of providers, it can impact competition and distort market efficiency. In addition, a single market provider increases the risk of shortages given the difficulty to manufacture biological medicines (5).
<b>Competition</b>	
<ul style="list-style-type: none"> <li>• Limited or no competition</li> </ul>	Generally, over-reliance on single-source suppliers may carry risks in decreased competition for certain products, and should be reconsidered (1).
	This underlying preference for local distributors and manufacturers creates limited competition, which tends to produce higher prices (2).
	The Italian Medicines Agency did not really exploit the potential competition between the two manufacturers at a national level because their prices were not negotiated at the same time (6).
<ul style="list-style-type: none"> <li>• Number of bidders</li> </ul>	Since 2007, Amgros has entered into many region-specific tender contracts. However, there has not been a trend of more suppliers bidding for these smaller tenders, most likely because they are more difficult to administer. In most cases, one supplier wins the tender in all regions (7).
<ul style="list-style-type: none"> <li>• Product differentiation</li> </ul>	Central authorities allow manufacturers to launch several packages with different dosages and forms, in order to differentiate their products (8).
	The dominant position of the payer may compromise competition and promote oligopoly, which must be monitored for long-term impact (9).

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Challenge	Quotation from the literature review
<b>Competitive prices</b>	
<ul style="list-style-type: none"> <li>Combining volume to strengthen purchasing power</li> </ul>	Regional authorities are conducting their own tenders; therefore, pooling volume is not available and economy of scale is not reached (8).
	A potential threat is for buyers to become so consolidated that their power lowers prices to the extent that a market segment becomes less attractive to industry, potentially diminishing research and development, and possibly even production. Some observers suggest that this phenomenon has taken place in the vaccine market, where there has been much consolidation on the supply side, along with consolidation on the demand side, through pooled procurement mechanisms. The vaccine market is special in that much of the buyers' global market is in the public sector; despite this, there is evidence that low-cost Asian companies find the market sufficiently appealing to involve themselves in both innovation and production. For most products, including contraceptives, there is no apparent long-term threat of buyers becoming too powerful as they consolidate their buying power. Indeed, just as Asian companies are beginning to produce vaccines, Asian countries, particularly India, are rapidly expanding their production of good-quality, low-cost generics, and this expansion includes contraceptives and vaccines (10).
<ul style="list-style-type: none"> <li>Higher pooled price due to bad payers</li> </ul>	When a buyer with a good reputation for paying suppliers in a timely manner is joined in the pool by a buyer with bad reputation, it may have its price increased due to the credit risk etc. on prices. This will happen because prices paid in a pooled procurement should reflect the (higher) average buyers' credit risk (11).
<b>Corruption</b>	Many countries are facing issues involving corruption at different levels of the procurement cycle (2, 10, 12, 13, 14).
<b>Decentralization</b>	A number of countries have decentralized procurement, shifting varying degrees of responsibility from the national to the provincial, district or municipal level. Experiences with decentralized medicine procurement have been mixed. General concerns include the impact on costs, impact on quality and management burden. To address the challenges posed by decentralization, it may be appropriate to retain some functions, such as price negotiations and quality control compliance, at the central level (2).
<b>Donors</b>	Funding for medicines comes from different donors, which have different priorities and procurement process (2).
<b>Flexibility</b>	The tender awarded product had low efficacy, so the second cheapest product was included under a co-payment or preapproval process scheme (9).
<b>Forecasting</b>	<p>Needs over short periods cannot always be estimated very precisely. The amount of required medicine can vary depending on the number of patients undergoing a certain treatment. Hence, only certain products with very stable consumption patterns are suitable to be negotiated using fixed volume tenders, such as paracetamol (7).</p> <p>National capacity to conduct forecasting and quantification is weak (2).</p> <p>As the volume forecasts are not accurate, the quantities tendered could cause shortages or overstocks of medicines. The price reductions achieved by the Coordinating Commission for Negotiating the Price of Medicines and other Health Inputs (CCPNM) may be large, but if these are not matched with accurate forecasts of the drug volumes needed, inefficiency could result and reduce potential savings (13).</p>
<b>Frequent change in medicine availability</b>	<p>Fixed volume tender contracts: product availability changes frequently and can potentially place patient safety at risk if the patient needs to change "product" frequently (7).</p> <p>Lower patient compliance due to switches in patients' pharmaceuticals was seen in Denmark and Germany (15).</p>

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Challenge	Quotation from the literature review
<b>Human resource capacity</b>	Personnel have the capacity to identify and address inefficiencies in antiretroviral (ARV) procurement (16).
	Procurement human capital (the number of staff working in procurement) is insufficient (17).
	Human resource challenges include a lack of trained personnel in procurement management and frequent staff turnover (2).
	There is a lack of permanent staff with sufficient technical expertise (13).
	The staff component of hospital purchasing committees is usually comprised of employees lacking knowledge of the procurement legislation and uninformed about current procurement practices (3).
<b>Information on the market</b>	Lack of data makes empirical research on procurement difficult (12).
	Not conducting benchmark analysis with prices in other countries when conducting procurement leads to forgone efficiencies (18).
<b>Insufficient funding</b>	Financing is limited (2).
	Financing is needed to allow countries to begin to participate in an existing mechanism, or to create a mechanism for basic essential products that does not currently exist. Pooled procurement is a health financing reform, and without financing there can be no reform (10).
<b>Legal aspects</b>	Countries should establish supporting policies aimed at improving the quality of supply chain data (16).
	There is a need for legislative support to implement framework agreements in sub-Saharan Africa (17).
	Some countries have national procurement or registration policies that, in effect, limit competition. For example, in Latin America, the procurement regulations in Nicaragua, Peru and the Dominican Republic do not contain a provision for international tendering. In several other Latin American countries, international tendering and procurement are legal only under special circumstances (2).
	A thorough and detailed legal framework will minimize areas of controversy that could lead to legal issues (9).
	Legal proceedings hindered implementation of tendering in countries such as Germany. In Cyprus only a few cases resulted in court litigation (9).
	A detailed national and EU legal framework is required (9).

### Monitoring

<ul style="list-style-type: none"> <li>Procurement body</li> </ul>	There is a lack of explicit indicators for assessing the CCPNM's performance. For instance, the CCPNM's annual reports say nothing about (i) negotiations that were not concluded on time; (ii) negotiations that resulted in a failure of the parties to agree on the target price and the possible reasons for this; (iii) the operational costs of the CCPNM; or (iv) the accuracy of volume forecasts and the under or oversupply of patented medicines (13).
	Although this centralization has proved to leverage economies of scale and specialization, the long-term impacts of this kind of standardization process are still debated (3).
<ul style="list-style-type: none"> <li>Suppliers' performance</li> </ul>	Suppliers' performances are not taken in consideration when conducting new tenders (1).
	Capacity is limited to conducting performance monitoring and evaluation of suppliers (2).
<ul style="list-style-type: none"> <li>Prescribing</li> </ul>	Doctors may switch to alternative branded products (with guidelines to monitor prescription and limit access to equivalent branded products in selected cases) (9).

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Challenge	Quotation from the literature review
<b>Planning</b>	There was poor management of the annual negotiation process, resulting in untimely preparation of background materials and inadequate communication between committees and institutions (13).
<b>Pricing aspects</b>	
• Hospital vs ambulatory	If tendering does not also cover the outpatient sector, suppliers may offer hospitals certain medicines at a very low price (or even free), which are mainly used in the community to ensure they continue with the same product once the patient leaves the hospital (9).
• Submitted bid is below cost	This has resulted in price wars among manufacturers, whereby firms submit commercial bids that are below cost (1).
	The lack of an integrated health care system has also resulted in the inability to establish an effective health technology assessment mechanism in Greece. In absence of a formal health technology assessment structure, procurement and reimbursement is currently based mainly on their price rather than value (3).
	There is a significant price gap between competitors (asking for utilities instead of quantities) (9).
	For certain new and expensive products, tendering has no effect on prices, in contrast to other countries' risk-sharing schemes (9).
	Countries experience difficulties in negotiating price reductions for medicines for which no therapeutic alternatives are available (19).
<b>Political support</b>	There is a lack of political support for the CCPNM, which threatens its sustainability after the federal administration turnover in December 2012 (13).
<b>Quality</b>	The quality of medicines tendered for is an issue (1).
	In most countries, quality of generic medicines is a concern (20).
	Countries face challenges in conducting quality assurance of medicines (2).
<b>Registration status of the medicine in the country</b>	Some countries have limitations on procurement directives and registration of medicines is a complex process (2).
<b>Safety</b>	Fixed volume tender contracts: product availability changes frequently and can potentially place patient safety at risk if the patient needs to change "product" frequently (7).
	There is a need to monitor adverse events, especially during the switch period between two agents (example of generic losartan in Cyprus) (9).
<b>Selection criteria</b>	The selection of products to be included in the tender is not always based on evidence. In some countries the committee in charge of selecting the products to include in the tender is not a multidisciplinary team (9).
<b>Simple administration</b>	Since 2007, Amgros has entered into many region-specific tender contracts. However, there has not been a trend of more suppliers bidding for these smaller tenders, most likely because they are more difficult to administer (7).

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Challenge	Quotation from the literature review
<b>Supply chain</b>	
<ul style="list-style-type: none"> <li>• Shortages</li> </ul>	<p>The winner-takes-all type of tender can have direct impact on the market. By limiting the number of providers, it can impact competition and distort market efficiency. In addition, a single market provider increases the risk of shortages given the difficulty to manufacture biological medicines (5).</p> <p>Risk for shortages due to long tender processes can be addressed with proper planning and forecasting effectively cope with this concern (9).</p> <p>Developing countries are not being able to afford advance purchase agreement (APA), making them reliant on traditional procurement methods which are likely to lead to short supplies in case of pandemic (21).</p> <p>The two main reasons that account for supply problems, according to the answers received, are the lack of submission for registration (41%) and supply discontinuation (31%). Other reasons are the transfer of market authorization holder (10%) and withdrawal of authorization by the market authorization holder (10%), unauthorization (distributed individual use art. 5.1 Directive 2001/83/EC) (5%) and marketing authorization not being renewed (3%). The two main assumed causes for the product not being launched in the country are lack of profitability for the economic operators (68%) and manufacturing problems (20%) (21).</p>
<ul style="list-style-type: none"> <li>• Mark-ups and taxes</li> </ul>	<p>“Some countries impose regulatory barriers, such as duties, value added tax, and tariffs on medicines that are imported, which increases medicine prices and can impact the procurement environment by indirectly limiting competition” (2).</p> <p>“In the Netherlands due to the specific remuneration system of pharmacists, some pharmacies suffered from the strongly declining profit margins” (15).</p>
<ul style="list-style-type: none"> <li>• Reliable supply of agreed quantity and timely delivery</li> </ul>	<p>“In Denmark delivery problems were also noted, especially if a smaller company had won” (15).</p> <p>A guarantee process and sanctions should be implemented to prevent failure to provide agreed quantity (9).</p>
<ul style="list-style-type: none"> <li>• Information about the supply chain</li> </ul>	<p>Countries should “establish supporting policies aimed at improving the quality of supply chain data” (16).</p>
<ul style="list-style-type: none"> <li>• <b>Transparency</b></li> </ul>	<p>The confidential nature of price reduction arrangements impedes transparency and may lead to a distortion of medicine prices (19).</p> <p>Countries are facing challenges in prices transparency (2).</p> <p>The work of the CCPNM needs to be made more transparent, since annual reports are circulated only within the three public health institutions belonging to the CCPNM and the subnational health ministries of the 31 states and federal district. Increased transparency and accountability to other stakeholders (e.g. civil society and academic institutions) could enhance trust and garner support for the work of the CCPNM, since procurement is an area perceived as easily harbouring corruption (13).</p>

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## Annex 14

# Summary of the key enablers identified in the literature

Challenge	Description
<b>Competition</b>	
<ul style="list-style-type: none"> <li>International procurement body</li> </ul>	The price of drugs supplied by the Global Drug Facility was reduced by: (i) consolidating orders to achieve large purchase volumes; (ii) transparent, international, competitive bidding; and (iii) medicine stockpiles funded by donors (1).
<ul style="list-style-type: none"> <li>Number of bidders</li> </ul>	Prices may fall steeply at a regional level even when competition is minimal, i.e. only two manufacturers producing their own vaccines judged equivalent for the prevention of cervical cancer by health authorities (2).
<b>Competitive prices</b>	
<ul style="list-style-type: none"> <li>Establishment of a national negotiation body for on-patent medicines</li> </ul>	The annual reports of the Coordinating Commission for Negotiating the Price of Medicines and other Health Inputs (CCPNM) showed that, for most patented medicines, every year the negotiations resulted in large price reductions with reference to the preceding year. According to the reports, the accumulated direct savings (e.g. price reductions resulting from the negotiation) over 2008–2011 reached a total of US\$ 355 million (3).
<ul style="list-style-type: none"> <li>Combining volume to strengthen purchasing power</li> </ul>	<p>A pool of buyers, which aggregates demand for its members, increases bargaining power and allows suppliers to achieve economies of scale and scope in the production. Such aggregation demand effect lowers prices paid for buyers (4).</p> <p>The price of drugs supplied by the Global Drug Facility was reduced by: (i) consolidating orders to achieve large purchase volumes; (ii) transparent, international, competitive bidding; and (iii) medicine stockpiles funded by donors (1).</p>
<b>Information on the market</b>	
<ul style="list-style-type: none"> <li>Information sharing</li> </ul>	<p>Another important success is the sharing of information on the patent status of a large number of medicines, since such information is often difficult to obtain in Mexico and other low- and middle-income countries (3).</p> <p>The Price List Observatory – a policy mechanism set forth to guide public procurement and serve as a reference pricing for designated products – has demonstrated its added value to the Greek economy and is used as a reference by other public sector agencies, e.g. military hospitals, public insurance organizations, and so on. Sickness funds and hospitals have recently started to reimburse only devices whose prices are in parity with those published by the Health Procurement Committee's Observatory (5).</p>
<ul style="list-style-type: none"> <li>Other</li> </ul>	<p>Preliminary results from another study [same authors, Cyprus] suggest that good estimators for greater price and value reduction include generic status medicines, tendering type by alternative, high wholesale prices and high volume. Innovation status (major innovation compared to marginal innovation) did not have any difference in value and price reduction (6).</p> <p>Less expenses for companies on advertising and promotion due to temporary market exclusivity for the duration of the tender also lower supply chain costs due to a few deliveries per year (6).</p> <p>Tendering can be very effective at securing supply and larger price discounts for biosimilars. For example, the Norwegian Drug Procurement Cooperation attained a price discount of 69% for an infliximab biosimilar compared with its reference drug (7).</p>



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Challenge	Description
<b>Pricing aspects</b>	
<ul style="list-style-type: none"> <li>Fixed volumes</li> </ul>	Tendering provides volume certainty to suppliers for the duration of the tender, which can incentivize them to offer lower prices for volume certainty. Another incentive for companies to offer lower prices in tenders is that it does not affect list prices (and thus external price referencing) (6).
<ul style="list-style-type: none"> <li>Managed entry agreements (MEAs)</li> </ul>	Issues with MEAs include the resources needed for their implementation and target products of uncertain cost–effectiveness. Analysis of the financial benefits of MEAs in Cyprus showed that they are not superior to tendering (6).
<b>Research and evidence</b>	<p>The development is under way of a model for price–volume decisions that can be used also in other therapeutic areas. The main advantage in using the models described is that these models have not a purely empirical nature, but incorporate an original conceptual framework, aimed at introducing a rationale into these price–volume agreements (8).</p> <p>In addition to ensuring savings, Amgro has been able to promote safety and quality of medicines used in hospitals across Denmark and has also engaged in research and development activities by promoting research collaborations with hospital pharmacies (9).</p>
<b>Corruption</b>	Centralization, other than allowing the exploitation of scale economies, could be also a good strategy for protecting public procurers from corrupt practices (10).
<b>Decentralization</b>	Regional tender contracts allow suppliers more flexibility as they can bid to supply either one or all regions, depending on their ability to deliver (9).
<b>Donors</b>	The price of drugs supplied by the Global Drug Facility was reduced by: (i) consolidating orders to achieve large purchase volumes; (ii) transparent, international, competitive bidding; and (iii) medicine stockpiles funded by donors (1).
<b>Framework contracts</b>	Framework contracts are the most common form of tender used by Amgro. Because treatment guidelines change, this form of tender allows hospitals the degree of flexibility they need. The framework contract gives Amgro the right, but not the obligation, to buy the amount of products included in the tender. When special medical reasons or issues regarding patients’ safety dictate, it is possible to use another supplier (9).
<b>Good governance</b>	One success was the establishment of a new government entity able to promote collaboration among public health institutions in negotiating lower prices for patented medicines despite the prevailing institutional fragmentation of Mexico’s health system (3).
<b>Human resource capacity</b>	Other successes include the mobilization of trained human resources capable of engaging in complex price negotiations and the promotion of interinstitutional learning and cooperation through shared procurement practices (3).
<b>Preferred supplier contracts</b>	The authors find that preferred supplier contracts are a powerful strategic instrument for generic manufacturers in a highly competitive environment (11).
<b>Quality &amp; safety</b>	Although the objective remains the same – to save costs in pharmaceutical procurement – Amgro has become more than a trading company. In addition to ensuring savings, Amgro has been able to promote safety and quality of medicines used in hospitals across Denmark (9).
<b>Selection criteria</b>	A well formulated and localized essential medicines list is imperative to make optimal use of the limited financial resources (12).
<b>Simple administration</b>	In addition to ensuring savings, Amgro has been able to promote safety and quality of medicines used in hospitals across Denmark and has also engaged in research and development activities by promoting research collaborations with hospital pharmacies. It also provides administrative support to hospital pharmacies, allowing them to focus more on patient care and their core tasks. Administrative savings for hospitals which do not have to conduct tenders (9).

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Challenge	Description
<b>Supply chain: mark-ups and taxes</b>	The public servant status of dispensing pharmacists and their remuneration through a monthly fixed salary, therefore not related to value or volume of medicines dispensed, eliminates any incentives for more expensive products, or financial sanctions for cheaper ones (6).
<b>Support: hospitals</b>	More commitment on the side of the hospitals may be needed to implement tenders for analogue substitutes in order to increase competition among therapeutic alternatives that have so far been largely unaffected by tendering. In January 2010 a new committee was created to align pharmaceutical use for expensive medical treatments across the Danish hospitals, and to work towards a consensus and binding clinical guidelines so that tenders for analogue substitutes may be implementable in the future (13).
<b>Transparency</b>	The price of drugs supplied by the Global Drug Facility was reduced by: (i) consolidating orders to achieve large purchase volumes; (ii) transparent, international, competitive bidding; and (iii) medicine stockpiles funded by donors (1).

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## Annex 15

# Case studies

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The following two case studies present countries' experience of addressing specific challenges affecting procurement of medicines.

### Use of price-volume agreements for the procurement of direct antivirals for Hepatitis C in Italy

When the first direct acting antiviral medicine for hepatitis C, sofosbuvir, came onto the market, there was a high degree of uncertainty around the actual prevalence of hepatitis C in Italy, owing to outdated and conflicting estimates from existing studies. This, coupled with the high price of sofosbuvir, led to the decision to develop a programme to prioritize access for patients on the basis of clinical urgency. A consultative permanent committee was created – including the Italian Medicines Agency, Italian regions, clinical societies, patient organizations and academics – to reach consensus on the estimated prevalence of hepatitis C in the country and to develop the access programme. Negotiations with the manufacturer were based on patient population estimations, cost-efficacy and budget impact analysis. Price–volume simulation models were built to create different scenarios in terms of an increasing number of patients treated and decreasing treatment cost.<sup>19</sup>

A competitive price to treat 50 000 patients was reached on the condition of absolute price confidentiality. The agreed price is per treated case, not per pack, and it was estimated based on minimal treatment cost. This agreement leverages the Italian monitoring registries for its implementation.<sup>20</sup>

When the combination of sofosbuvir and ledipasvir came to the market, it was also included in the agreement. The total number of patients to be treated remained the same (50 000), shared between the two products.

At the time of its negotiation, this was not the first agreement of its kind in Italy but it was the largest in terms of patients to be treated, and it had more price–volume tiers than previous agreements. Such price–volume agreements based on the population of patients to be treated are suitable for high-cost medicines with good clinical evidence and effectiveness but uncertainty around the number of patients to be treated. As of September 2016, nearly 50 000 patients had been treated in slightly less than two years. The length of such contracts is usually 18–24 months, after which they are renegotiated. During renegotiation, new therapeutic options have been authorized for hepatitis C treatment. As more competitor products come to the market, more opportunities to reduce prices and to guarantee sustainable access for patients are created.

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<sup>19</sup> Messori A. Criteria for drug pricing: preliminary experiences with modeling the price–volume relationship. *Sci Pharm.* 2016;84(1):73–9.

<sup>20</sup> Montilla S, Xoxi E, Russo P, Cicchetti A, Pani L. Monitoring registries at Italian Medicines Agency: fostering access, guaranteeing sustainability. *Int J Technol Assess Health Care.* 2015;31(4):210–3.

## Reforming procurement practices to improve supply security in Malta

From 2014 a series of reforms was introduced to procurement practices in Malta, with the main objective of eliminating stock-outs. This was done through a number of initiatives addressing the partnership relationship with industry, limiting the risks and wastages on both sides. The following steps were also undertaken to guarantee availability of hospital supplies.

- An annual forecast of pharmaceutical needs of all hospitals was posted on the Central Procurement and Supplies Unit portal and is updated quarterly.
- An annual supplier conference was set up, at which the Central Procurement and Supplies Unit, the Medicines Regulatory Authority, the Department of Contracts of the Ministry of Finance, the Competition and Consumer Affairs Authority and industry stakeholders share ideas about how to improve the procurement process.
- Invoice payment terms were set to 60 days after receipt of goods – these have been adhered to in 99% of cases.
- An emergency response unit process was introduced.
- The protocol was changed so that monthly deliveries are now scheduled at the time of order placement.

Additional changes to previous procedures include the following.

- Supplier performance guarantees are now set up as single performance bonds based on the value of purchases made the previous year, rather than multiple guarantees, thus reducing administrative setup charges and assigning greater control over renewals to the purchaser.
- Product registration can take place after the award is assigned, so that suppliers of non-registered products are not prevented from participating in tenders.
- No penalties are imposed on the supplier as long as there is more than one month of stock available.
- In cases of proven manufacturing issues, the supplier can offer alternative products for the consideration of the Central Procurement and Supplies Unit, instead of the Unit directly reverting to purchasing on the supplier's behalf.
- Suppliers maintain stocks at their premises to reduce stock holding by the Government of Malta.
- Monthly regular orders are made, rather than bulk orders.
- Stock with a short expiry date is accepted as long as it is refunded if not used prior to the expiry date.

Depending on the type of market forces in place, the Central Procurement and Supplies Unit makes use of various procurement tools. These include but are not limited to open tenders, restricted tenders, negotiation, pay per use/dispensing through award criteria that include the most economical advantageous offer, best and final offer and so on.

An up-to-date weekly list of out-of-stock items is maintained by the Ministry for Health.<sup>21</sup> In an effort from the government to improve patient-centredness and transparency, the Ministry is proactively taking measures to ensure that patients' needs are addressed on time.

The Government of Malta is now looking further at implementing innovative risk-sharing agreements based on pay-for-performance agreements. Work has therefore begun on setting up patient registries, which would support the implementation of such agreements.

It is important to note that the main focus of the reforms is to reduce the total cost of a medicine; this includes not only the acquisition cost but also the handling and storage costs. The aim is that suppliers will eventually distribute directly to hospitals, pharmacies and patients. Any savings accrued in a particular therapeutic class are used to treat more patients.

<sup>21</sup> POYC out of stock information. In: Ministry for Health [website]. Valletta: Ministry for Health; 2016 (<https://health.gov.mt/en/cpsu/Pages/POYC-OOS.aspx>, accessed 4 October 2016).



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