



**BREVE 18**

# **PROCUREMENT POLICIES FOR PHARMACEUTICALS: THE INTERNATIONAL EXPERIENCE**

*Based on a webinar presentation at CRITERIA by Panos Kanavos, October 11, 2016.*

A series on policies and methods based on presentations for experts. Prepared by CRITERIA, a knowledge network on prioritization and health benefit plans from the Inter-American Development Bank.



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# ACRONYMS

**HTA** Health Technology Assessment

**MEA** Managed Entry Agreements

**NDP** National Drug Policy

**POM** Prescription-only Medicines

# INTRODUCTION

This *Breve* is based on a webinar presented by Panos Kanavos,<sup>1</sup> Associate Professor of International Health Policy at the Department of Social Policy of the London School of Economics. He is also Program Director of the Medical Technology Research Group.

The presentation was delivered on October 11, 2016, to the members of CRITERIA, the Inter-American Development Bank's knowledge network on priority setting and health benefit plans.<sup>2</sup>

Financial sustainability is a crucial issue in a context of public healthcare systems' limited resources. Countries have to take wise decisions about their spending on medicines, especially prescription drugs, which make up a significant proportion of total pharmaceutical spending. Procurement is one of the areas where major cost reductions can be. A wide range of tools is available to make procurement more efficient, reduce pharmaceutical prices, and implement demand-side and supply-side interventions.

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<sup>1</sup> Panos Kanavos has advised several governmental and non-governmental organizations in the economics of medical technology, medicines and medical devices. He has also worked extensively in regulation, competition, prescribing appropriateness, and quality of care, access to medical technologies in developing countries, disease management, and the effectiveness of medical technology.

<sup>2</sup> The audio, PowerPoint slides, and transcript of this presentation can be accessed on the CRITERIA website at <http://www.redcriteria.org/webinar/procurement-policies-pharmaceuticals-experience-webinar/>

This *Breve* first highlights the importance of pharmaceutical procurement policies. It then focuses on the goals of National Drug Policies. Based on these goals, it looks into the reasons for intervening in pharmaceutical markets and different forms of intervention. The subsequent sections analyze in further detail the procurement of in-patent and off-patent medicines, since there are fundamental differences in the procurement of these two medicine types. Finally, the *Breve* concludes by summarizing the most important issues for policymakers to keep in mind when defining procurement policies.

## IMPORTANCE OF PROCUREMENT POLICIES FOR PHARMACEUTICALS AND BASIC ASSUMPTIONS

*“The pricing, procurement, and use of prescribed medicines are a big source of inefficiency across healthcare systems around the world.”<sup>3</sup>*

Drug spending makes up a considerable part of any healthcare budget. In OECD countries, expenditure on medicines as a percentage of the healthcare budget is between 17% and

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<sup>3</sup> Kanavos, P. (2016), the transcription of the webinar is available at: <http://www.redcriteria.org/publication2/transcription-procurement-policies-pharmaceuticals/>

25%.<sup>4</sup> In middle-income countries it can be as high as 35% to 45%. After salaries, it is the single most important item in any country's healthcare budget. Therefore, it is crucial to look into these medicines, especially inefficiencies in their procurement and the ineffectiveness of regulation in this area.

In-patent medicines account for a significant proportion of total drug spending, despite there being a fairly small number of them. As a result, approximately 15 to 20% of the total number of molecules accounts for 70 to 80% of drug expenditure. Off-patent medicines constitute 70 to 80% of the total volume of drugs and represent around 30% of total expenditure.

This Breve looks specifically at prescription-only medicines (POM) and procurement strategies for both in-patent drugs and off-patent drugs.

Before looking into the goals of National Drug Policies, which constitute the basis for market interventions and procurement decisions, there are three basic assumptions that should be considered as a starting point for policy recommendations to ensure that the procurement policy interventions set out in this Breve have a positive impact. The first assumption is that there should be a third-party player at the national, regional or local health system level who pays for a significant proportion of pharmaceutical costs and

intervenes to regulate the performance of the market from a health insurance perspective, particularly regarding price. Second, it is important that there should be a National Drug Policy in place that includes a system of reimbursements of certain medicines at a certain price and establishes co-payments. The third assumption is that there should be an effective regulatory framework in place, guaranteeing safety, efficacy, and quality, especially of new medicines and bioequivalence or bio-similarity of off-patent medicines. This third condition represents a significant challenge in many regions like South-East Asia, Sub-Saharan Africa and frequently in Latin America.

## NATIONAL DRUG POLICY (NDP) GOALS

This section sets out some of the main policy goals, which policymakers focus on when establishing a National Drug Policy (NDP). Specific goals vary depending on the country-specific context and political priorities.

Generally, countries establish both health-related goals and economic goals.<sup>5</sup>

NDP goals tend to ensure:

- 1. Access:** This means that drugs are available in sufficient quantities and that they are

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<sup>4</sup> OECD (2016)

<sup>5</sup> WHO (2003): Essential Medicines and Health Products Information Portal

affordable for the health system, and that any copayment is affordable to the patient;

**2. Quality of medicines:** If the quality is compromised, the implications can be serious. In cases where healthcare systems rely on cheaper medicines, they will eventually have to find resources to pay for very expensive consequences. Quality also depends on a properly functioning regulatory framework.

**3. Rational use:** This means the promotion of therapeutically sound and cost-effective use of drugs by health professionals and

consumers. Healthcare systems have to look at issues such as inappropriate use or overuse of medications.

Table 1. shows a list of more specific goals interrelated with the three key goals described above. For example, essential drug lists promote access and rational use and may contribute to the quality of care, while monitoring and evaluation contributes to all three goals. National Drug Policies have to take into account several more specific goals, listed in the table below, to ensure a holistic policy.

**Table 1. National Drug Policy Components and Goals**

Components/ Objectives	Access	Quality	Rational use
Selection of essential drugs	✓	( ✓ )	✓
Affordability	✓		
Drug financing	✓		
Supply systems	✓		( ✓ )
Regulation and quality assurance		✓	✓
Rational use			✓
Research	✓	✓	✓
Human resources	✓	✓	✓
Monitoring and evaluation	✓	✓	✓

✓ : Direct link / ( ✓ ) : Indirect link

Source: Kanavos, P. (2016)

Some of these components of NDPs are discussed below, providing specific examples to illustrate their importance.

## **Affordability**

Affordability is a crucial consideration of any NDP, especially given that medicines may well be cost-effective but not affordable.

One example in this context is sofosbuvir, a drug for the treatment of Hepatitis C. It is a very cost-effective medicine because the health gain occurs over a very long period of time, about 20 or 30 years. However, the price of this medicine is very high. The cost of treatment is approximately \$45,000 to \$50,000 dollars per patient, for a treatment period of just six weeks. In this case, the goal of affordability is not met. Just because it is cost-effective does not mean that it is affordable. Many countries in Latin America, Europe, and other regions, cannot afford these highly-priced drugs. Affordability is therefore a crucial aspect and it is essential to define benchmarks for it.

## **Supply systems**

Another very important aspect to take into consideration is supply systems, particularly because of their cost. A medicine supply system comprises selection, quantification and forecasting, procurement, storage, and distribution.<sup>6</sup> All these areas imply costs. In pharmaceutical supply systems, the total cost of operating the supply system is the sum of

pharmaceutical purchase cost, inventory-holding cost, transport, ordering cost, and shortage cost.<sup>7</sup> In Europe it costs about 25% to 30% of total drug costs to run an effective supply system. But in Latin America these costs can run to 60%, 100% or even 200% of the wholesale and retail costs. In other regions, like Sub-Saharan Africa, it can be as high as 900% or 1000%.<sup>8</sup> Effective and functioning distribution systems therefore play a crucial role since the procurement chain includes several steps: production, purchase by the health system, sale to wholesalers and supplying retailers, and finally sale to patients.

## **Monitoring and Evaluation - Information systems**

Aspects of monitoring and evaluation are typically neglected in NDPs. It is important to strengthen monitoring and evaluation mechanisms to ensure that goals set out at the outset are met, such as quality, rational use, availability, affordability, etc. This aspect is closely tied to the existence of well-functioning information systems, which are the basis of effective monitoring mechanisms. For example, if there is no functioning information system including accurate records of drugs prescribed and consumed, it is impossible to effectively monitor pharmaceutical spending.

Based on these broad and more specific goals, countries decide how to intervene in their pharmaceutical markets to guarantee efficiency and reduce costs as much as possible. The

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<sup>6</sup> WHO (2016 b)

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<sup>7</sup> WHO (2012)

<sup>8</sup> Kanavos, P. (2016)

following section look at reasons for intervening in pharmaceutical markets as well as main mechanisms and forms of intervention.

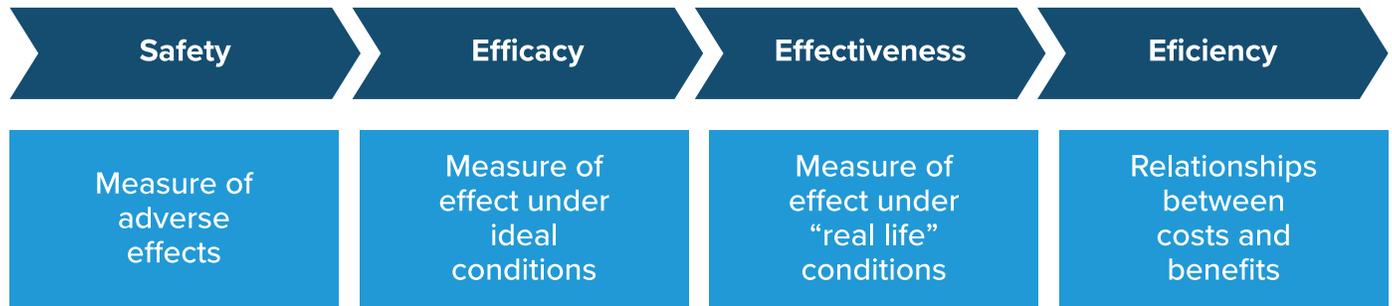
# INTERVENTIONS IN PHARMACEUTICAL MARKETS

Interventions are generally justified because pharmaceutical markets are inherently imperfect and characterized by market failures. For example, in the case of in-patent drugs, monopolies are created through the award of a patent to an innovator company. This monopoly

power enables a company to charge a monopoly price by underserving or undersupplying that market. It is the goal of a central planner, a drug policy expert within a Ministry of Health or a health insurance institution, to effectively implement interventions or controls to mitigate the consequences of market failures in pharmaceutical markets.

Figure 1, shows the main aspects that decision makers seek to attain with prescription medicines: safety (measure of adverse effects), efficacy (measure of effect under ideal conditions), effectiveness (drugs work in a real-life setting) and efficiency (use for money).

**Figure 1: What decision makers want**



Source: Kanavos, P. (2016)

Safety and efficacy lie in the sphere of responsibility of the regulatory agencies, while effectiveness and efficiency are the responsibility of payers and insurers. If a drug meets efficacy requirements this does not imply that it is effective, while the effectiveness of a drug does not imply its efficiency.

*“Safety and efficacy are the first steps to provide evidence for a new drug. Effectiveness and efficiency need to be proven.”<sup>9</sup>*

<sup>9</sup> Kanavos, P. (2016), the transcription of the webinar is available at: <http://www.redcriteria.org/publication2/transcription-procurement-policies-pharmaceuticals/>

The main tool in place to assess whether decision makers obtain use for money by purchasing and covering a medicine is the Health Technology Assessment (HTA). HTA can be done through cost-effectiveness analysis or an explicit ranking of technologies based on an assessment of use of their relative effectiveness, comparing the new therapy to the standard of care of the most widely-used therapy.

## FORMS OF INTERVENTION

There are several forms of intervention.

A simple equation can be used as a framework to look at these interventions: Expenditure for medicines is a function of price and volume ( $\text{Expenditure} = \text{Prices} \times \text{Volume}$ ).<sup>10</sup> Consequently, policy measures intended to manage pharmaceutical expenditure try to influence prices or quantities. Price is a key element, which can be negotiated for new medicines with pharmaceutical companies. Volume can also be controlled, for example, in combination with prices as a price-volume agreement.<sup>11</sup>

Interventions can take place on the supply side

(producers, suppliers) as well as on the demand side (physicians, pharmacists and patients).

On the supply side, an important intervention decision that has to be taken by health policymakers concerns which pharmaceuticals should be included in the benefits package. Since resources are limited, they should be spent in the best possible way. Policymakers use a number of criteria to decide whether pharmaceuticals are included in a benefit package and are therefore reimbursed. These criteria include a number of endpoints that help us understand whether there is a significant benefit from a new therapy relative to an existing one. Criteria often used are:

- **Clinical criteria:** the most widely-used criteria.
- **Budget criteria**
- **Cost-effectiveness**
- **Industrial policies:** Incentives for inward investment through research or manufacturing are an important aspect in this context.
- **Volume:** It is important for policymakers to know how large the market is and who stands to benefit the most. Volume can be influenced, for example, by restricting the reimbursement to a certain sub-group within the approved indication. This can help economize and spend resources where the evidence shows that they are most needed.
- **Definition of who benefits most:** This can be a critical aspect. By way of example, omeprazole was a huge success although its efficacy was only proven in a very small

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<sup>10</sup> For a graphic representation of this concept and a more detailed description of measures to regulate price and volume, on both demand and supply side, see [Breve 11: "Use Based Drug Reimbursement: Introduction to The Main Features of The German Pharmaceutical Policy"](#), based on a presentation by Dr. Wolfgang Greiner.

<sup>11</sup> This mechanism works by setting prices according to expected or realized volume, such that if volume passes a threshold, the price level will decrease and/or companies will have to repay the government or health insurance plan. (Mossialos et al. (2004) p.123.)

group of patients. This led to huge expense without a proven need for it.

- **Foreign prices** are frequently taken into consideration to make sure that prices paid are not too high.
- **Tenders:** Off-patent medicines in particular are procured through tenders and evidence has shown that this process produces good results.<sup>12</sup>

The weight given to each of these factors and the criteria taken into consideration depend on the policies and national priorities of each country, and the local context. Table 2, gives an overview of the criteria used in various countries.

**Table 2: Criteria used to admit pharmaceuticals for reimbursement**

Criteria	UK	GER	FRA	SPA	NET	POL	ITA	CAN
Clinical	✓	✓	✓	✓	✓	✓	✓	✓
Budgetary	✓	✓	✓	✓	✓	✓	✓	✓
CEA	✓	✓	✓		✓		✓	✓
Industrial policy	✓	✓	✓	✓				✓
Defining who benefits most	✓	✓	✓	✓	✓	✓	✓	✓
Volume	✓	✓	✓	✓	✓	✓	✓	✓
Foreign prices	✓	✓	✓	✓	✓	✓	✓	✓
OTC exclusion	✓	✓	✓	✓	✓		✓	✓
Tender	✓	✓	✓	✓	✓	✓	✓	✓

Source: Kanavos, P. (2016)

<sup>12</sup> For an in-depth study on the impact of tender processes on prices, expenditure and volume, see WHO (2016 a): “Challenges and opportunities in improving access to medicines through efficient public procurement in WHO European Region”.

In conclusion, deciding which drugs are included on the “positive list”, and therefore reimbursed, is a complex process and an important form of intervention in the pharmaceutical market. Other forms of intervention will be analyzed in more detail in the following section, which looks at the

procurement policies of in-patent as well as off-patent drugs. There are significant differences between these two groups regarding their procurement, which will be described below.

## PROCUREMENT OF IN-PATENT DRUGS

In-patent drugs represent a minority of total drugs in terms of use, but a majority in terms of expenditure. As mentioned above, in-patent drugs account for 20-25% of all medicines consumed in a developed or middle-income country and make up 60-80% of the total pharmaceutical expenditure.<sup>13</sup> Since these drugs are protected by patents, monopoly power is a challenge in this context. Therefore, price regulation is crucial to control costs and monopoly power. There are four key methods used internationally to achieve affordable prices:

### 1. Profit or Rate of Return (ROR) Regulation

This regulatory intervention focuses on regulating profits rather than prices.<sup>14</sup>

Profit or rate-of-return regulation seeks to ensure that pharmaceutical firms do not make excessive profits, specifically from patent-protected products paid for by public healthcare systems, but at the same time the

regulation seeks to reward innovation. For this tool it is essential that a strong institution is in place to oversee the process. This method consists of a profit control measuring the returns on sales where the profit exceeds a certain established percentage. In such cases, prices have to be reduced or the manufacturer has to return the surplus profits. The UK is one of the countries that uses this system.

### 2. Price setting

The two main tools used in this method are External Price Referencing and Cost-Plus Pricing. **External Price Referencing**, where countries compare their prices to those set in other countries, can be challenging because prices can vary significantly. It is problematic because external price referencing does not necessarily show the transaction cost,<sup>15</sup> which is the real price compared to the list price of a drug. Transaction costs can vary greatly and can constitute between 50-60% of the total price. Nor does it reflect discounting, which is normally the result of confidential price negotiations. It is therefore a questionable method, especially if it is not used in combination with other tools. Countries using this method in combination with others include Spain, France, Germany, Turkey, Brazil, Canada and South Korea.

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<sup>13</sup> Kanavos, P. (2016)

<sup>14</sup> Currently, this regulatory mechanism is unique to the UK where pharmaceutical pricing at drug launch is free, but later is subject to a non-statutory profit control. (Mossialos et al. (2004))

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<sup>15</sup> Transaction costs for medicines include, for example, transportation, storage, fulfilling regulatory requirements and discounts to retailers. (Kanavos, P. et. al. (2004))

**Cost-Plus Pricing** is a method for setting retail prices of medicines by taking into account medicine production cost, together with allowances for promotional expenses, manufacturer's profit margins, charges, and profit margins in the supply chain.<sup>16</sup> Like External Price Referencing, Cost-Plus Pricing should not be used as an overall pharmaceutical pricing policy.<sup>17</sup> Countries using this method include India, Pakistan and Iran.

### 3. Price setting relying on use assessment through Health Technology Assessment

There are different types of methodologies that can be used in this category. The most common one is **Cost-effectiveness pricing**, which is applied in countries like England, Scotland, the Netherlands, Sweden and Australia.

The second method is the **Assessment of Clinical Benefits** where products are ranked according to their actual or relative efficacy (France and Germany). The prices are then negotiated between suppliers and health insurers.

**Use-based pricing** takes into account cost-effectiveness as well as additional aspects, such as social factors, to set prices.

### 4. Controlling use

Use can be controlled through an ex-ante negotiation between suppliers and the healthcare system to define how the medicine is used. Volume caps and price-volume agreements are used in France, among other countries.

These four methods of intervention help safeguard an effective allocation of resources. The following section will look at the use of Health Technology Assessment in more detail, since in some areas this has become the standard method.

## A closer look at Health Technology Assessments

Health Technology Assessments (HTAs) aim to evaluate the added benefit of new technologies relative to their cost in order to obtain their opportunity cost (health gain forgone by not reimbursing other medications).<sup>18</sup> HTAs rely on scientific use judgments: clinical evidence, safety evidence, and generalizability across settings. Trials are therefore applied in the different settings to ensure results are context-specific.

Increasingly additional uses are included through social use judgments related to severity of disease, end of life interventions, age, innovativeness, and health inequalities. However, these aspects are frequently taken into account in an ad-hoc way without appropriate metrics.

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<sup>16</sup> WHO (2015), p. 2

<sup>17</sup> WHO (2015)

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<sup>18</sup> Szerb, A., Kanavos, P. (2015)

The way medicines are assessed from a clinical and economic perspective, together with social use judgments, leads to different HTA-based recommendations in different settings. Even though the evidence is the same, or varies only marginally in the different settings, the understanding and interpretation of this evidence varies considerably. Consequently, the coverage recommendations resulting from this method differ significantly.

In order for countries to benefit from the data obtained from HTAs, it is crucial that they have well-functioning information systems in place. For example, if a country has no means of auditing through an online information system how drugs are prescribed, there is no way that it can benefit from Health Technology Assessments.

Table 3, shows the results of a study carried out by the London School of Economics (LSE), including 31 drug indication pairs (10 orphan drugs, 13 cancer drugs and 8 central nervous system drugs) and 19 coverage recommendations for different countries. The results show that 19 out of 31 drug indication pairs resulted in a different HTA recommendation. In the table, the color orange highlights the results where divergent recommendations were received across countries and even among neighboring countries. Gefitinib, for example, was listed with conditions in England, without conditions in Scotland, not accepted in Sweden, while the benefit was considered very minor in France. The study showed that there were many

differences in the interpretation of evidence and significant differences in terms of other considerations such as the severity of illness, equity implications, or budget constraints.

The impact of Health Technology Assessments is important since it can lead to refusal to reimburse, or refusal to cover the technology concerned. It can also result in restrictions of certain drugs. In most cases, the HTA leads to coverage with constraints or limitations.

Aside from assessment results, the study led to additional findings. It found that, depending on the setting, there is a high willingness to pay for certain drugs. In some cases, additional criteria beyond economic evaluation are taken into account and sometimes separate purchasing procedures or budget schemes are in place, such as for orphan drugs.

**Table 3. Similarities and differences in HTA recommendations**

HTA recommendatios		NICE England	SMC Scotland	TLV Sweden	HAS France (SMR/ASMR)
ORPHAN DRUGS	Eltrombopag	DNL	LWC	LWC	substantial/II
	Romiplostim	LWC	LWC	LWC	substantial/II
	Everolimus	DNL	DNL	L	substantial/IV
	Lenalidomide	LWC	LWC	L	substantial/III
	Mifamurtide	LWC	L	LWC	insufficient/DNL
	Azacitidine	LWC	LWC	NA	substantial/II
	Imatinib	DNL	LWC	NA	substantial/III
	Mannitol dry	LWC	DNL	NA	weak/V
	Ofatumumab	DNL	DNL	NA	moderate/V
	Trabectedin	LWC	DNL	NA	substantial/V
CANCER DRUGS	Abiraterone	LWC	DNL	LWC	substantial/III
	Bendamustine	L	DNL	L	substantial/III
	Eroltinib	DNL	L	DNL	DNL
	Getifinib	LWC	L	DNL	substantial/IV
	Pazopanib	LWC	L	LWC	DNL
	Bevacizumab	DNL	NA	DNL	substantial/IV
	Cabazitaxel	DNL	NA	DNL	substantial/III
	Eribulin	DNL	NA	DNL	substantial/IV
	Erlotinib	LWC	N/A	L	substantial/IV
	Ipilimumab	LWC	NA	L	substantial/IV
CNS DRUGS	Pemetrexed	LWC	N/A	DNL	substantial/IV
	Rituximab	L	N/A	L	substantial/IV
	Vemurafenib	LWC	DNL	DNL	substantial/IV
	Alemtuzumab	L	L	L	NA
	Dimethyl fumarate	LWC	L	LWC	substantial/V
	Fingolimod	LWC	LWC	L	substantial/V
	Nalmefene	LWC	L	DNL	NA
	Natalizumab	L	L	L	substantial/III
Retigabine	L	L	L	substantial/V	
Teriflunomide	LWC	L	DNL	substantial/V	
Varenicline tartrate	L	L	L	substantial	

L: LIST / LWC: LIST WITH CONDITIONS / DNL: DO NOT LIST

Source: LSE (2016)

The multiplicity of criteria that policymakers use to inform decisions has led to the introduction of multi-criteria decision analysis. At the London School of Economics the Advanced Use Framework<sup>19</sup> was devised to explicitly consider burden of illness circumstances with a number of criteria, such as therapeutic benefit safety and innovation level, but also socioeconomic impact. The advantage of such a multi-criteria model is that academics and policymakers can break down a difficult problem to make a decision on very expensive new therapies, dividing it into individual sub-problems, thus ensuring that all dimensions are evaluated. At the same time this method also captures the feedback and preferences of different stakeholders in the decision-making process.

### **Risk sharing: Managed Entry Agreements (MEAs)**

Another aspect is the existence of risk-sharing agreements, which are crucial because many drugs are not cost-effective or the additional cost is disproportionately high in relation to the additional benefit.

Risk-sharing agreements are used extensively because they have significant implications for the efficiency of price regulations. The significant uncertainties that exist at coverage level, whether regarding cost-effectiveness, clinical evidence, dose regimen, etc., has led to (i) **financial arrangements**, (ii) **outcome-related arrangements**, or (iii) a **combination**

**of outcome and financial agreements.** A financial agreement links the expenditure to a particular endpoint, such as in the case of a price discount, which remains confidential, or an explicit price-volume agreement. In this case the financial agreement is not linked to a particular outcome or clinical endpoint. Outcome-based agreements (outcome guaranteed) can be considered pay for performance scenarios, for example it is established that only the treatment of responders is paid for. This option requires a well-functioning budget information system and the use of real life evidence.

The third option is that an agreement is negotiated that includes both financial or outcome based elements. For example, for a new cancer therapy the budget and the number of patients may be fixed. Then a discount and a register for the eligible patients is requested as well as a performance indicator that states that if patients respond the therapy continues, and if not the therapy is discontinued and the money must be repaid.

These agreements therefore reduce decision uncertainty, allow evidence of effectiveness to be considered and improve affordability.

Table 4. summarizes some examples of instruments used to confront specific risks and to address policymakers' concerns. The risks are related to patient rights, uncertain clinical uses, low cost-effectiveness and budget overspending. Price-volume deals, for example, can help control the risk of overspending, but they do not address the other risks. Conditional

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<sup>19</sup> Kanavos, P., Angelis, A. (2013)

coverage, on the other hand, can contribute to reducing all the risks mentioned.

**Table 4. Risks addressed by individual schemes**

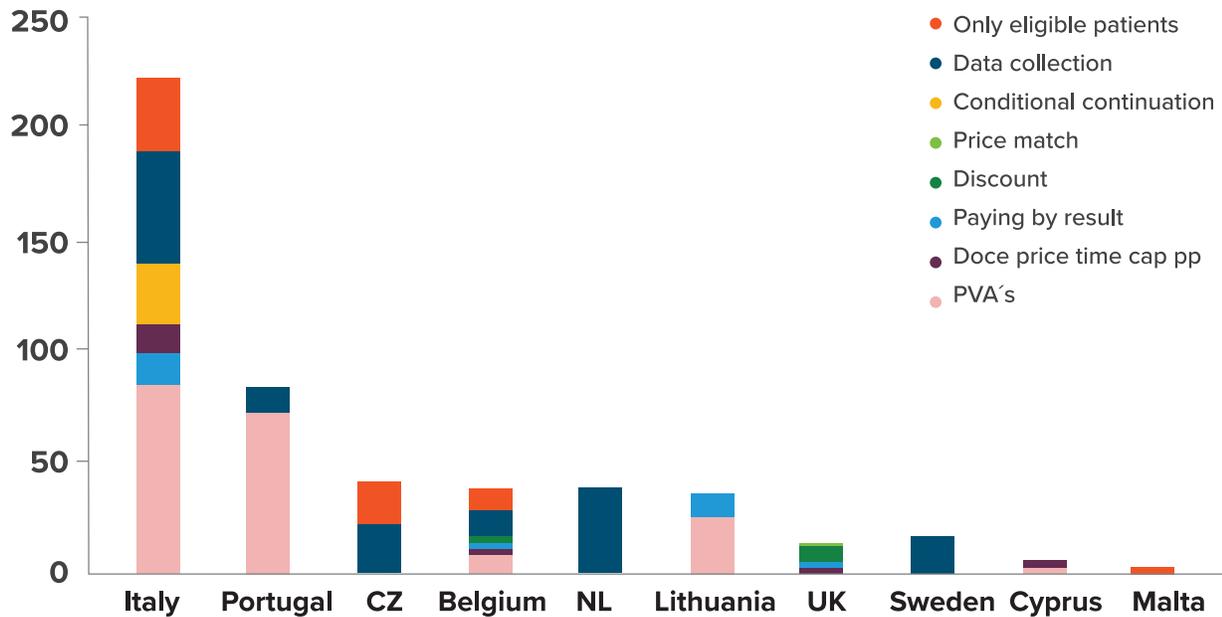
	Patient rights	Uncertain clinical value	Low cost-effectiveness	Budget overspending
Coverage with ED	✓	✓	✓	X
Conditional coverage	✓	✓	✓	✓
Outcome guarantee	✓	✓	✓	X
Price-volume deal	X	X	X	✓

Source: Kanavos, P. (2016)

Graph 1, shows how risk-sharing schemes are used in different countries. The vertical axis shows the number of schemes in place. Italy, for example, has many price-volume agreements and several data collection schemes, meaning that it revisits every reimbursement agreement based on additional data collected through registries. Other countries, like Sweden or the Netherlands, specialize in particular schemes, in these cases data collection coverage.<sup>20</sup>

<sup>20</sup> Coverage with Evidence Development (CED) allows coverage of certain items or services where additional data gathered in the context of clinical care would further clarify the impact of these items and services on the health of Medicare beneficiaries.

**Graph 1. Price differentiation based on negotiation and value endpoints: impact of MEAs**



Source: Ferrario and Kanavos (2013)

## PROCUREMENT OF OFF-PATENT DRUGS

Off-patent drugs account for approximately three quarters of all the medicines available in any given country and approximately 20-40% of expenditure. Therefore, policymakers can achieve significant savings by focusing on efficiency and opting for a suitable procurement modality.

### Supply-side interventions

There are several supply-side modalities for off-patent medicines:

#### 1. Price capping

Price cap regulations set a limit to the price that the manufacturer is allowed to charge. Therefore, the price of a given generic is fixed at a certain percentage lower than the originator brand.

#### 2. Internal reference pricing

This concept groups together similar or identical drugs. Once a patent expires, all similar drugs are grouped together (clustering of molecules) and the reference price is set. While external reference pricing determines the reference price based on prices of similar products in other countries, with internal reference pricing the price of the cheapest domestic substitute is

the reference price. Reimbursement is then generally set as the lowest price.<sup>21</sup> The insurer therefore sets a maximum reimbursement ceiling. The greater the shift from molecular to therapeutic reference pricing, the higher the budget savings. The precondition for this method to function well is a properly functioning regulatory framework where generics are considered to be bioequivalent to branded medications. In the case of therapeutic reference pricing, there has to be an assumption of perfect substitutability between therapeutic therapies.

This type of reference pricing is used in several countries but more extensively in a certain type of therapeutic categories. Price reductions due to this method are generally between 40-60%. After the first wave of price reductions, generic prices normally remain relatively stable in countries with reference pricing and then decline slowly (e.g. Germany, France, Spain, Italy).

### 3. Free pricing and competition

In this procurement modality, there is no intervention in the market and the assumption is that the market itself will make the adjustments.

### 4. Tendering<sup>22</sup>

Tendering is common practice in in-patient care and increasingly so in out-patient care. Usually the decision is taken by looking at the lowest price (MEAT, Most Economically Advantageous Tender) and sometimes other criteria are taken into consideration, such as quality, ability to supply a share of the market or non-exclusion of competition. The supplier that wins the tender then supplies the whole market or the part of the market the particular fund covers.

Tenders generally lead to a significant reduction in prices and are very successful in the short term. The problem in the long term is that they might pose a threat to competition.

One example of the impact of tendering on prices of generics was the reduction in the omeprazole price in the Netherlands. Omeprazole is a very widely used medication which itself is low in cost, but because of the large volume the cost to the healthcare system is very high. In 2008, this medicine was subject to reference pricing. Reference pricing showed that the cost per unit was 36 euro cents (daily dose.) The tender was put out between May and June. The price dropped from 36 euro cents to 5 euro cents. Successive waves of tenders show that the price dropped even further to 2 euro cents, which means that

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<sup>21</sup> Kaiser, U, et.al. (2013)

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<sup>22</sup> For a more detailed insight on tendering in the pharmaceutical sector, see Wilkinson, T. (2014) and Bañuelos, F. (2016)

it is possible to treat a patient for 60 euro cents per month.<sup>23</sup> This is a very aggressive policy where manufacturers have to show their reservation price<sup>24</sup> in order to win the particular market.

In order to ensure an optimal generic procurement policy, a holistic approach is required which looks at several aspects, not only supply-side factors. Issues to consider are an emphasis on generic prescriptions, generic substitution, differential co-payments, incentives and disincentives to promote generic prescriptions, reimbursement regulations, information systems, robust regulatory authorities etc. Only a handful of countries (e.g. Denmark, Sweden, the UK, the Netherlands South Africa) implement a holistic approach

While it is important to address the issue of prices, it is also necessary to look at demand-side interventions.

### **Demand-side interventions**

On the demand side it is important to have an optimal policy mix to address physicians and pharmacists. If they have proper resources and are properly incentivized this helps to meet the goals that decision makers set out initially. Incentives for physicians can be financial (budgets, pay for performance schemes, etc.) and also non-financial (pre-authorizations,

adherence to clinical and prescribing guidance, use of information systems, etc.)<sup>25</sup> It is important to implement these and capitalize on measures such as widespread mandatory generic prescribing, known as generic substitution at pharmacy level. At patient level, the way copayments are established can influence their behavior.

## **CONCLUSIONS**

This Breve highlights the various procurement policies and strategies used to address the issue of pharmaceutical costs and procurement, and describes some of the tools that can be used and shows that significant savings can be achieved. None of these strategies are perfect and, depending on the context and the policy goals, certain methods will work better than others. Most countries combine several different tools to prevent the limitation of a certain method from having a negative impact on procurement decisions.

The main issues influencing the choice of strategies include 1) the market segment (in-patient or off-patient medicines), the type of stakeholder involved and the type of measure involved (e.g. internal reference pricing versus tendering), and 3) the type of outcome sought (e.g. encouraging competition vs. increasing efficiency or cost containment.) It is also crucial to underline that for supply-side (price related)

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<sup>23</sup> Kanavos, P. (2016)

<sup>24</sup> The reservation price is the lowest price at which a manufacturer is willing to sell.

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<sup>25</sup> For a more detailed analysis of demand-side interventions, see [Breve 11: "Use Based Drug Reimbursement: Introduction To The Main Features Of The German Pharmaceutical Policy"](#), based on a presentation by Dr. Wolfgang Greiner.

strategies to work very well, these have to be complemented with actions on the demand side, especially related to generic policies.

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