PART II

Chapter 4

Reducing ineffective health care spending on pharmaceuticals

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This chapter focuses on opportunities to spend less on pharmaceuticals and other medical supplies. It starts with a discussion of perhaps the most intuitive case of waste, which occurs when prescribed pharmaceuticals (and other medical goods) are discarded unused. Next, the chapter proceeds to the foregone opportunities associated with not substituting originator drugs with cheaper therapeutic alternatives, such as generics or biosimilars. The final issue explored is whether lower prices for pharmaceuticals and other medical supplies could be obtained with more efficient procurement processes.

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Introduction

Pharmaceuticals account for a significant share of overall health care expenditures across all OECD countries. Existing estimates suggest that when hospital use is included, one out of every five health dollars on average is spent on purchasing pharmaceuticals. As such, trends in pharmaceutical spending contribute largely to determining overall health spending patterns (Belloni et al., 2016). Making sure such pharmaceutical expenditures are well spent is therefore crucial to reducing waste and ineffective spending in health care systems.

Pharmaceutical spending that does not add value materialises at different stages of the value chain. This chapter starts with a discussion of perhaps the most intuitive case of waste in the area of pharmaceuticals (and other medical goods), which occurs when purchased products are unused and subsequently discarded. Next, the chapter proceeds to the foregone opportunities associated with not substituting originator drugs with cheaper therapeutic alternatives. The final issue explored is whether lower prices for pharmaceuticals could be obtained through better procurement processes.[1]

1. Discard of unused pharmaceuticals and other medical supplies

1.1. To what extent are discarded medicines and other medical supplies wasted?

Discard of unused, and often unexpired, medicines and other medical supplies imposes unnecessary additional costs on health care systems. But not all instances of discarding are avoidable and as such, not all discards can be deemed wasteful. This include situations when patients recover before all of their dispensed medicines have been taken or when therapies need to be stopped or changed because of ineffectiveness and/or unwanted side effects. This fine distinction as well as indications that most unused medicines are disposed of informally, notably in patients' homes, pose a challenge to assessing the scale of this type of waste (Trueman et al., 2010).

In fact, in most countries, the value of discarded prescription pharmaceuticals is likely to be underestimated, as only medicines returned to authorised collection points are included in official calculations. For example, in Australia, an audit of the contents of "Return of Unwanted Medicines" bins revealed discarded medicines worth AUD 2 million, of which nearly 70% were prescription medicines (Monash University, 2013). In National Health Service (NHS) England, survey-based estimates indicate that the annual cost of discarded prescription medicines could be in the order of GBP 300 million. This figure includes an estimated GBP 200 million of unused prescription medicines either retained by patients or returned to pharmacies and GBP 50 million of medicines disposed of by care homes, as well as the direct costs associated with fulfilling various legal requirements for safe disposal of medicines. Most importantly, the study estimates that approximately 50% of discarded medicines are likely to be preventable waste (Trueman et al., 2010).

Even less is known about the value of pharmaceuticals and other medical supplies unnecessarily discarded by hospitals. A systematic attempt to measure the extent of the problem was undertaken recently by a Johns Hopkins Hospital research team; among large

US academic medical centres, which represent 4% of all hospitals nationwide, simple medical supplies worth at least USD 15 million are discarded every year despite being recoverable (Wan et al., 2015).

Discard of pharmaceuticals used in hospitals often occurs due to the too-large package size of single-dose drugs. This is particularly true for drugs whose dosage is based on a patient's body weight or size and come in single-dose packages. Such packaging means that these drugs must be either administered or discarded once open. When packaging is such that a patient's body size is unlikely to match the amount of drug in a single dose, some is nearly always left over. For example, a recent study estimates that unused leftover infused single-vial cancer drugs cost an additional USD 2 billion annually in the United States (Bach et al., 2016). Notably, cancer drugs are the largest single category of specialty drug spending in many OECD countries (Belloni et al., 2016).

1.2. *Errors, suboptimal decisions and organisational shortcomings drive unnecessary discard*

Referring back to the drivers of waste identified in Chapter 1, pure waste of pharmaceuticals and other medical supplies is mostly driven by errors and suboptimal decisions of both clinicians and patients. Inappropriate prescribing, notably repeated prescriptions that are not effectively reviewed by physicians or pharmacists, leads to dispensation of excessive volumes of medicines. On the part of the patient, waste is driven by a lack of understanding of, or accidental non-adherence to, the course of medication, which particularly affects vulnerable individuals who cannot independently adhere to their treatment regimen (Trueman et al., 2010).

Alongside behavioural factors, some shortcomings in organisation can lead to unnecessary discard of medicines. In individual health care facilities, room likely exists for improvement in the organisation of supplies and stocks. Likewise, unexploited possibilities remain to improve organisation of stocks at a system level. In particular, distribution of excess supplies between health care facilities belonging to a given network, such as a local or regional hospital system, could be improved or still needs to be established.

To a smaller extent, waste can be induced by poor packaging standards. Distinct cases arise where unclear or lax regulations incentivise manufacturers to offer package sizes that lead to unnecessary discard. For instance, some medicines are used in single-dose presentations, meaning the entire dose of the drug must be either administered or discarded once open. Depending on regulation of packaging standards for these drugs, manufacturers might manage to offer doses that are too large on average, making buyers accept more of a given drug than needed (Bach et al., 2016).

1.3. *Guidelines and education initiatives are the appropriate tools to tackle unnecessary discards*

Policies aimed at tackling unnecessary discard of pharmaceuticals and other medical supplies need to focus predominantly on the above-described errors and suboptimal decisions of patients and clinicians. The appropriate tools are guidelines, education initiatives and campaigns. To motivate clinicians and patients to recognise the problem, these tools should emphasise improving health outcomes related to appropriate use of medication rather than waste reduction alone. To solve the problem, guidelines, education initiatives and campaigns should continuously encourage improvements in communication

between clinicians and patients to enable as many patients as possible to reveal and resolve medication-related concerns. Patients also need to be better educated about the importance of completing prescribed courses of treatment.

Controlled clinical trials carried out in the United Kingdom and Sweden reveal that wastage of medicine can be reduced by up to 30% if patients starting a new course of treatment are given an option to discuss their medication-related concerns on top of the one-time standard instruction given in the moment of prescribing. A telephone line dedicated to discussion of such concerns, where patients can reach trained pharmacists, was proven to cost-effectively reduce instances of patients' suboptimal decisions (Clifford et al., 2006; Schedlbauer et al., 2007).

Additionally, organisational solutions at the level of community care should be created to better support vulnerable patients in taking their medicines as prescribed, especially those who cannot independently adhere to their treatment regimens. For example, the training of (social) care workers could include a dedicated module on how to effectively provide medicine-taking support. This can be enhanced by introducing a targeted medication review undertaken periodically by community care providers to regularly follow patients' consumption of medication and establish their need (or lack of thereof) for a prescription renewal (Trueman et al., 2010).

Providing patients with information on prescription adherence is important. NHS England's *MedicineWaste* campaign is a promising example, although this policy has not yet been formally evaluated. The campaign, mostly disseminated through the Internet and posters at pharmacies and health care facilities, informs about common reasons for discarding medicines and describes simple steps that each patient should follow, usually with the help of the prescribing clinician or a pharmacist. The campaign also targets clinicians with a simple, short checklist to evaluate repeated prescriptions.

For physicians and pharmacists, organisational solutions such as e-prescription systems or electronic patient journals, which allow review of patients' medication history in one place (as introduced in Denmark), could reduce errors and suboptimal decisions in prescribing, especially for repeated prescriptions. As discussed in Chapters 2 and 3, such systems increase patient safety, notably by minimising the risk of medication errors, and help to tackle overprescription of antimicrobials.

Along with clinicians, patients should also have access and become routine users of electronic patient journals. For example, in Denmark during the 2013 launch of the National Health Record (NHR) – a global electronic patient journal – informational campaigns promoted it as a useful tool for self-monitoring of medication history, among others. In addition to NHR, the *Common Chronic Patient Data* project allows patients with diabetes to access cross-sectoral information on their treatment history, including detailed information on dispensed medication, and to analyse the data with support of decision aids and other educational material. One of the project's aims is to support actions promoting self-management among patients with diabetes (MedCom, 2012). Such improved and comprehensive information can help patients better monitor their medication use, thereby reducing waste.

Incentives can also be used to keep this kind of waste in check. A well-documented example is the use of continuous positive airway pressure (CPAP), an effective treatment for obstructive sleep apnea. Studies show that between 29% to 83% of patients do not adhere to the treatment (non-adherence is defined as a mean of less than four hours of use

per night) (Sawyer et al., 2011). In the United States, most insurers, including Medicare, condition reimbursement of the device on actual use, at least during a trial period. In France in 2014, the highest administrative court rejected an attempt by the health insurance fund to similarly condition reimbursement on use.[2]

Finally, reducing waste of pharmaceuticals and medical supplies requires managerial as well as regulatory efforts. Managers can identify organisational changes needed to improve the flow and use of goods within health care facilities such that unnecessary discards are minimised. Regarding transfers of excess medical supplies between health care facilities, notably hospitals, joint stock management and monitoring (in connection with joint procurement) is a suitable solution shown to improve management of stocks and reduce waste, as seen, for example, in Greece (Kastanioti et al., 2013) and Mexico (OECD, 2013a). The associated policies are discussed in greater detail in Section 3.

Regulators might attempt to systematically diagnose where regulation – or regulatory loopholes – can lead to unnecessary waste and take appropriate steps. For instance, regulators could require manufacturers to provide drugs in a reasonable set of variable package sizes to ensure that the amount of drug is more likely to correspond to a patient's body weight or size and that the amount left over is low. Alternatively, buyers could stipulate that there is no payment for the leftover drug or require manufacturers to refund the cost of leftover drugs. Moreover, clearer guidelines or rules on vial-sharing between patients could be issued (Bach et al., 2016).

2. The untapped potential for generic drug substitution

In the vast majority of cases, substituting an originator product with a generic can induce direct savings without any loss of benefit to the patient. Many countries effectively use a range of policy levers to ensure a high penetration of generics. But while this section focuses on generics, a more recent question raised is whether biosimilars could present analogous opportunities (Box 4.1).

2.1. The opportunity for cost savings from increased generics uptake remains substantial

Substituting originator medicine with cheaper and therapeutically equivalent generics[3] offers significant cost savings with no adverse health effects. In the United States, where the generics market is very dynamic, the price of a generic drug is on average 80% to 85% lower than that of the originator product (IMS Institute for Healthcare Informatics, 2013). Indeed, the shift to generic drug use and the so-called "patent cliff" (a large number of blockbuster drugs losing patent protection) are responsible for the recent decline in overall drug spending observed across OECD countries (Belloni et al., 2016).

Over time, most OECD countries increased generics uptake, with several countries expanding their efforts to encourage uptake after the onset of the global economic crisis of 2008. However, scope remains for improvement, as many OECD countries have still not fully exploited the potential cost savings from generics. In 2015, generics accounted for more than three-quarters of the volume of pharmaceuticals covered by basic health coverage in Germany, New Zealand and the United Kingdom, while they represented less than one-quarter of the market in Greece, Luxembourg and Italy (Figure 4.1).

Box 4.1. **Current and future savings from the use of biosimilars**

In parallel with generic drug competition, opening the market to biosimilar competition could realise significant savings for health care systems. For example, between 2016 and 2020 eight key biologics are scheduled to lose patent protection. Analysis of data available for five European countries (France, Germany, Italy, Spain and the United Kingdom) and the United States suggests that a 20% reduction in price per treatment-day across these eight products could result in cumulative savings exceeding EUR 50 billion by the end of 2020 (IMS Institute for Healthcare Informatics, 2016). In 2015, following the introduction of biosimilar competition in one of the most often used classes of biologics – erythropoietins (EPOs) – the observed price reduction (across the class, i.e. for originators as well as biosimilars) varied from 39% in France to 55% in Germany (IMS Institute for Healthcare Informatics, 2016).

Regulation of market entry varies significantly between countries. The European Union approved the first biosimilar in 2006 and is the leader in the number of approved products: 20 as of June 2016. Yet biosimilars' use shows wide variation in the European Union. Even the first biosimilar still has little or no uptake in some countries (e.g. Greece, Ireland and the Slovak Republic), while in Poland it is used in almost all relevant therapies (Ekman and Vulto, 2016). The United States adopted the legislative framework for licensing biosimilars in 2010, but the first biosimilar was approved only in March 2015 (Belloni et al., 2016).

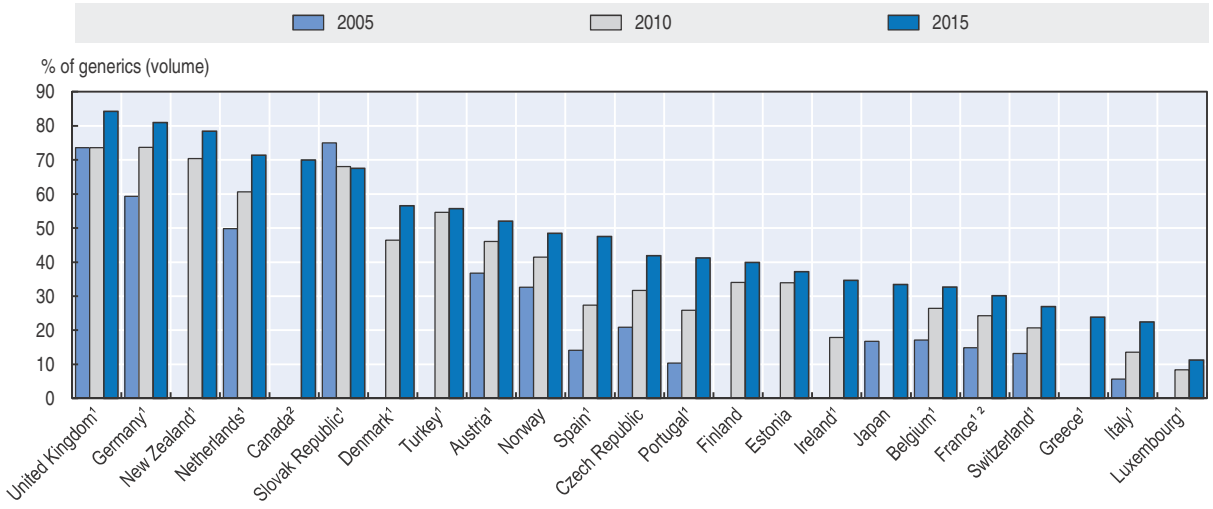
Some policies discussed in this chapter to increase uptake of generics can also be applied to biosimilars. For example, physicians and patients often worry that biosimilars will compromise quality of treatment (IMS Institute for Healthcare Informatics, 2016). Thus regulators should communicate their knowledge more actively and, most importantly, strive to take clear positions on interchangeability between biologics and biosimilars. In Norway and Denmark, where physicians are at the heart of decision making, uptake of biosimilars was rapid and sustained. Similarly, biosimilar competition is strong in Germany, where insurance funds invested in communication with physicians on the subject and subsequently introduced prescribing quotas for biosimilars (IMS Institute for Healthcare Informatics, 2016). A number of countries took a clear position on allowing a switch to biosimilars in the course of treatment, including Denmark, Finland, France, Germany and Norway (Ekman and Vulto, 2016).

2.2. Generics uptake and penetration can be slowed by regulation and stakeholder reluctance

Only some of the observed differences in generics uptake across countries can be explained by the fact that patents are country-specific and expire at different moments in time in different countries (leading to variations in the number of off-patent medicines and their generic substitutes) (Belloni et al., 2016). Generics uptake also depends very much on policies implemented by countries. In particular, systemic issues such as inadequate regulation often hinder penetration of the market by generics.

The use of generics might be hampered by suboptimal decisions taken by clinicians, pharmacists and patients, who fail to switch from the established practice of using the originator drug. Especially when generics are new on the market, patients but also clinicians may be reluctant to recognise their therapeutic equivalence with the original branded products. Concerns over generics' safety and effectiveness compared to originators largely reflect regulators' failure to address them adequately. Regulators often do not effectively communicate the benefits of generics and as such do not provide the necessary decision-making support for clinicians and patients.

Figure 4.1. **Trends in generics market shares in volume in OECD countries between 2005 and 2015 (or the nearest year)**



1. Data refer only to reimbursed pharmaceutical market.
2. Most recent available data are for 2013.

Source: OECD Health Statistics (2016), *http://dx.doi.org/10.1787/health-data-en.*

StatLink http://dx.doi.org/10.1787/888933444162

Economic incentives are often misaligned with the aim of increasing generics' share of prescribed or dispensed medicines. In most OECD countries, margins of pharmacies or dispensing clinicians are fixed and correspond to a certain percentage of the realised turnover. Thus dispensing clinicians' and pharmacies' income increases with the price of dispensed drugs. The incentive to stock and dispense cheaper generics is hence significantly lower than the incentive to stock and offer to patients the original brand name drugs.

In some OECD countries, the use of generics instead of originators produces only limited savings because of the price paid. This can be the case when regulations stipulate that generic drug prices are subject to price caps, set as a fixed fraction of the price of the original branded product (Kanavos, 2014) or when all therapeutically equivalent products (including originator and generics) are subject to the same reimbursement level – a practice referred to as Internal Price Referencing (IPR) (Seiter, 2010), discussed in more detail in Section 3. In these cases, generics manufacturers face a maximum price/reimbursement ceiling. While this prevents prices/reimbursement from growing above that ceiling, it incentivises generics manufacturers to set their prices at this ceiling and pay generous "professional allowances" to pharmacies to secure shelf space instead of eliminating competition by lowering the price below the ceiling. For example, numerous studies have shown that Canada, where regulations setting generic drug prices relative to the price of the original branded products were in place until 2013, had some of the highest generic drug prices in the world (IMS Institute for Healthcare Informatics, 2016). Similarly, a study of off-patent drug markets in 12 European countries revealed that countries with administrative controls on prices of generics experienced significantly slower price reductions over time than countries that do not have them (for example, Denmark and the United Kingdom) (Kanavos, 2014).

2.3. A large array of policies can effectively increase generics uptake

Policies encouraging uptake of generics can be grouped into two main categories: i) policies that aim to increase availability of generics on the market, including entry-level legislation and pricing methods; and ii) policies that steer main stakeholders such as physicians, pharmacists and patients towards the use of generics already available on the market.

Encouraging early entry of generics and competitive pricing methods create the potential for the generics market to develop

Policies to promote the use of generic medicines start with enhancing their availability in the market. Through early entry legislation, generics manufacturers can be allowed to complete their regulatory requirements prior to the patent expiry of the originator. In addition, market exclusivity can be granted to the first generics on the market to incentivise generics manufacturers to produce them and speed up market entry, although this can limit competition. In the United States, the first generic drug developed post-patent expiry has six-month market exclusivity (Belloni et al., 2016). Other regulatory measures include revisions of patent applications and oversight over competition law, which allow for early detection of activities carried out by manufacturers of originator drugs that aim at preventing or delaying market entry of generics. Such actions belong to the scope of inappropriate business practices and are discussed in more detail in Chapter 7, which deals with integrity violations in the health care sector.

Introduction of generics will not ensure the full potential of savings is realised, however, unless effective price competition exists in the generics market. Policies that promote a competitive market environment are the optimal way to achieve this goal. The majority of OECD countries rely on price regulations (except for Denmark, the Netherlands, Sweden, the United Kingdom and the United States). Within price-regulated systems, generic drug prices are often set either as a percentage of the price of the equivalent originator drug or as a maximum price based on external reference pricing (Box 4.2) (Medicines for Europe, 2016). But price regulation has certain drawbacks, as discussed in more detail in Section 3. In general, with regard to the number of generic drug producers attracted to a given market and the prices of generics, systems relying on price regulation appear to be inferior to systems in which prices are established through competitive mechanisms such as tenders or competitive negotiations between buyers and manufacturers (OECD, 2013b; Kanavos, 2014; IMS Institute for Healthcare Informatics, 2016; Vogler et al., 2016b).

After a generic enters a market, the extent of competition also depends on whether regulators consider the generic to be a substitute only for the equivalent branded originator drug (inducing narrow within-molecule competition) or also for similar patent-protected drugs belonging to the same therapeutic class (inducing broader within-class competition) and across related therapeutic classes (inducing the broadest possible competition). OECD countries differ with regard to how broadly competition is actually induced by a generic's entry. While any therapeutic substitution decisions should be transparently supported by robust evidence on the comparative safety and efficacy of the products, countries with different regulations should consider exchanging experience and knowledge to reach optimal decisions. For example, Norway, the United Kingdom and the United States actively encourage opportunities for generic drug substitution where the effectiveness and safety of a particular generic product is similar to a patent-protected product in the same or related class.

Box 4.2. **Pharmaceutical price regulations: Advantages and main drawbacks**

OECD countries use various price regulations to establish ceilings on pharmaceutical prices. The most common type is *external price referencing* (EPR), also known as external reference pricing or international price comparison/benchmarking. It is defined as the practice of using the price(s) of a medicine in one or several countries to derive a reference price for a medicine in a given country. Alternatively or in addition, countries can set a single price for equivalent drugs – a practice referred to as *internal reference pricing* (IRP) – where the price of the cheapest drug applies to all drugs within a therapeutic class. Also, the price of a generic drug within a given therapeutic class can be set as a percentage (e.g. 70%) of the originator's price.

Price regulations have several limitations. With EPR, it is necessary to recognise that list prices of pharmaceuticals in other countries do not necessarily reflect actual prices because buyers might receive discounts and rebates, which often are confidential. Thus referring to the list price as a measure for setting prices in another country may lead to unnecessarily high prices. More importantly, manufacturers of patent-protected drugs might succeed in maintaining narrow price bands across different markets, knowing that concessions in one country may lead to regulatory price adjustments in other countries (OECD, 2008; Seiter, 2010).

IRP models can also cause distortions that limit their effectiveness. Under this policy, manufacturers of equivalent products (competing within a given therapeutic class) tend to set their price at the reference price level, after which they seek to eliminate competition with non-price strategies such as offering "professional allowances" to wholesalers and/or pharmacists to secure shelf space. Such policies may put wholesalers and pharmacies into the role of "market makers" because they can decide which pharmaceutical brands they carry (IMS Institute for Healthcare Informatics, 2016). Effectively, the manufacturer's revenue for each item sold is reduced by the amount of "professional allowances" paid to pharmacies or wholesalers, but third-party payers such as governments and other insurers are not involved in the transaction and reimburse the full reference price, creating significant incremental profits for wholesalers and pharmacies (Seiter, 2010). This problem is increasingly observed in OECD countries, resulting in adoption of several countermeasures, such as regulatory ceilings on wholesalers' and pharmacies' margins or arrangements for profit-sharing between wholesalers/pharmacies and governments or insurance funds (European Commission, 2012).

In summary, price controls are useful but their advantages are diminished by strategic response from pharmaceutical manufacturers. Also, actors in the lower level of the supply chain, namely wholesalers and retail pharmacies, have opportunities to exploit the reference price setting to their sole benefit.

Physicians can be encouraged to prescribe generics

While the need to systematically promote the use of generic (i.e. bio-equivalent) medicines is widely accepted, the extent to and means by which the choice of cheaper therapeutic alternatives within a therapeutic class or across related therapeutic classes should be encouraged are more contentious. Cost-conscious physicians can be encouraged to prescribe cheaper products by explicit guidelines on the prescription of the cheapest alternative as first-intention medication or nudged by prescription software that highlights price differences, provided they accept that the products are therapeutically equivalent for the patient. Other measures include the encouragement or mandate to prescribe by International Non-proprietary Names (INN). Physicians are allowed to prescribe by INN in more than two-thirds of OECD countries and mandated to do so in five countries (Table 4.1). France implemented mandatory INN prescribing in 2015 (Belloni et al., 2016).

Table 4.1. **Policy tools to promote use of generics**

	Prescription in INN			Generic drug substitution			Incentives to prescribe/dispense/ purchase generics		
	Not allowed	Allowed	Mandatory	Not allowed	Allowed	Mandatory	Incentives for pharmacists	Incentives for patients	Incentives for physicians
Australia		X			X		F	F	-
Austria	X			X			-	NF	NF
Belgium		X		X			NF	F	F&NF
Canada[1]		X[1]	X[1]		X[1]	X[1]	F[1]	F[1]	[1]
Chile			X[2]		X		-	F	NF[2]
Czech Republic		X			X		..	F	F
Denmark		X				X	NF	F	NF
Estonia		X				X	-	NF	NF
Finland		X				X	NF	F	NF
France			X		X		F	F	NF&F
Germany		X				X	NF	F	F
Greece		X			X		-	F	NF
Hungary		X			X		NF	F	F
Iceland					X		..	F	..
Ireland		X			X		NF	F	NF
Italy		X				X	NF	F	NF
Japan		X			X		F	F	[3]
Korea		X			X		F	F	..
Luxembourg		X		X			..	NF&F	NF
Mexico			X		X			F	NF
Netherlands		X			X		F	F	..
New Zealand		X			X[4]		F	F	NF
Norway		X			X		F	F	NF
Poland		X			X		NF	F	-
Portugal			X		X		N	NF&F	N
Slovak Republic		X				X	NF	F	NF
Slovenia			X		X		NF	NF	NF&F
Spain		X				X	NF&F[5]	NF&F	NF&F[5]
Sweden		X				X	NF&F	F	NF
Switzerland		X			X		F	F	-
Turkey		X			X		..	F	-
United Kingdom		X			X		F	-	NF
United States[6]							F[6]	F[6]	-

Note: F = Financial incentive; NF = Non-financial incentives; .. = Information not available. For pharmacists, this table only considers incentives provided by drug coverage schemes. Market incentives (such as rebates from manufacturers, vertical integration, etc.) are not reported.

1. In Canada, the regulation of prescription and generic drug substitution differs across provinces and territories. Incentives for doctors, pharmacists and patients vary across drug plans.
2. Only in the public sector.
3. In Japan, there is no direct incentive for physicians, but an incentive for medical institutions exists. Generics prices are revised after market entry.
4. If the pharmacist has a substitution arrangement with the prescriber.
5. In some regions.
6. Legislation on prescription in INN and substitution is not uniform across states. Incentives for pharmacists, patients and doctors vary across drug plans. Patients' co-payments are generally lower for generics.

Source: Medicines for Europe (2016), *Market Review – European Generic Medicines Markets*; Belloni, A., D. Morgan and V. Paris (2016), "Pharmaceutical Expenditure and Policies: Past Trends and Future Challenges", *OECD Health Working Papers*, No. 87, OECD Publishing, Paris, *http://dx.doi.org/10.1787/5jm0q1f4cdq7-en*; OECD (2010), *Value for Money in Health Spending*, OECD Health Policy Studies, OECD Publishing, Paris, *http://dx.doi.org/10.1787/9789264088818-en*.

Financial incentives can be leveraged to encourage physicians to prescribe generics. Not many OECD countries use financial incentives targeting prescribers. One exception is Belgium, where since 2005, physicians who issue at least 400 prescriptions annually are evaluated on whether they prescribe a certain required percentage of "cheap medicines". The scheme, updated in 2015, envisages between 16% and 65% target share of "cheap medicines" in total prescriptions across different medical specialities, with an average of 42%. The target is set at 50% for general practitioners (GPs) and 75% for dentists (Belloni et al., 2016). Germany uses similar target levels and introduced financial penalties for physicians who do not reach them (Godman et al., 2012). In recent years, France (in 2009) and Hungary (in 2010) introduced incentives for GPs to prescribe generics through a pay-for-performance (P4P) scheme. Japan's scheme has been in existence for a while; in 2012, it increased the value of bonuses associated with reaching the target share of generics in total prescribing, leading to an increase in generic drug prescriptions (Belloni et al., 2016). In Greece, public hospitals are required to reach a 50% share of generics in total volume of administered pharmaceuticals.

Pharmacies have a role to play in increasing the take-up of generics

To encourage the dispensing of generics, pharmacists might be allowed to substitute the more expensive drug prescribed with a generic. As mentioned earlier, the possibility of allowing therapeutic substitution is controversial (i.e. the dispensing by pharmacists of a drug considered to be therapeutically equivalent to that initially prescribed including with specific prescriber permission). Generally, therapeutic substitution decisions should: i) be transparently supported by robust evidence on the product's comparative safety and efficacy; and ii) result from informed decisions by patients and clinicians. But such decisions could be encouraged more systematically and framed by a requirement to supply the cheapest drug unless otherwise specified by the prescriber or if an exceptions policy is in place.

Pharmacists are allowed to substitute brand name drugs with generics in a majority of OECD countries, and generics substitution is mandatory in a handful of countries (Denmark, Finland, Spain and Sweden). Italy introduced such a mandate in 2012, while in other countries (e.g. Norway) pharmacists are obliged to inform patients about the possibility of a cheaper alternative. In most countries, substitution is allowed when the generic exists, although a handful of countries maintain exceptions for some drugs (e.g. anti-epileptics). In contrast, substitution by pharmacists in France is limited to a list of molecules established by the National Agency for Medicines and Health Product Safety.

In addition, pharmacists need to be reimbursed in a way that encourages them to dispense the least expensive products. Instead of proportional mark-ups that encourage dispensation of more expensive drugs, fixed fees per prescription or regressive margins (the higher the drug price, the lower the margin) lead pharmacists to be either indifferent or willing to dispense generics, respectively. Some countries recently changed their policies to better incentivise pharmacists to dispense generics. In 2012, Portugal changed from linear to regressive remuneration. Other countries went a step further. In Switzerland and Belgium, for instance, pharmacists receive an additional fee for generics substitution. France introduced a P4P scheme for pharmacists in 2012 with a bonus for achievement of generic drug dispensing targets. Similarly, to further encourage substitution Japan in 2012 increased pharmacists' bonuses associated with target levels for dispensed generics.

Patients can be incentivised to opt for generics – if convinced

Patients have a financial interest to choose cheaper drugs when their co-payment is lower for generic drugs than for the branded equivalent. This is generally the case in all systems using a single reimbursement amount (IPR) for a cluster of products. Greece, Ireland and France recently introduced other incentives for patients. In Greece and Ireland, patients choosing the originator over the generic drug now pay the difference between their prices. Since 2010 in France, patients refusing a generic drug substitution have to pay in advance for their drugs and are reimbursed later, whereas purchase of generics does not require advance payment.

Recognising that few patients might actually be aware of the broader debate over generic medicines, several countries carried out information campaigns to promote the use of generics, explaining their equivalence to brand name drugs (e.g. Belgium, Denmark, France, Greece, Italy, Portugal and Spain) (Medicines for Europe, 2016). While no formal evaluation is available, these policies, associated with patent expiries of several blockbusters in recent years, certainly contributed to the significant increase in the market share of generics observed over the past decade in most countries. More specifically, the share of the generics market increased significantly over the past decade in some countries that had low levels in 2000. In Portugal, the generics market share grew from virtually zero in 2000 to 41.3% in volume in 2015. In Spain, the generics market share reached 47.6% in volume in 2014, up from 9% in 2000.

Table 4.1 provides an overview of policies incentivising the main stakeholders such as clinicians, pharmacists and patients towards use of generics. It indicates whether physicians are allowed to prescribe by INN and, if yes, whether it is optional or mandatory, as well as whether generic drug substitution by pharmacists is permitted.

While most of the policy debate on opportunities to substitute expensive originator drugs with cheaper and therapeutically equivalent alternatives focuses on generics, the emergence of biosimilar medicine brings in new perspectives for releasing resources. Biosimilars are essentially generic versions of original biologic medicines, with the latter a rapidly growing part of the global market for pharmaceuticals. By 2020, biologic medicines may account for nearly 30% of the value of the global market (IMS Institute for Healthcare Informatics, 2016). As such, biosimilars, their cheaper alternatives, open a significant potential for savings (Box 4.1).

A growing number of conditions are treated with biologic medicines. In particular, these innovative medicines opened a new era of precision therapies for cancer, but these are very expensive (e.g. USD 25 000-USD 200 000 per year) (Belloni et al., 2016). Hence, the emergence of biosimilars brings the promise of more affordable therapies and relief for health care budgets. Adoption of biosimilars faces the same obstacles that had to be removed to realise the potential of generics, however (Box 4.1).

3. Procurement as a core strategic instrument

3.1. *Ineffective procurement increases the prices paid for pharmaceuticals and other medical goods*

Pharmaceutical procurement is complex, but can still be strategically designed

Procurement of pharmaceuticals, and to a certain degree other medical goods, is a complex process. In contrast, the process for bringing over-the-counter (OTC) medicines[4] and basic medical goods to market is far simpler. But for pharmaceuticals and other

medical goods that require a prescription or those administered to patients within health facilities, the procurement process typically involves a number of activities that can be categorised into three broad stages, each of which has its own challenges:

- Pre-procurement. This involves licensing, selection of essential commodities, needs quantification and coverage decisions.
- Core procurement activities. This describes negotiation and tendering processes. It includes market research, communication with potential suppliers, determination of price and other conditions of supply, and ultimately supplier selection.
- Post-contract management. This relates to supply execution, supplier management and performance monitoring.

Complexity in procurement largely reflects the nature of the market. In particular, large, internationally operating manufacturers, whose products are often patent-protected, dominate the pharmaceutical market. While logical reasons explain why the pharmaceutical market developed this way, notably to encourage research and innovation, such a market structure limits competition with a consequent impact on prices. Further, patients' demand for prescribed drugs is derived rather than direct. Patients are not traditional consumers, who react to market prices and make their own choices. Rather, patients rely on health professionals to determine which medicines are right for them, and in OECD countries the associated costs are fully or partially covered by a third-party buyer such as the government or another insurer. Taken together, these factors make it challenging for buyers to ensure that prices paid for pharmaceuticals are not too high.

Yet even within this market structure, governments and other health insurers can reduce the costs of pharmaceuticals and other medical supplies. Similar to health care activities discussed in previous chapters, procurement of these products is not free of inefficient spending and waste. This final section identifies these shortcomings and discusses suitable policy solutions. The latter include building and meaningfully using market power, developing expertise, and improving contract designs and procurement tools such as e-platforms and standards.

The analysis herein focuses on the core procurement activities. In other words, the analysis assumes that the pre-procurement activities listed above are adequately performed.[5] This is a simplification, particularly as pre-procurement and core procurement activities often take place simultaneously; notably, coverage decisions are often taken in concert with pricing decisions. Nevertheless, negotiations and tendering processes and other such core procurement activities have the most crucial impact on price paid.

This section thus ultimately pinpoints shortcomings in procurement that lead to overly high prices being paid for pharmaceuticals and other medical supplies. Still, while pricing is the key indicator used to gauge inefficiencies in procurement, an exclusive focus on prices can generate unintended adverse effects. In particular, two other criteria are important: i) system responsiveness, the ability to ensure availability of the right products – as perceived by clinicians and patients – in the right quantities and on time; and ii) long-term economic sustainability, the objective that lower prices in one year should not be offset by non-proportional price hikes or lack of product availability in subsequent years. In other words, the dynamics in procurement over time should also be considered.

Between- and within-country price variations are striking and at least partially unwarranted

Having outlined some of the complexities in procurement of pharmaceuticals and other medical goods, it is useful to highlight actual variation in prices within and across countries, which reflect inefficiencies in procurement to a significant extent. Comparing prices, particularly across countries, is not a straightforward task. For example, prices can be measured at different stages (from ex-factory to retail); and differences in prices – which are in part determined by market forces – may reflect the different values countries attach to health outcomes in relation to their income. Official and actual prices can differ, as manufacturers can provide discounts to countries but typically condition them on non-disclosure agreements. As a result, price comparisons are difficult and not all price differences can be deemed wasteful. Yet as with the variation observed in the use of specific medical procedures (see Chapter 2), some price differences are certainly wasteful. In particular, most within-country price variation is probably a sign of inefficient procurement practices, and if comparable countries pay vastly different prices for the same drug, those who pay higher prices could probably question why this might be the case.

Within-country price variations tend to be non-negligible. For example, in Italy the same types of buyers pay prices differing up to 23% for the same pharmaceutical product intended for hospital use (Baldi and Vannoni, 2015). Similarly, within-country price variations exist for other medical goods, as documented by the *Procurement Atlas of Variation* published by NHS England (NHS, 2014, 2016). One of the most striking examples is that of the simple identification wristband for hospital patients, for which the price paid by different NHS trusts varied more than two-fold in 2014. Other examples from the *Atlas* include needles and blood sample tubes, with between-trust price variations of 47% and 25%, respectively.[6] Saving opportunities on these types of simple medical supplies were estimated to be between 5% and 8% of total spending for a majority of trusts, and up to 15% for some of them in 2014 (NHS, 2014).

Additional insights are offered by the experiences of countries that implemented changes in their procurement strategies, for instance modifying organisational structure (associated policies are discussed later). Such a move presents a natural experiment in which a comparison of prices before and after can reveal inefficiencies inherent to a given version of a procurement system. The most recent examples of such a change include Greece and Mexico, where substantial savings were achieved, proving that prices previously paid for pharmaceuticals were overly high. In Mexico, a move from decentralised to centralised procurement contributed to savings of around USD 2.8 billion between 2007-10 compared to the budget planned based on the performance of the former decentralised system (OECD, 2013a). A similar change in Greece in 2010 contributed to savings of EUR 180 million compared to the expected budget for 2011 (Kastanioti et al., 2013).

Regarding price variations between OECD countries, studies in the past decade show that Germany, Sweden, Switzerland and the United States tend to be high-price countries for originator drugs, whereas ex-factory prices for originator drugs in Greece, Mexico, New Zealand, Portugal, Spain and recently the United Kingdom rank at the lower end (Kanavos et al., 2013, Leopold et al., 2013; Vogler et al., 2016b). For example, for a selected group of medicines, ex-factory prices in Germany were up to 27% more expensive than the average price among the studied countries, versus Greece where prices were up to 32% cheaper than the average. Moreover, differences in ex-factory prices of a number of cancer

drugs, which in most countries are the top category in terms of value of pharmaceutical expenditures, varied from 28% to 388% between the highest- and lowest-priced country (Vogler et al., 2016a).

Between-country price variations do not seem to be well explained by differences in national income as measured by purchasing power and/or average wages. Indeed, a recent investigation into ex-factory prices of an innovative drug for hepatitis C in 30 countries reveals that after adjusting for purchasing power parity (PPP) or average wages, the price differences are magnified instead of reduced, and the highest paying countries by far in the OECD are Poland and Turkey (Iyengar et al., 2016).

3.2. Organisational shortcomings and misaligned incentives drive inefficiencies in procurement

Existing organisational structures frequently do not support economies of scale

Given the market characteristics discussed earlier, many manufacturers enjoy a monopolist advantage or face competition from only one or two other manufacturers of equivalent patent-protected products. In absolute monopolies (one manufacturer) and oligopolies (a few manufacturers), suppliers can set higher prices than under competition.

Manufacturers are not alone in their ability to exert market power. Buyers can powerfully influence prices, particularly when a single buyer operates in a sizeable market such as a country or a large region. For example, when multiple sources of equivalent products exist, a single buyer can incentivise manufacturers to compete on price. The single buyer's position is of course less effective against suppliers of single-source medicines (patent-protected medicines for which no alternatives exist). Nevertheless, even in this situation a single large buyer is in a better position to exert market power than a number of dispersed smaller buyers (Kesselheim et al., 2016; MHS and WHO, 2012).

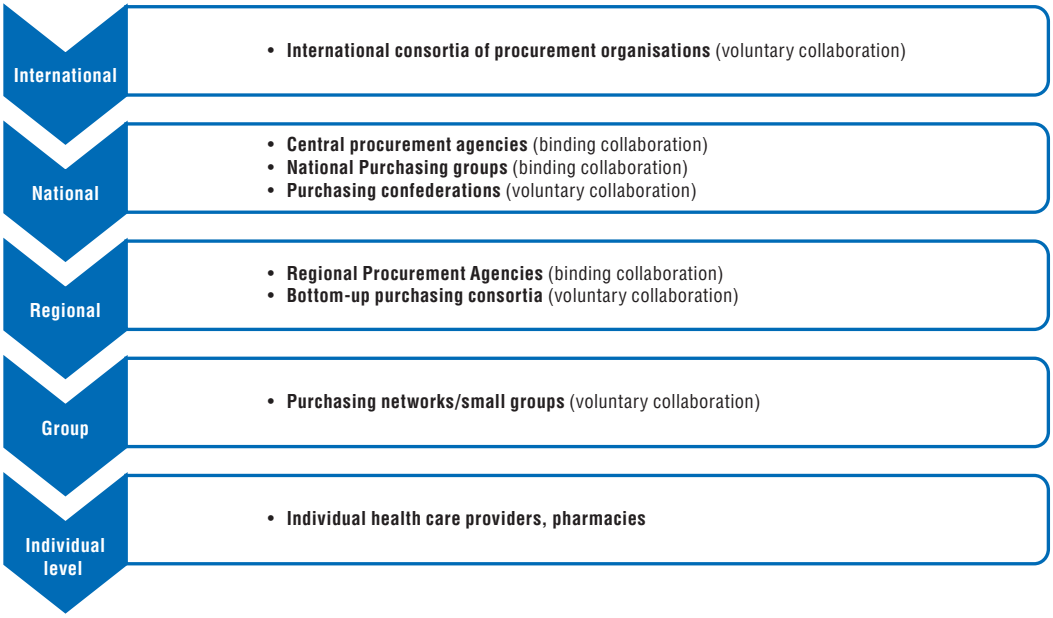
Relatively high prices of pharmaceuticals and other medical supplies may reflect organisational structures of the procurement system that hinder building market power through bulk purchasing. For example, this occurs when small insurers or providers contract separately for limited volumes of the same products. Indeed, in many OECD countries, individual hospitals, pharmacies and local government units and insurers carry out procurement separately (e.g. Belgium, the Czech Republic, Germany, the Slovak Republic, Slovenia, Sweden and Turkey). This not only precludes volume-related discounts but also creates unnecessary task repetition by each buyer.

A majority of OECD countries use price regulations to moderate prices for pharmaceuticals. These take the form of external and/or internal price referencing and occasional one-time price cuts to establish maximum prices in a country. But while price regulations contributed to pricing transparency and had the desired initial impact on pharmaceutical expenditures in many (but not all) countries, the impact declined over time (Vogler et al., 2015; Seiter, 2010). The main problem is that price regulations do not automatically engage the potential market power of a given health care system, and active procurement strategies can be more effective in that respect. Box 4.2 discusses the advantages and drawbacks of price regulations in more detail.

Buyers' size affects their ability to negotiate volume-related discounts

To illustrate how procurement systems in OECD countries exploit (or fail to exploit) their potential market power, this subsection classifies systems by the extent of collaboration/consolidation of purchases. This classification distinguishes between

Figure 4.2. **Levels of collaboration/consolidation of purchases in procurement systems**



Source: Authors' own compilation (2016).

procurement systems in which each buyer purchases independently and those that rely on larger or smaller collaborations of buyers. Moreover, the classification distinguishes between voluntary and binding forms of collaboration (Figure 4.2).

Collaboration in procurement is defined as co-operation between two or more organisations in one or more of the core procurement activities by bundling their purchasing volumes and/or sharing information and resources (Bakker et al., 2008; Schotanus and Telgen, 2007; Nollet and Beaulieu, 2003). The various legal frameworks and organisational structures of countries' health care systems led to a wide array of collaborative procurement forms. These forms range from national and regional government-led agencies or private consortia, which legally bind collaborating members, to public or private confederations in which collaboration is voluntary:

- Individual level (no collaboration): Individual pharmacies or providers purchase directly from suppliers, usually under regulatory price ceilings. This model exists in some OECD countries in the retail market for pharmaceuticals and medical supplies dispensed to patients in pharmacies (for example, Australia, the Czech Republic, Hungary, Portugal, the Slovak Republic and Turkey). In the majority of OECD countries, this procurement model applies to medicines administered to patients within health facilities, notably hospitals (except in Denmark, Italy, New Zealand, Norway, Portugal, Slovenia, Sweden, the United Kingdom and the United States).
- Regional/group level:
  - Purchasing networks/small groups: A few entities, usually hospitals or a local government, consolidate their purchases. These small groups might be informal and operate on an ad hoc basis rather than regularly (for example, small groups of hospitals in Germany or nursing homes in the United Kingdom).

- Purchasing consortia: Also referred to as co-operative purchasing, these are larger groups of pharmacies, hospitals (sometimes represented by a common health fund) or a smaller group of insurers regularly carrying out joint procurement activities. Consortia-type initiatives typically do not have dedicated staff but are run by a host organisation, which usually rotates between members. Consortia are bottom-up organisations and as such leave their members free to buy outside the established contracts, referred to as framework contracts; for example, local hospital consortia in France, Italy, the United Kingdom or a consortium of local governments in Sweden purchase medicines for pharmacies.
- Regional procurement agencies: These are similar in size to purchasing consortia; the main difference is the top-down instead of bottom-up nature of the collaboration, which means that buying outside the contracts is considered a violation of compliance or is limited by the procurement budget being allocated to the level of the agency. Among countries with a significant share of public health care, such agencies exist in England, Greece, Italy, Spain and Sweden. In countries with a significant private sector share of health care, such as the Netherlands and the United States, the corresponding form is Pharmaceutical Benefit Managers or large purchasing groups.

- National level:
  - Purchasing confederations: National-scale collaborations operate similarly to the above-described purchasing consortia, with the distinction that a central entity is created solely for the purpose of serving the collaboration and as such has its own staff. For example, confederations include all hospitals in a country or all regional governments – pan-Canadian Pharmaceutical Alliance, Norwegian Drug Procurement Cooperation (LIS), and Danish procurement collaboration (AMGROS). Members finance the central entity through contributions proportional to their size. Still, similar to purchasing consortia, collaboration is voluntary and based on framework contracts.
  - Central procurement agencies (also referred to as third-party purchasers) are separate organisations, usually a government agency, to which all procurement and budgetary powers are delegated. This form of centralised system is the most prevalent procurement mechanism in OECD countries for purchasing prescription pharmaceuticals for the retail market (for example, Greece, Poland and New Zealand). Central agencies are less present in the market for pharmaceuticals used in health care facilities, except in Italy and Spain.
- Supranational level: This is the domain of a few international projects in specified areas, such as equipment for the elderly or pandemic vaccines. One example is the European project HAPPI (supported by European Commission and Ministry of Social Affairs and Health, France), which brings together ten partners from six countries with the intention to enlarge the group with any European public authority involved in health care procurement. Its main functions include executing joint calls for tenders, with the first joint cross-border procurement successfully completed in 2015. Another example is a co-operation between 21 European Union governments that aims at joint procurement of vaccines for pandemics. Moreover, a number of collaborative projects are currently under construction, such as: the Nordic Pharmaceutical Forum; "Beneluxa" (Belgium, Luxembourg, the Netherlands and Austria); and a collaboration between Bulgaria and Romania.

Grouping procurement systems in the above-described manner reveals that in half of OECD countries, international manufacturers face relatively small and dispersed buyers. In such systems, potential for bulk purchasing remains largely unexploited, which seriously limits possibilities for obtaining favourable volume-related discounts. Moreover, for each product the contracting effort is unnecessarily repeated by different purchasing organisations.

The remaining countries rely on a range of collaborative procurement systems that differ with respect to the number of organisations represented and the voluntary versus binding character of the group. These collaborative procurement systems are better suited to exert market power.

Even large buyers often fail to obtain volume-related discounts due to communication problems and ineffective e-procurement tools

Relatively high prices of pharmaceuticals and other medical supplies can reflect passive procurement practices of large organisations that simply do not exercise their potential market power. Large organisations might fail to exploit economies of scale if they lack strategic perspective on procurement and treat it as an administrative function. This kind of failure often involves weak monitoring of consumption and unreliable forecasting, which do not give suppliers any guarantee of selling specific volumes. In other instances, large buyers do not even have the mandate to engage in negotiations with suppliers on more favourable purchase conditions, as is the case for Medicare and Medicaid in the United States (Kesselheim et al., 2016).

When several equivalent products for a given condition exist, large buyers frequently face obstacles in allocating the biggest share of the market to the most cost-effective product. For example, Medicaid is legally obliged to cover all authorised medicines so cannot exclude from its purchases even the least cost-effective product within a therapeutic category. US law requires similarly broad coverage for Medicare in some therapeutic classes, such as oncology (Kesselheim et al., 2016). Other large buyers could but do not manage to implement appropriate procurement strategies. Payers' willingness to respect therapeutic freedom may drive them to cover as many products as possible, but as already mentioned in the context of generics substitution, choice of the most cost-effective alternative should be encouraged whenever possible. Involvement of administering/prescribing clinicians in the design of procurement strategies is required for this. At a minimum, clinicians should have a transparent view of both the clinical- and cost-related factors that procurement organisations take into account in their decisions.

As large procurement organisations often fail to effectively communicate with clinicians, it remains difficult to convince them to accept the preferred product supplier, within a therapeutic class for example. If none of the suppliers has a prospect of winning a relatively higher market share, obtaining volume-related discounts is difficult for buyers. Even if a procurement agency is authorised to exclude some products within a class and give a larger market share to only one product, lack of insight into the decision-making process causes unnecessary frustration among clinicians. For instance, a survey among GPs in New Zealand revealed that only few participants were able to correctly identify the procurement strategies of the pharmaceutical management agency (PHARMAC) (Babar et al., 2015).

In addition to communication problems, ill-designed e-procurement tools impede bulk purchasing. In particular, in large voluntary collaborations, which offer their members an option (not an obligation) to procure through framework contracts, lack of user-friendly e-procurement tools might lead to purchases outside the collaboration since they appear to be simpler and faster. For instance in the 2000s in NHS England, adherence to framework contracts was estimated to be approximately 50% (Karjalainen et al., 2008; Lonsdale and Watson, 2005; Knight et al., 2003). Similar problems were reported in Finland (Karjalainen et al., 2008). In the worst-case scenario, a procurement collaboration plagued by compliance problems can be seen by suppliers as a "nuisance customer". This situation might have long-lasting negative effects as manufacturers might be less inclined to enter framework contracts and/or demand higher prices to compensate for their risk of not realising the expected volume of sales (Karjalainen et al., 2008).

Establishing and maintaining collaborative procurement requires efficient modes of communication to ensure transparency and minimise costs of collaboration, be it time or direct administrative costs. This is, however, not always the case. The bigger the collaboration, the greater the potential for savings through economies of scale. Yet a greater risk arises of creating complicated and opaque structures that might be abandoned by their members over time.

Poor tender designs might increase prices in the short and long term

Buyers rely on two general procurement methods: negotiations and tender-like mechanisms. Negotiations are the only choice for single-source pharmaceuticals and medical supplies. Otherwise, it is a common perception that prices of pharmaceuticals and other medical commodities should be set in competitive tenders whenever possible. Designing a well-performing tender mechanism is not straightforward, however. The practice has produced a number of examples of tenders with undesired effects in the form of selective provision or shortages of supplies and reduced competition, which in the long term naturally led to price increases (Merlob, 2010). In particular, as soon as a bigger share of a market is subject to tendering (for bulk purchasing), the optimal design of tenders gains importance. Under bulk purchasing, consequences of bad tendering not only affect individual buyers but can extend to the entire region or country and as such are much more likely to have long-term consequences. The following provides examples of issues that can arise.

Lack of transparency on how suppliers are selected, especially when non-price criteria are used in the selection, can seriously undermine a tender's efficiency. Indeed, price is never the only decisive criterion as other criteria such as suppliers' capacity to deliver a given volume, product quality standards, and performance obligations are equally important. If the weights of these criteria are not clear, some suppliers might be discouraged from participating in tenders in a given country or sector, while others might file complaints, causing disruptions in supply (Baldi and Vannoni, 2015). For example, tenders organised within the competitive bidding programme initiated by Centers for Medicare & Medicaid Services (CMS) in 2008 were subsequently cancelled by the US Congress due to complaints about unfair qualification procedures (Cramton and Katzman, 2010). In consequence, delays in product availability occurred and expensive ad hoc purchases had to be made. Similarly, in the Slovak Republic, lack of transparency in the tendering process as well as accompanying administrative burden effectively

discourage manufacturers from competing for the country's market. If the tenders take place but not more than one contestant participates, the whole exercise is rendered futile (European Observatory on Health Systems and Policies, 2016).

Moreover, in tender designs in which bids are not binding commitments, any tender winner can decline to sign a supply contract following the tender. This encourages suppliers to submit low bids, with which they acquire at no cost the option to win a contract, and withdraw should they find a more profitable market in the meantime. Such practices weaken the procurement system's credibility and frequently result in too few or sometimes even no units being procured – as illustrated by the example of post-2008 CMS auctions (Merlob, 2010). This situation has been known to arise when the contract price is determined by the value of the mean or median of a certain number (usually three to seven) of the lowest bids. The opportunistic low-bidding suppliers withdraw but this does not affect the contract price, which might be so low that not a single remaining supplier is ready to deliver at this price. The tender process must then be repeated with no guarantee that the next outcome will be any better.

The critical mass of bulk purchasing means that poor tender designs can have negative effects in the long term. In other words, under bulk purchasing, the trade-off between low prices achieved by a given procurement system today and the potential long-term risk of having fewer pharmaceutical products with which to treat patients in the future must be recognised (Bergman et al., 2015). An example of failure to ensure such balance is offered by the experience of NHS England on the market for prosthetics. In the early 2000s, annual tendering was replaced by three-year contracts with an option to extend for two more years. This change was aimed to reduce administrative costs related to more frequent tenders. Early on, these much longer contracts were seen as highly desirable for suppliers. It was not long, however, before suppliers and NHS buyers started to recognise that bulk purchasing (34 procurement centres tendering together) made suppliers more vulnerable. If a supplier did not win a contract, it was a long time (up to five years) before another significant opportunity arose to win business. This increased firms' incentives to cut their bid price to win business, just to maintain turnover. Eventually, only one firm survived the "race to the bottom", effectively creating a monopoly on the prosthetics market (Caldwell et al., 2005). Similarly, bulk purchasing combined with irregular tendering patterns locked suppliers of generics out of the market in Denmark, France and Sweden, seriously harming competition in the long term.

3.3. Policy solutions to improve procurement systems' performance

Better information is essential for improving procurement system performance

Solutions at a national level are becoming progressively harder to find, especially given the global nature of the pharmaceutical industry. Hence, countries should engage in dialogue regarding future policies addressing the complex societal challenges of high medicine prices. The global character of the market also means that all countries face the same challenges, so consideration should be given to sharing information about actual prices paid for pharmaceuticals. As discussed earlier, price comparisons, especially between countries, are difficult since official prices do not include rebates offered by manufacturers in exchange for non-disclosure agreements. This and the large differences in official list prices suggest that governments relying solely on external price referencing (EPR) in procurement are likely to overpay for pharmaceuticals and other medical supplies

depending on which countries are included in the EPR. And those governments that use EPR as a starting point for negotiation of discounts should ask themselves whether the discounts they obtain are meaningful in light of other countries' discounts.

Countries should try to more systematically capture and publish data on price variations within their territory. Such information will automatically pave the way towards more collaborative forms of procurement. For example, in 2014 NHS England launched the *Procurement Atlas of Variation* to deliver greater transparency by comparing prices paid by different hospitals for the same types of products. At present, the *Atlas* covers more than 500 product lines, predominantly medical devices and simple supplies. The aim is to allow buyers as well as suppliers to understand how they could improve performance (Box 4.3).

Box 4.3. **The NHS England Procurement Atlas of Variation**

In 2014, NHS England created the online *Procurement Atlas of Variation*. The *Atlas* shows differences in the amount hospitals pay for everyday items such as catheters, gloves and needles. The aim behind the *Atlas* is to help hospitals compare prices and identify where they need to drive down costs so they can release resources and invest more in patient care.

The *Atlas* contains data on products purchased through the NHS Supply Chain and the Crown Commercial Service – voluntary procurement collaborations that offer their members the option to purchase through framework contracts. The *Atlas* will also contain products from other sources in the future. The price information within the *Atlas* is for product lines, which contain multiple products – it is possible to see which products each line contains and which units were used to express the price. An extensive normalisation of unit price data ensures that prices are comparable. The portal includes detailed information on the methodology used.

Initially, the *Atlas* covered 100 product lines; at present it covers more than 500. Users can create interactive maps with hospitals color-coded according to the price they paid for each product line as well as overall performance on all products. Estimates of annual potential savings are also readily available.

Another successful example of benefits associated with increased transparency in pricing is the price disclosure policy implemented in Australia in the market for off-patent pharmaceuticals (including generics). Price disclosure requires suppliers of medicines listed on the F2 formulary (which consists of drugs with at least one competitor) to disclose information on sales revenue and incentives offered to community pharmacies to preferentially dispense their product. This information is used by the Pharmaceutical Benefits Scheme (PBS) –the Australian government's agency responsible for supplying/subsidising medicines to publicly insured patients – to work out the true average market price at which pharmacies are reimbursed for medicines dispensed to patients. Price disclosure now applies to approximately 350 drugs. Market price disclosures occur on 1 April and 1 October each year. The price disclosure programme resulted in significant price reductions and the consequent savings to the PBS are estimated to reach AUD 20 billion by 2019-20.

Various organisational changes can improve procurement

Moving towards collaborative procurement can help reduce prices. Consolidation of purchases through larger collaborative forms of procurement at regional, national and ultimately international level can help to reduce prices (Caldwell et al., 2005). Consolidation can support favourable agreements such as price-volume contracts, with free goods, or with further discount prices, triggered if an agreed volume threshold is passed (Kastanioti et al., 2013; Baldi and Vannoni, 2015; Sanderson et al., 2015). Consolidated purchase help payers transform into savings the surplus that might otherwise have benefited wholesalers and retail pharmacies (Box 4.2).

Collaborative forms of procurement can reduce not only unit costs per product but also the per transaction cost due to the reduced number of contracts to be negotiated, prepared and managed. In other words, elimination of unnecessary duplication of procurement activities by individual buyers leads to additional savings. Last but not least, large volume effectively serves as a tool for ensuring supplier compliance with terms of contract – suppliers have too much to lose in case of contract breach.

Moreover, collaboration allows for knowledge building, be it pooling of market information and experience with past purchases or greater ability to manage stocks effectively and attract expert staff. Collaboration facilitates dissemination of efficient standards and improved practices as well as collection of information on, e.g. supplier performance and product quality, which in turn supports more comprehensive valuation of contracts.

Section 1 mentioned the cases of Greece and Mexico, where the transition to centralised procurement contributed to considerable savings as compared to the budget planned based on the performance of the former decentralised systems. Until 2007, the procurement function of the Mexican Institute of Social Security (IMSS) was embedded in 60 separate entities. IMSS's gradual centralisation efforts resulted in price reductions for pharmaceuticals and other medical supplies: between 2007 and 2010, cumulative savings of USD 2.8 billion were realised due to improved stock management and creation of a centre of excellence in procurement, which currently serves all public health care stakeholders in Mexico (OECD, 2013a). In Greece in 2010, the government undertook efforts to unify the annual tenders for hospital pharmaceuticals and medical devices. In the first year of operations, the centralised agency – the Health Procurement Committee (EPY), comprising only 26 employees – reported a 10% overall price reduction for pharmaceuticals and a 20% price reduction for selected medical devices. Additionally, payment times were significantly shortened (previously exceeding three years on average) and stock management improved, allowing for transfer of redundant stocks between hospitals (Kastanioti et al., 2013).

In 2010, all 13 provinces and territories of Canada established the pan-Canadian Pharmaceutical Alliance with the aim of conducting joint procurement of pharmaceuticals. As of 2015, these collaborative efforts contributed to an estimated CAD 490 million in combined savings annually (Council of the Federation Secretariat, 2016). In the United States, the Marketplace@Novation purchasing alliance, including over 2 500 health care organisations, is another example of centralisation leading to increased procurement effectiveness through structural improvements and economies of scale. A study of 31 hospitals showed that each hospital saved USD 12 million annually by joining the alliance, particularly thanks to lower prices for pharmaceutical items, as well as by lowering transaction costs through commonly negotiated contracts (Derek et al., 2008).

Other countries such as Denmark, New Zealand and Norway can be considered veterans of collaborative procurement. Since 1993, PHARMAC, the New Zealand government agency, has been the sole purchaser of publicly funded pharmaceuticals. According to estimates, based on pharmaceutical prices in 2005 mapped onto actual prescribing activity, joint procurement allowed for cumulative savings of about NZD 5.1 billion between 2005 and 2015, including about NZD 1.9 billion in 2014-15 (PHARMAC, 2015). For more than two decades, Denmark and Norway have both operated single procurement agencies for hospital pharmaceuticals (including pharmaceuticals for home therapies) and report significant annual savings, ranging from 30% to over 60% compared to list prices or average wholesale prices in a group of neighbouring countries.

As illustrated by Figure 4.2, collaborative procurement is an option to be exploited at the international level. It is becoming progressively harder to find satisfactory solutions at national level in a strong, global market. Countries need to work together to continue effective management of medicine costs. Greater co-ordination between countries can result in greater volume discounts and reduce repetition of tasks at national level. Barriers such as variation of reimbursement processes between countries and different willingness-to-pay thresholds make joint purchasing difficult and experience with common procurement of medicines is currently limited. Issues also arise in terms of different packaging, labelling and indications for use that would affect joint procurement. However, this should not preclude countries with similar characteristics from pro-active collaboration on strategic procurement, within the limits of what current regulations allow (especially for EU countries).

Improving system responsiveness through better communication and e-procurement tools reduces waste. While procurement is largely perceived as payer-driven, be it a government or a private insurer, physicians must be at the heart of decision making (IMS Institute for Healthcare Informatics, 2016). Successful collaboration is much more than just bundling of similar purchases. It requires a well-thought-out design that ensures all relevant actors (notably clinicians) at hospitals, nursing homes and pharmacies are equally involved and understand the collaborative process. In an ideal situation, collaboration should be organised well enough to attract members without forcing them to participate (Schotanus and Telgen, 2007).

In other words, a successful collaboration performs well not just on volumes of purchase but also in terms of system responsiveness. Some centralised procurement systems with mature operating practices deliver the benefits of economies of scale without compromising system responsiveness (e.g. Denmark and Norway). Notably, these mature collaborative procurement agencies are based on voluntary participation; i.e. they do not have any legal tools to influence member hospitals' decision making. Their success appears to be linked to the fact that clinicians remain at the heart of decision making. In consequence, these collaborations are leaders in strategic selection of preferred suppliers (within a class of therapeutic products), which not only induces price competition but also facilitates rapid and large-scale adoption of generics and biosimilars (Box 4.4).

The multitude of collaborative forms as well as the fact that majority of them are voluntary is the result of countries addressing differently the need for communication, transparency and participation. These collaborative procurement systems reflect a trend towards strategic, evidence-based procurement as well as professional development and specialisation of procurement personnel. Rather than being a slow bureaucratic machine,

Box 4.4. **Norwegian Drug Procurement Co-operation (LIS)**

LIS was established in 1995 by public hospital enterprises including 80 hospitals as of 2016. LIS administration consists of six fulltime-equivalent employees. In each of the 80 hospitals, one contact person is designated to liaise with LIS. The organisation includes an expert committee with medical, pharmaceutical and procurement professionals – its five members meet several times per year. The committee provides advice on the criteria used in selection of products. Moreover, LIS works closely with boards of experts in relevant medical specialties, including members of the Norwegian Medicines Agency and patients' representatives. LIS activities are financed through annual fees paid by each member hospital – EUR 1 million in 2015. Hospitals' participation in the co-operation is voluntary. Nevertheless, all public hospitals are members of LIS.

LIS administration manages tenders and negotiations as well as the resulting agreements with suppliers. In 2016 LIS is managing 7 400 agreements. The agreements have a form of framework contract through which individual hospitals can but do not have to purchase medicines. Hence, LIS does not commit to buying any predefined volume of products. In each therapeutic class LIS issues non-binding recommendations on preferred products/suppliers. All the same, hospitals follow LIS recommendations and only with rare exceptions do they buy outside the framework contracts.

The range of medicines purchased by LIS gradually expanded and now includes a number of high-cost oncology drugs, hepatitis C drugs, growth hormones and immunostimulants, which are usually in the domain of medicines paid for from a separate government/health insurance budget and not hospitals' budgets. In 2015, the total value of the purchased hospital medicines exceeded EUR 800 000 million, with an average volume-related discount of 30.4% compared to list prices in neighbouring countries or to the average wholesale price.

How does LIS manage to obtain such sizable volume-related discounts despite the voluntary character of the co-operation and the non-binding recommendations on preferred suppliers? The answer seems to lie in its highly specialised procurement team and its maintenance of very close operational links with clinicians. Notably, clinicians have detailed insights into both clinical- and cost-related factors that are taken into account in the selection of suppliers. For LIS, involving clinicians and trusting them to make the right decisions is a key component of ensuring the collaboration's longer-term success. Thanks to this truly co-operative process for supplier selection, LIS's recommendations are followed, effectively leading to high-volume purchases from preferred suppliers and triggering the discounts.

The involvement of clinicians and transparency of the procurement process are reinforced through regular seminars during which LIS and hospitals' representatives meet the industry in the presence of media. The seminars have an academic character with regard to presentation of information and discussion on efficacy and cost-effectiveness of medicines. Both clinicians as well as competitors can challenge the presenting manufacturers. Seminars' outcomes are widely publicised and the culture to follow them is very well-developed among medical professionals. LIS also organises less formal seminars for representatives of collaborating hospitals to exchange experience on products and past purchases.

they belong to a different category of innovative solutions with low personnel costs (e.g. 6 employees in Norway, 20 in Denmark, 26 in Greece), and evolve continuously to address the increasing complexity and dynamics of the medical goods market.

Moreover, a collaborative procurement system requires efficient communication between individual units and the group. The most obvious is communication of requests for supplies, which are initiated at the individual unit level and from there communicated to the level of the system dealing with suppliers. In a fully centralised system, this usually involves an intermediate entity at the regional level. Keeping in mind that before organising a call for a tender or engaging in negotiations with suppliers a central procurement agency or regional purchasing group will likely explore the possibility of standardising similar requests, communication also flows back to each individual provider/hospital for appropriate alternations. Indeed, the need to communicate requests creates an additional stage(s) in the procurement process. Hence, it is crucial that these additional stages are not hurdles.

Tools facilitating collaboration and communication are e-procurement platforms and standards such as Common Vocabulary Codes (CVC), which assign a unique code to each product, ensuring that members of the collaboration use the same language when formulating their orders. E-procurement must be user-friendly; optimally it should have a "one-stop-shop" character, allowing for easy, fast completion of necessary steps and collection and revision of all necessary documents in one place. It should also increase transparency on spending to allow for identification of improvements and additional opportunities to save (Karjalainen et al., 2008).

Advanced contracts and tenders minimise prices while ensuring long-term economic sustainability. Collaboration in procurement allows going beyond the initial advantage connected with economies of scale alone to building expertise to address the increasing complexity and dynamics of the medical goods market. By pooling financial, administrative and human resources, collaborating buyers can afford to design and negotiate innovative contracts and tenders.

Procurement contracts, when tailored to fit a given market situation, increase value for money

To maximise both short- and long-term savings, procurement strategies need to move away from "one-size-fits-all" contracts to more sophisticated procurement tailored to fit a given market situation. For example, the Danish hospital procurement agency AMGROS adopted a product lifecycle-dependent procurement strategy. The agency performs a separate detailed analysis of the market situation for each product. The analysis defines six main categories of products depending on their market situation: single-source medicines; other monopolies; analogue competition between two or more patent-protected medicines; generics competition; market segments with decreasing number of suppliers; and market segments with supply shortages. For each product category, different primary procurement instruments apply, optimising the outcome of the process (AMGROS, 2016).

It is particularly important to recognise and distinguish between opportunities to induce different situations of product competition: competition between two or more equivalent patent-protected products; competition between originator and generic products; and competition between generic products and patent-protected products in the same or related therapeutic class. And as mentioned earlier, to stimulate competition in any of these situations, clinicians must be on board. In other words, if disagreements exist among physicians or between the procurement agency and physicians on whether the products are truly equivalent, the choice of preferred supplier will not be supported. The Norwegian Drug Co-operation (LIS) provides a good example of ensuring clinicians'

participation (Box 4.4). Similarly, in Denmark, AMGROS co-operates with the Danish Council for the Use of Expansive Hospital Medicines (RADS) that issues statements on whether given products are fully or partially substitutable (for example, whether biologics can be substituted by biosimilars and whether this can be done for all patients or only for those who start a given therapy).

Contracts should not only focus on the unit price but also reflect patient outcomes and total costs of care. A growing number of countries –particularly the United Kingdom and the United States – have experimented with innovative outcome-based procurement contracts for medicines in which the price of a therapy depends on patient outcomes. However as mentioned in Chapter 2, data on patient outcomes are not readily available and countries are still learning how to collect and use these data in a systematic manner. Consequently, many of these initiatives are deemed ineffective. Another reason behind the scepticism is the challenges encountered in enforcing suppliers' compliance with the terms of the contracts, particularly when it comes to clawing funds back in the absence of desired outcomes – as experienced by NHS England (OECD, 2016).

While it is indeed true that administration of outcome-based contracts requires additional resources, it is too early to discard them as too costly or too difficult to enforce, considering the current state of evidence (Kesselheim et al., 2016). Moreover, implementation of these contracts appears to have suffered from the same communication problems at the interface between procurement teams and clinicians, as discussed in the previous section. It is possible that physicians do not have enough insight into factors behind the choice of these contracts, and hence do not universally support collection and reporting of the required outcome data.

The use of outcome-based contracts could start with simple medical supplies such as gloves, wound care products or intravenous (IV) catheters. For instance, if a nurse can spend much less time dressing a wound because of an easy-to-use wound care product, the equivalent savings should be factored in the procurement decision. A recent report on procurement of medical devices highlights an example of low-cost IV catheters that broke easily, required considerable amount of time for proper handling by clinical staff, and posed a safety risk to staff (BCG and MedTech, 2015). Yet the extra personnel costs associated with the purchase of these products were not accounted for since they did not affect the procurement department's budget.

Tender design helps attract and retain reliable suppliers

The three cornerstones of efficient tendering are: binding bids; a mechanism for setting the tender price that incentivises manufacturers to reveal their real costs of production; and appropriate selection of the number of suppliers. The latter is particularly important for preserving the right balance between short- and long-term savings (OECD, 2013b).

Reliable suppliers are a cornerstone of effective procurement. While supplier reliability should not be strictly determined by the tendering techniques used in a given market, some practices are not desirable, such as non-binding bidding. In particular, in connection to tenders being awarded to a single lowest bidder, leaving the winner the option to withdraw exposes the system to additional risk of fluctuation in product availability. Bidding should be binding, meaning that the supplier that wins a tender must fulfil the contract according to the conditions set through the tendering procedure. A supplier may still not fulfil the contract. In this event, a procedure should be in place to effectively prevent unreliable suppliers from participating in tenders in a given market.

It is also not trivial to design an auction with an outcome that balances the interests of both buyers and suppliers. Each tender relies on a chosen auction mechanism in which participating suppliers reveal their prices and the final contract price is settled. As discussed in Section 3.2, the simplest lowest bid auctions might create shortages of supplies or induce suppliers to exit the market. An auction with good design properties is one that encourages suppliers to reveal their true costs but at the same time allows them to earn competitive revenue (Box 4.5).

Box 4.5. **Cornerstones of good tender designs: Alternative mechanisms for setting price**

An auction with good design properties is one that encourages suppliers to reveal their true costs but at the same time allows them to earn competitive revenue. The Vickrey-Clarke-Groves (VCG) auction mechanism offers high potential to achieve such an outcome. In a VCG auction the contract price is determined by *the first excluded bid*, as opposed to an auction in which the price is determined by *the value of the lowest bid* or *the mean value of the three lowest bids*. In other words, a VCG auction sets the price at the value of the fourth lowest bid, which is the first excluded bid. However, only the suppliers who submitted the three lowest bids are offered the contract. This creates an incentive for suppliers to make offers that reveal their true costs of production, so as to be included in the group of contract winners. At the same time, suppliers receive a guarantee that the contract price will actually be set above their costs and that they will be able to make reasonable profits.

The choice of the number of winners can have long-term implications for a given market segment. Awarding the entire volume of a contract to a single winner for a longer time period might lead to significant short-term savings that dissipate over time. This is due to market exit of other suppliers and the associated reduction in price competition in following years (Bergman et al., 2016). For example, Denmark, similar to other small countries such as Hungary, experienced product shortages and monopolies even in the generics market due to market exit of suppliers. A strategy based on tenders with two winners (split awards) kept multiple suppliers in the market to bid in the next round of tenders and provided insurance against failure to supply by one of the winners.

Any procurement system that splits tender awards routinely risks so-called "bid rigging" – a practice in which two or more suppliers agree beforehand what bids will be offered, with the realisation that all will benefit from a share of the pie. Hence, bid splitting is mostly advocated in countries making one huge annual purchase. Otherwise, instead of splitting the awards, countries can award a contract to a single bidder but increase the frequency of tenders to monthly or quarterly intervals. This limits the potential for adverse effects, such as non-winning bidders leaving the market, and prevents bid rigging. Sweden successfully implemented use of monthly tenders, while Hungary resorted to quarterly tenders. Again, clinicians' involvement is the necessary factor behind the success of such a strategy. Short-term tenders lead to a high turnover of products within a therapeutic class, which might cause confusion and unnecessary frustration if administering/prescribing doctors do not anticipate them or do not have sufficient insight into the reasons for such changes.

Conclusion

Pharmaceuticals account for a significant share of overall health care expenditures across all OECD countries (Belloni et al., 2016). Yet as discussed in this chapter, a share of the spending on pharmaceutical does not add value for patients. These instances result from suboptimal decisions of clinicians and patients, organisational shortcomings and outdated regulations.

- An enormous value of unused medicines and other medical supplies are unnecessarily discarded due to redundant repeated prescriptions, patients' non-adherence to the prescribed course of treatment, and shortcomings in hospitals' management of stocks.
- The potential to free up financial resources through the use of generic drugs is often not fully exploited – the share of generics in pharmaceuticals covered by basic health benefits varies between 10% and 80% in OECD countries.
- Large unexploited potential similarly exists in the market for biosimilars – estimates for five European countries and the United States suggest that savings could reach EUR 50 billion by the end of 2020.
- Between- and within-country price variations are striking and at least partially unwarranted; for example, the price of a simple patient wristband differs by a factor of two between trusts in NHS England. And in 2015, differences in ex-factory prices for a number of cancer drugs were as much as 388% between the highest- and lowest-priced country among a sample of 18 OECD countries.

Within the complex pharmaceutical market, a number of opportunities to reduce spending on pharmaceuticals remain unexploited. This chapter highlights those opportunities. The actions policy makers can take derive from the standard toolbox of policy interventions: behaviour change, economic incentives, regulation and systematic collection and use of information.

Regarding unnecessarily discarded pharmaceuticals and other medical supplies, solutions include empowering patients and improving their communication with clinicians, the same behaviour change tools advocated to address clinical waste.

When it comes to the foregone opportunities to increase penetration of generics and biosimilars in the market, a wider range of actions should be taken, starting with improving regulation of market entry for generics producers, through amending price regulation, to convincing clinicians and patients of the therapeutic equivalence of generics and the original branded products. Almost a half of OECD countries use at least one policy tool to achieve these objectives and their experience is encouraging. Those countries lagging behind have no reason not to follow this path.

Procurement is perhaps the most complex domain of inefficient spending, but at the same time it most likely offers the highest potential for releasing resources for better use. Procurement organisations frequently fail to exploit all options left to them to build market power that matches that of international manufacturers. By consolidating purchases and transforming procurement from a merely administrative function into a strategic tool for price setting, health care systems could release additional resources and expand treatment options to larger groups of patients.

Experiments with value-based contracts illustrate that procurement can be used as a lever for change, promoting the departure from price- or volume-based to value-based health care financing. In other words, addressing operational waste in procurement could simultaneously contribute to curbing wasteful clinical care.

Notes

1. Given the focus of this report on waste, the question of how to price innovations in relation to their benefit is not explored. It is, however, a core topic of the second background report to the 2017 Health Ministerial, "Managing New Technologies in Health Care: Balancing Access, Value and Sustainability" (NOTE THIS IS PROVISIONAL TITLE WILL NEED CHECKING AT LAST MINUTE).
2. *www.ameli-sante.fr/apnee-du-sommeil/le-traitement-de-lapnee-du-sommeil.html*, accessed 06/10/2016.
3. The word "generics" refers here to generics of small molecule medicines as opposed to biosimilars of large molecule (biologic) medicines.
4. For certain indications, third-party insurers also pay for selected OTC medicines in some countries. Yet in such cases a prescription is required to justify the reimbursement and the OTC medicines effectively become prescription medicines.
5. Although the selection of drugs and coverage decisions have a budget impact and can be strategically managed to keep expenditure down, these activities are unlikely to be intrinsically wasteful.
6. *http://ccgtools.england.nhs.uk/procurement/ProcAtlasOctober2014/atlas.html* (accessed 17/05/2016).

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