

BREVE 6

HEALTH BENEFITS PLANS IN OECD COUNTRIES

Presentation by Valérie Paris. May 2014

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

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Inter-American Development Bank

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INTRODUCTION

This *Breve* is based on a webinar presented by Valérie Paris, health economist at the Organization for Economic Cooperation and Development (OECD), on May 15, 2014, to the members of the Knowledge Network on Health Benefits Packages and Priority Setting in Health.¹ The presentation focused on research carried out by the OECD and on data from the 2012 Health System Characteristics Survey (<http://www.oecd.org/els/health-systems/characteristics.htm>). Two studies were specifically referenced: (i) “Value in Pharmaceutical Pricing,” published in 2013, which explores the methods used by 14 OECD countries to make decisions on reimbursement and the pricing of pharmaceutical products on the basis of their value; and (ii) an ongoing study that seeks to identify how OECD countries define the health benefits packages covered by their systems. The current brief presents key results emerging from these two studies.

Part I characterizes benefits packages (BP's) in OECD countries and includes information on how countries approach the selection of services to be included (whether implicitly or explicitly, or based on positive or negative lists), the criteria taken into account when making coverage decisions, and the agencies involved in the decision-making process. **Part II** provides an overview of cost-sharing arrangements with service users, an important element related to the design of benefits packages. In **Part III**, countries' health accounts data is examined to determine if entitlements defined by law match actual health coverage, as shown by who pays for health care. Lastly, **Part IV** looks at how countries decide whether to include new drugs in their benefits packages and how the prices of these drugs are determined.

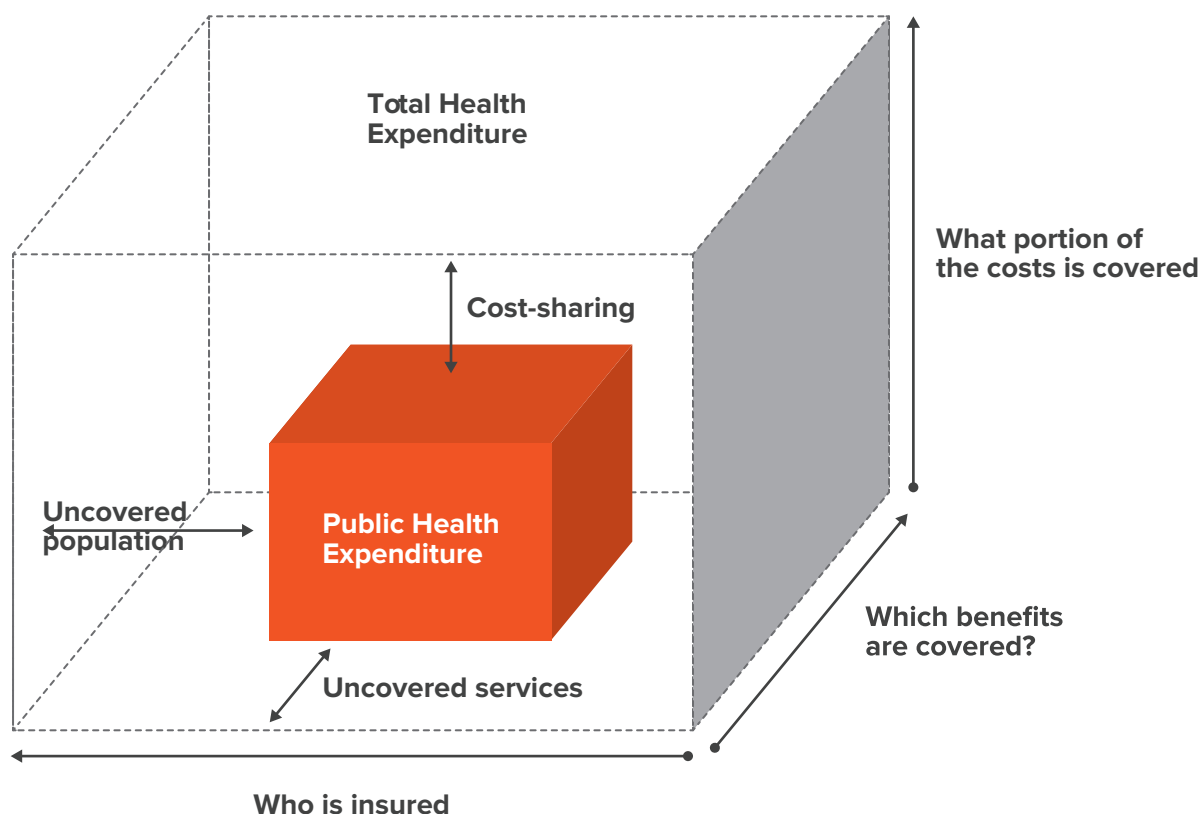
PART I. BPs IN THE OECD

While some OECD countries are in the process of implementing universal health coverage, others are facing challenges to the sustainability of their already-established systems. The definition and dynamic adjustment of an explicit health benefits package, or HBP (see definition in box 1), are fundamental elements of health policies for countries in both situations, allowing them to respond to limited resources while aiming to maintain the highest possible quality of care. Adopting an explicit benefits package constitutes one way countries define the scope of services they provide to their citizens, which is one of the key dimensions of health coverage, as depicted in figure 1. In addition, considering that spending on pharmaceutical products has been the fastest growing category in countries' health budgets for some time now, regulating the drug prices has become an option increasingly used by OECD countries to control health spending.

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¹ Registered members of the Knowledge Network on Health Benefits Packages and Priority Setting in Health can access the audio and PowerPoint files of the presentation here: <http://www.redconocimientopbs.org/webinars#>

Figure 1. The three dimensions of health coverage



Source: Adapted from Busse, Schreyogg and Gericke, 2007

Box 1. Definition of a health benefits package (HBP)

A health benefits package (HBP) (also referred to as a basket or plan) denotes all services, activities and goods covered by a publicly-funded statutory (mandatory) insurance scheme (social health insurance), or by a national health service. (This definition was proposed by Busse et al., 2005, in the European context.) Although the word “covered” suggests that the goods or services would be fully financed by the public entity, in effect some countries allow cost-sharing with the patient (see section II). “Publicly funded” refers to the agent who finances health care, with the word “public” referring either to the government paying for services through general taxes, or to social insurance or publicly-mandated private health insurance (as would be the case of mandatory health insurance contributions).

HOW DO OECD COUNTRIES DEFINE THE BENEFITS COVERED ?

An analysis of HBPs was carried out for the many different types of health systems that exist in OECD countries. These can be grouped into two basic types: a) tax-funded health systems (Australia, Canada, Denmark, Finland, Iceland, Ireland, Italy, New Zealand, Norway, Portugal, Spain, Sweden, and the United Kingdom) and b) health insurance systems. The latter can be further subdivided into (i) single payer (Greece, Hungary, Korea, Luxembourg, Poland, Slovenia, and Turkey); (ii) multiple insurers with automatic affiliation (Austria, Belgium, France, Japan, and Mexico); and (iii) multiple insurers with choice of insurer (Chile, Czech Republic, Germany, Israel, the Netherlands, Slovak Republic, Switzerland, and United States).

OECD countries have a number of ways of framing the benefits they cover. Those countries that describe their benefits packages explicitly use itemized lists of activities and goods, for example, lists of reimbursed medicines, catalogs of procedures and activities, fee schedules, etc. These itemized lists can be *positive*, stating which services and goods are covered, or *negative*, stating which services or goods are excluded. Many countries use either one or the other, but a few countries use both types. Countries with implicitly-defined benefits packages describe them in broad terms, through policy statements, as for example, “all medically necessary services” (Germany)²

To understand how and by whom the benefits packages were defined in each of the surveyed countries, the researchers asked the survey responders to choose from the following options:

- (a) For medical/surgical procedures:
  - A positive list established at the central level
  - A negative list established at the central level
  - Individual health insurance funds establish their own positive lists
  - Individual health insurance funds establish their own negative lists
  - Providers under budget constraints establish their own positive lists at the local level
  - The benefit basket is not defined, and every procedure performed by a clinician is considered by basic primary coverage schemes.
- (b) For pharmaceuticals:
  - A positive list established at the central level
  - A negative list established at the central level
  - Individual health insurance funds establish their own positive lists
  - Individual health insurance funds establish their own negative lists
  - Providers under budget constraints establish their own positive lists at the local level
  - The benefit basket is not defined; prescription drugs that are approved for marketing are systematically covered by basic primary coverage schemes.

Results of the survey revealed a different pattern with regard to defining the benefits package in countries with tax-funded health systems, as compared to countries with health insurance systems.

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² Note, however, that Germany has a detailed fee schedule for health services provided in the context of its mandatory health insurance system. This fee schedule serves much like a benefits package, as shown later.

Figure 2: Sources of health care

MAIN SOURCE OF BASIC HEALTH CARE COVERAGE		COUNTRIES
Tax-funded health system		Australia, Canada, Denmark, Finland, Iceland, Ireland, Italy, New Zealand, Norway, Portugal, Spain, Sweden, United Kingdom
Health insurance system	Single player	Greece, Korea, Luxembourg, Poland, Slovenia, Turkey, Hungary
	Multiple insurers, with automatic affiliation	Austria, Belgium, France, Japan, Mexico
	Multiple insurers, with choice of insurer	Chile, Czech Republic, Germany, Israel, the Netherlands, Slovak Republic, Switzerland, United States

Source: OECD Health Systems Characteristics Survey , 2012

Most countries with *tax-funded health systems* (Denmark, Finland, Ireland³, New Zealand, Norway, Portugal and Sweden) tend **not** to define the benefits package for the entire population at the national level. Nevertheless, many nuances can be observed in how they attempt to delimit their HBP. For instance, Australia establishes a positive list for medical procedures used in outpatient care and drugs, which also serves as the providers’ fee schedule. Canada defines very broad categories of services that must be covered by the provinces, but since provinces are charged with financing and providing health care services, most of

them define positive lists of covered services. In Italy and Spain, a minimum package is defined at the national level using positive lists, but regional authorities are in charge of organizing and financing a big share of health services and, therefore, are allowed to define supplemental benefits and offer them to their citizens. In the UK, the providers are responsible for defining medical services.

Countries with tax-financed health systems most often define positive lists at the central level to indicate the coverage of medicines. Canada is an exception, since pharmaceuticals are not included in the benefit package guaranteed to all residents. Many people purchase voluntary (private) health insurance to cover this gap,

³ Ireland was, however, in the process of defining an explicit benefits package at the time of writing this brief.

while low-income population groups or individuals with serious diseases are covered by local/provincial public plans for medicines. In these cases, positive or negative lists are used to define what they reimburse. In England and Wales (UK), all medicines that enter the market are covered by default, except for some categories that are excluded either by law, or because they have not been

found to be cost effective by the National Institute for Clinical Excellence (NICE). This HTA appraisal entity issues recommendations to not use certain pharmaceuticals in the National Health System (NHS). Providers also define some positive lists, in the sense that Clinical Commissioning Groups⁴ in the UK often prepare drug formularies, which

Figure 3. Mechanisms to define benefits in countries with tax-funded systems

	Positive list, central level	Negative list, central level	Individual payers positive lists	Individual payers negative lists	Providers positive lists	Benefit basket not define		Positive list, central level	Negative list, central level	Individual payers positive lists	Individual payers negative lists	Providers positive lists	Benefit basket not define
	Medical procedures							Pharmaceuticals					
Australia	✓							✓		✓			
Canada			✓							✓	✓		
Denmark						✓		✓					
Finland					✓			✓					
Iceland								✓	✓			✓	✓
Ireland						✓		✓					
Italy	✓	✓						✓					
New Zealand					✓	✓		✓					
Norway						✓		✓					
Portugal						✓		✓					
Spain	✓	✓	✓					✓	✓				
Sweden						✓		✓					
UK (England)					✓				✓			✓	

Source: OECD Health Systems Characteristics Survey, 2012

⁴ Clinical Commissioning Groups (CCGs) are National Health Service (NHS) organizations set up by the Health and Social Care Act of 2012, to organize the delivery of NHS services in England. CCGs are composed of general practitioners and other clinicians in a given geographic area, and they commission the majority of health services, including emergency care, elective hospital care, maternity services, and community and mental health services. Commissioning involves continually assessing the community's health needs and designing, specifying and procuring services to meet those needs with the available resources. Source: <http://www.patient.co.uk/doctor/clinical-commissioning-groups-ccgs>

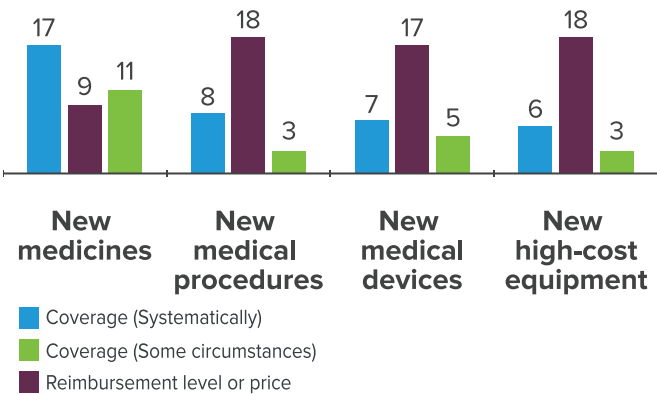
providers at the local level are expected to follow. These lists are generally used by providers, but are not binding, and prescribers can deviate from the formularies.

In countries with *health insurance systems*, a very different picture emerges in the definition of the benefits basket. Most of these countries use positive lists defined at the central level to indicate which medical procedures and pharmaceuticals are covered. For medical procedures, this can be partly explained by the fact that these systems often pay providers on a fee-for-service basis and so must define prices for each procedure in order to formulate a fee schedule for providers. Very often, the list of services covered and the fee schedule are the same, but not necessarily. For example, in Austria and Germany, services are covered as long as, and as soon as, they are provided by an authorized provider. Austrian law simply states that the services must be sufficient, appropriate and not exceed what is necessary, while German law states that services must be sufficient, effective, economical, and should not exclude what is necessary. This means that, even if the procedure is not yet included in the fee schedule, one can find a way to get it funded by health insurance. As a general rule, pharmaceutical benefits in countries with health insurance systems are defined by a positive list, which is an itemized list with the generic or brand names of drugs covered by the scheme. The one exception would be Germany, where all pharmaceuticals are reimbursed, except for categories excluded by law, such as over-the-counter medicines and drugs for minor illnesses.

DO COUNTRIES USE HTA TO MAKE COVERAGE DECISIONS ?

A question in the 2012 survey asked whether OECD countries use a health technology assessment (HTA)⁵ to make coverage decisions.

Figure 4. Number of countries that systematically or occasionally use HTA to make coverage decisions or set reimbursement prices



Source: OECD Health Systems Characteristics Survey, 2012

The above graph shows the number of countries systematically or occasionally using HTA to make coverage decisions or to set reimbursement prices by type of health technology (medicines, procedures, medical devices and high-cost equipment). The majority

⁵ Health technology assessment (HTA) refers to the systematic evaluation of properties, effects, and/or impacts of health technology. It is a multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a health intervention or health technology. The main purpose of conducting an assessment is to inform policy decision-making. WHO. Health technology assessment of medical devices WHO in Medical device technical series, 2011.

of OECD countries stated that they systematically use HTA to make decisions on new medicines, but the situation can vary widely from one country to another. For instance, when a country stated that HTA is systematically used for new medicines, this meant that each new product is assessed, with an HTA report for each new drug; however, the type of evaluation done varies. In France, for example, the drug assessment does not include an economic evaluation. By contrast, in England, the assessment of new drugs is not systematic (not all new drugs are being evaluated in a systematic way), contrary to what might be expected. Drugs are assessed only under some clearly defined

circumstances, but once they move into the appraisal process, an economic evaluation is included.

WHAT HTA METHODS DO COUNTRIES USE?

Given that HTA methods used by OECD countries vary substantially, the survey asked whether countries included economic evaluation in HTA, and which (or whose) perspectives⁶ were included in the evaluation.

Figure 5. What HTA methods do countries use?

Country	HTA includes economic evaluation	Public payer perspective included	Health system perspective included	Societal perspective included	Affordability or budget impact considered
Australia	●	●	●	●	●
Austria	●	●	●	○	
Belgium	●	●	○	●	●
Canada	●	●	●	○	●
Chile	○				○
Czech Republic					
Denmark	●	●	●	○	○
Estonia	●			●	
Finland	●	●	●	●	●
France	●	●	●	●	●
Germany					
Greece	●	○	●	○	●
Hungary	●	●	●	●	●
Iceland	●	●	●		
Ireland	●	●	●	●	●
Israel	●	●	●	○	●

⁶ Including a wider perspective in the HTA means, that the assessment will bring more balance between costs and benefits through the identification of all actors, interests, sources and mechanisms involved in the use of the technology.

Figure 5. What HTA methods do countries use?

Italy	●	●	●	●	●
Japan	○				○
Korea	●	●	●	●	●
Luxembourg					
Mexico	●	○	●	○	●
Netherlands	●	○	○	●	●
New Zealand	●	○	●	○	●
Norway	●	●	●	●	●
Poland	●	○	●	○	○
Portugal	●	○	○	●	
Slovak Republic					
Slovenia	●	●	○	○	●
Spain	●	○	●	○	○
Sweden	●	○	●	○	○
Switzerland	●	●	●	○	○
Turkey	●				
United Kingdom	●	○	●	○	○
United States					

A **black dot** in the above table means “yes” while a **white dot** means “no”; an **empty box** indicates that **no answer was given**.

Source: Paris, V., 2014

The majority of countries stated that they include an economic evaluation in HTA; however, this does not mean that their decision-making is based solely on the economic assessment. Economic assessment information is included, but the decision is usually based on additional criteria; the economic evaluation is never the only criterion taken into account. Finally, just about half of the OECD countries surveyed perform budget impact analysis as part of HTA.

Most of the time, when an economic evaluation has been conducted, countries adopt the public payer perspective (see box 2 for a description of the different

perspectives or methods adopted for an economic evaluation). The term “public payer” makes reference to government-funded social health insurance, which pays for health care, but it can also include the perspective of public payer in terms of social services. Some countries also adopt a health system perspective, which takes into account the costs and benefits for all payers in the health system, including patients, private insurers, etc.

A few countries, mostly Nordic countries and the Netherlands, approach the economic evaluation from a social perspective, which means that they consider costs and benefits beyond the health system,

Box 2. What is the impact of perspectives or methods adopted for economic evaluation?

The different perspectives and methods adopted by a given country for an economic evaluation can potentially influence the price paid for a medication. Several perspectives are possible:

- **Public payer:** considers direct costs (and savings) to public payers for health system and social services, where relevant (e.g., Australia, Canada's public plans, UK)
- **All health care payers:** just for health care services; includes patients, families, or private supplemental coverage (e.g., Belgium, France)
- **Societal perspective:** considers and monetizes all costs and benefits to society (cost-benefit analysis) (e.g., Nordic countries, the Netherlands)

Among the OECD countries surveyed, they most often consider only the public payer perspective and direct costs rather than the "wider" benefits beyond clinical improvement. The survey found no evidence that "innovation per se" was rewarded or that wider social benefits were valued; however, the sample of products surveyed was not representative of the market.

for example, the gains or losses in labor productivity thanks to a new treatment. Not all countries consider social impact as a full part of the HTA.

The survey also asked who is in charge of HTA for decision-making in OECD countries (figure 6). In effect, HTA is performed by a variety of stakeholders, but most of the countries stated that an independent body or agency is responsible for conducting HTA at the central level. It does not mean that other institutions are not allowed to conduct HTA, but decision-makers refer to this one entity for their information needs. Other countries stated that purchasers might also perform HTA, which could mean regions or provinces in decentralized countries, or individual health insurance funds.

Figure 6. Entities responsible for HTA in OECD countries

Country	Independent body at central level	Purchasers at central level	Purchasers at local level	Independent body on request	Not performed
Australia	●	●	●	○	○
Austria	○	○	○	●	○
Belgium	●	●	○	○	○
Canada	●	○	●	●	○
Chile	○	○	○	○	●
Czech Republic	○	○	○	○	●
Denmark	○	●	●	○	○
Estonia	○	○	○	●	○
Finland	●	○	○	○	○
France	●	○	○	○	○
Germany	○	○	○	○	○
Greece	○	○	○	●	○

Figure 6. Entities responsible for HTA in OECD countries

Hungary	○	●	○	○	○
Iceland	○	○	○	○	●
Ireland	●	●	○	○	○
Israel	○	●	○	○	○
Italy	○	●	●	○	○
Japan	●	○	○	○	○
Korea	○	●	○	○	○
Luxembourg	○	○	○	○	●
Mexico	○	●	●	○	○
Netherlands	●	○	○	○	○
New Zealand	●	●	○	●	○
Norway	●	○	○	○	○
Poland	●	○	○	○	○
Portugal	●	○	○	○	○
Slovak Republic	○	○	○	○	○
Slovenia	●	○	○	○	○
Spain	○	●	●	○	○
Sweden	○	●	○	○	○
Switzerland	○	○	○	○	○
Turkey	●	○	○	○	○
United Kingdom	●	○	○	○	○
United States	○	○	○	○	●

Source: Paris, V., 2014

In summary, a trend emerged among OECD countries with regard to the definition of health benefits packages and the use of economic evaluation in the decision process, depending on the method of financing the health system. Countries with general taxation-funded health systems tend to use very broad definitions of what services and procedures (with the exception of drugs and pharmaceutical products) are included in the benefits package, while countries with health insurance systems mostly rely on explicit positive lists.

Interestingly, both types of systems use positive lists to define pharmaceutical coverage. When asked about the inclusion of HTA in the decision-making process, a decidedly greater number of countries rely on HTA when making decisions regarding pharmaceuticals than when deciding on whether to fund a new procedure or device. HTA tends to be conducted by a designated independent agency in most countries; however, fewer than half of the countries conduct affordability analyses when deciding whether or not to include a service or drug in the benefits package.

PART II. COST-SHARING REQUIREMENTS FOR COVERED SERVICES IN OECD COUNTRIES

Cost-sharing requirements and the range of covered services are typically presented as separate and independent dimensions of health care coverage (see figure 1); however, it can be argued that cost-sharing requirements are also a dimension of a benefits package's design.⁷ For example, there is quite a difference between a service that is fully covered under the public scheme versus one that is only 30% covered, or a service that has a €10 copayment but is otherwise free. In order to understand how OECD countries share the cost for publicly-funded services with users, information was collected from section 4 of the Health Systems Characteristics Survey on services for a "typical adult"(see box 3)

Box 3. Comprehensiveness of basic health care coverage

Section 4 aims to assess the level of basic health care coverage to which **"typical" working-age adults** are entitled. Responses should not consider children, seniors or other categories of the population that may be entitled to higher levels of benefits (e.g., people with serious illnesses). In countries where multiple insurers are allowed to offer different levels of benefits, responses should refer to the most frequent or typical situation.

Question 13 of the survey asks: "Is there a general deductible that must be met before basic health coverage pays a share of the cost or the full cost of covered services? If so, what is the amount of the deductible that must be met before basic primary health coverage pays/reimburses? What is the period in which the deductible applies (e.g., year, lifetime, episode of illness, etc.)?"

Question 14 asks: "Are patients required to share the costs of health care for the services and goods listed below?"

- Outpatient primary care physician contacts
  - o Free at the point of care;
  - o Copayment per visit;
  - o Copayment for the first of each semester;
  - o Co-insurance;
  - o Not reimbursed if not referred.
- Pharmaceuticals
  - o Copayment per prescription item;
  - o Cost-sharing
  - o Deductible
  - o Any difference between actual price and reference price for medicines subject to reference price

TYPES OF COST-SHARING ARRANGEMENTS

Definitions were provided in the survey to ensure that all key informants understood the terminology of cost-sharing requirements:

⁷ This view has also been adopted in the Institute of Medicine's recent report on essential health benefits. Defining Essential Health Benefits — The View from the IOM Committee. Iglehart, John K. N Engl J Med 2011

- **Co-insurance:** cost-sharing requirement whereby the insured person pays a share of the cost of the medical service (e.g., 10%)
- **Copayment:** fixed sum paid by an insured individual for the consumption of itemized health care services (e.g., per hospital day, per prescription item); synonymous with **user fee**, **prescription fee**
- **Deductible:** lump sum threshold below which an insured person must pay out of pocket for health care before insurance coverage begins. It is defined for a specific period of time: one year, one quarter or one month. Deductibles can apply to a specific category of care (e.g., physicians' visits, pharmaceutical spending) or to all health expenditures (general deductible).
- **Extra-billing:** refers to any difference between the price charged and the price used as the basis for reimbursement. In the pharmaceutical sector, where "reference prices" are often used, a

Figure 7: User charges for outpatient medical services

Cost-sharing on outpatient medical care	Primary care	Specialized care
Free of charge for all	Canada, Denmark, Hungary, Italy, Poland, Spain, United Kingdom	Canada, Denmark, Hungary, New Zealand, Poland, Spain, United Kingdom
Free of charge for some	Australia (80% of GP services) Chile (public-public) Germany (SHI- 85% pop.) Greece (public provider) Ireland (40% of population) Israel (3 out of 4 HIFs) Mexico (public-public)	Australia Greece (public provider) Ireland (40% population) Mexico (public-public)
Deductible	Austria (specific) Netherlands (general)	Austria, Israel (specific) Netherlands (general)
Copayment	Czech Republic, Finland, Iceland, Norway, Portugal, Sweden	Czech Republic, Finland, Italy, Iceland, Norway, Portugal, Sweden
Co-insurance	Chile (provider choice), Japan, Korea, Luxembourg, New Zealand, Slovenia	Chile, Japan, Korea, Luxembourg, Slovenia
Copayment + co-insurance	Belgium, France	Belgium, France, Iceland
Deductible + co-insurance	Switzerland	Switzerland
Full price	Ireland (60% of population)	

Source: Paris, V., 2014

fixed reimbursement amount is determined for a cluster of products, while sellers remain free to set a higher price. The patient pays out of pocket any difference between the price charged for a medicine and the reference price.

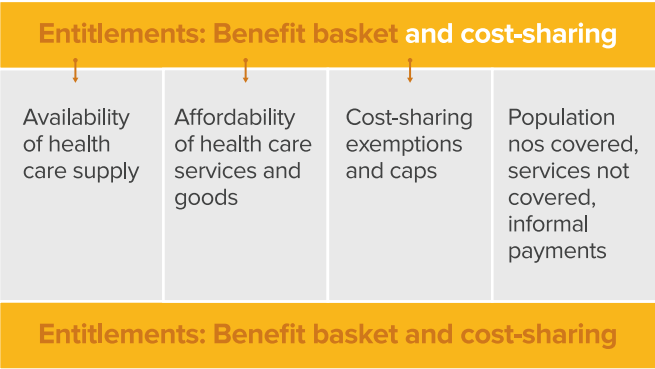
Figure 9 shows OECD countries’ approach to user charges for outpatient medical services, with most countries charging some part of their population for primary care services while using copayments or mixed schemes for specialized care. Inpatient care is more often free of charge or only subject to small daily copayments, except in a few countries with co-insurance rates (France, Japan, Korea, etc.). In a few countries, inpatient care is free for patients admitted as public patients in public hospitals but subject to copayments for patients admitted as private patients (e.g., Australia, Italy). User charges are the common rule for pharmaceuticals, and are usually higher than for medical services, with a few exceptions (e.g., the Netherlands). Typically, they take the form of co-insurance (with differentiated rates) or fixed prescription charges. Several countries also have deductibles. Eye and dental care are not covered in the majority of countries.

PART III. WHAT DO HEALTH ACCOUNTS TELL US ABOUT HEALTH COVERAGE AND THE BENEFIT BASKET?

In this part of the project, an effort was made to understand and map entitlements to the information revealed by health accounts data on actual health care coverage, in terms of who pays for health care.

Health accounts make it possible to get an idea of the actual level of coverage and relate it to the entitlements stated in legislation, as illustrated in figure 11.

Figure 8. From entitlements to actual coverage



Source: Paris, V., 2014

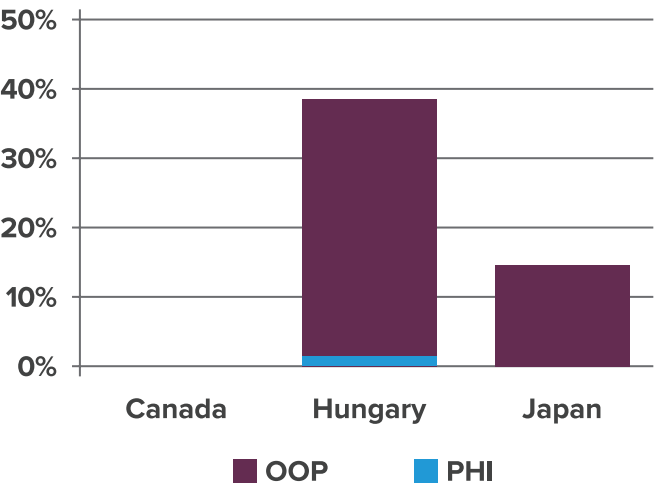
In practice, there are always services and populations that are not covered. For example, people may be entitled to free care provided by public providers;

however, in reality, these providers may not be available, or there may be long wait times for services. As a result, patients resort to paying for private services, as in the case of dental care in the UK.

For instance, Canada and Hungary indicated in their replies to the survey that patients access primary care services for free, and Japan indicated a 30% co-insurance rate for these services. Health accounts data (figure 12) showed that Canada’s services are consistent with entitlements, while in Hungary, patients pay nearly 40% of the cost of the services. In Japan, out-of-pocket spending accounts for about 16%.

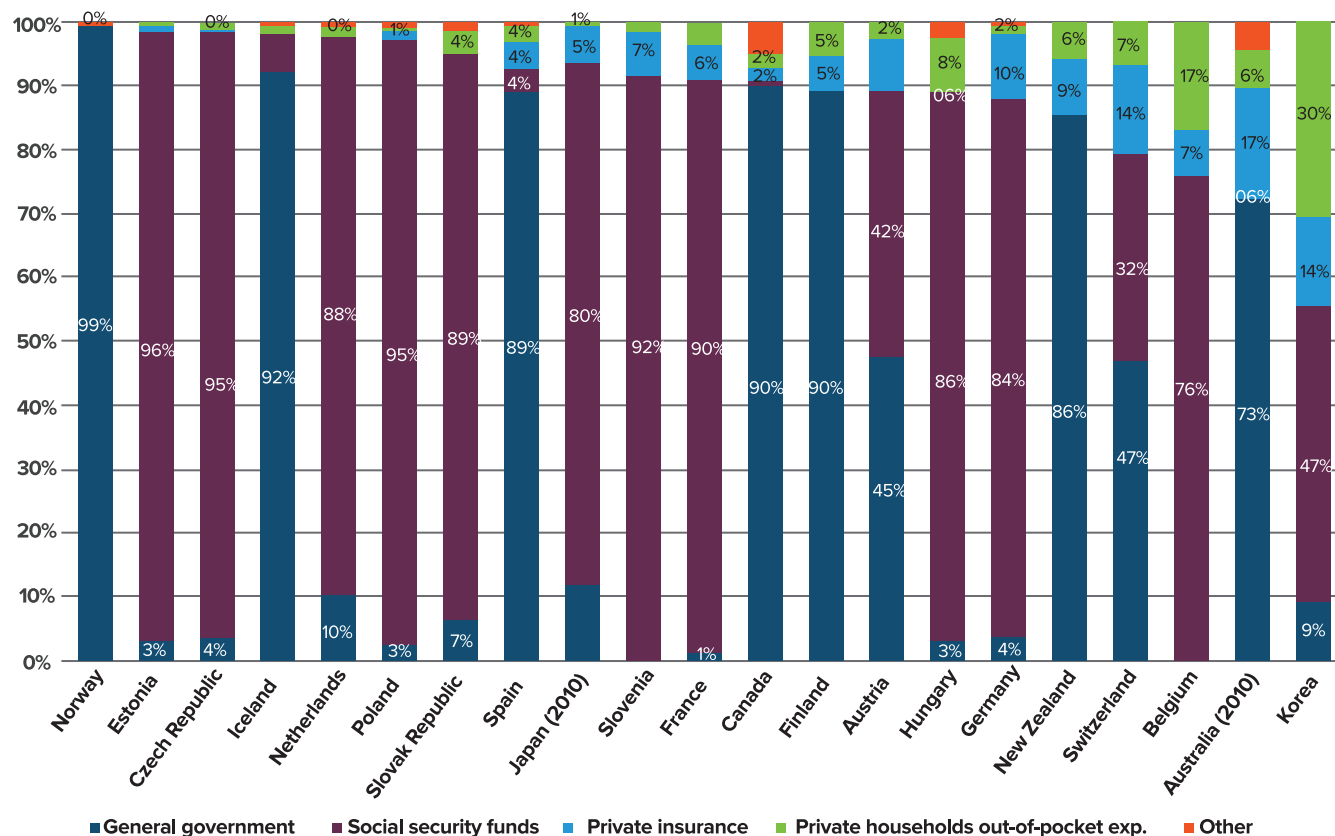
In comparison to inpatient care costs, pharmaceutical costs are much more heavily borne by the population, in part because self-consumption of OTC medicines is not covered, but also because pharmaceuticals are not well covered by the benefits baskets of the OECD.

Figure 9. Differences between health accounts data



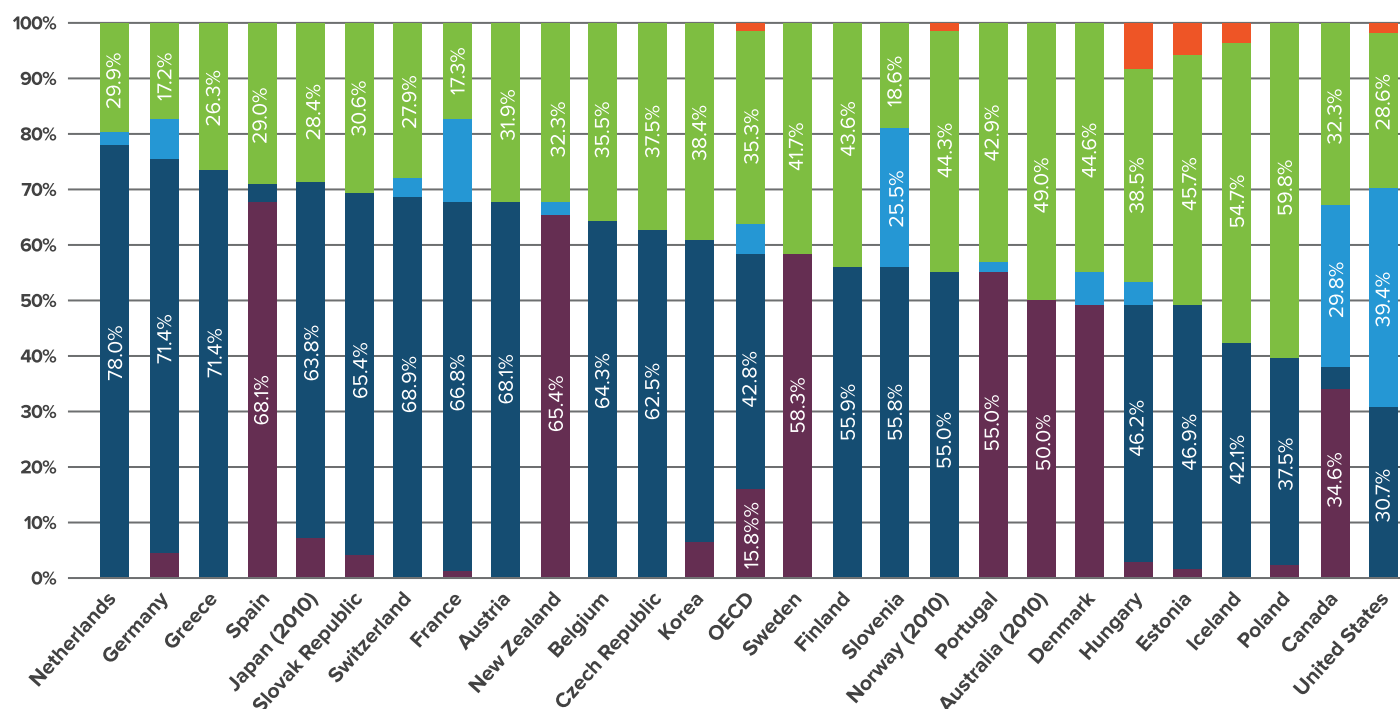
Source: Paris, V., 2014

Figure 10. Share of spending on inpatient care, by financing agent, 2011



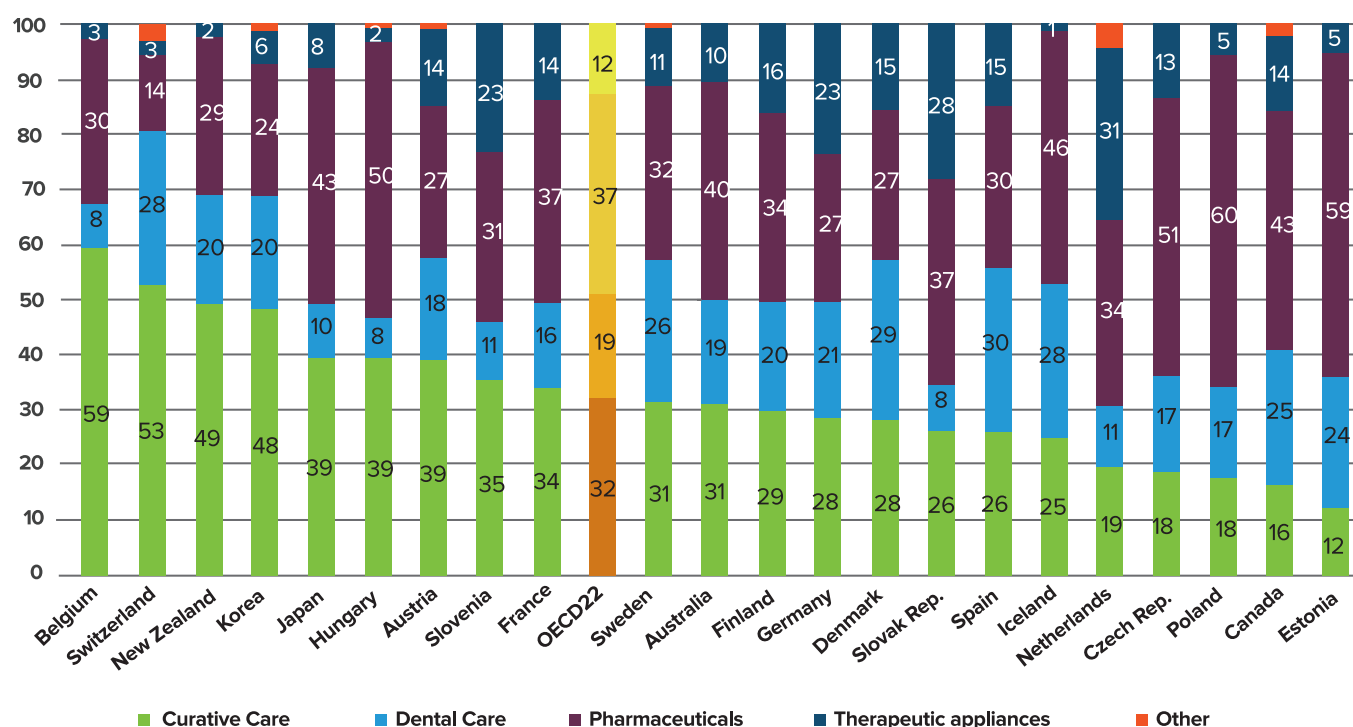
Source: OECD Health Statistics 2013

Figure 11. Share of pharmaceutical spending, by financing agent, 2011



Source: OECD Health Statistics 2013

Figure 12. Share of out-of-pocket medical spending, by services and goods, 2011 (or nearest year)



Note: This indicator relates to current health spending excluding long-term care (health) expenditure.

● Including rehabilitative and ancillary services

● Including eye products, hearing aids, wheelchairs, etc.

Source: OECD Health Statistics, 2013

PART IV. DRUG COVERAGE AND PRICING DECISIONS

The OECD performed a study in 2013, which looked at how countries make decisions on the coverage and pricing of pharmaceuticals. This information is of great interest to OECD member countries, since all face the dilemma of containing pharmaceutical spending growth while providing incentives. As a result, there has been a growing interest in implementing value-based pricing strategies (see box 4 for a definition).

Box 4. “Value-based pricing (...) proposes to link payments for pharmaceuticals or health care services to evidence-based assessments of value for patients, their carers, and the society as a whole. (...) Many OECD countries already use some sort of “value-based pricing” in the sense that they regulate reimbursement or price of pharmaceuticals—at least under some circumstances—on the basis of their therapeutic value.” (Source: Paris and Belloni, 2013)

The OECD study aimed to answer the following questions:

- How do OECD member countries refer to “value” when making decisions on reimbursement and prices of new medicines?
- How is this value assessed?
- Are countries willing to pay a price premium for innovation?

- Which kind of innovation receives an extra premium?
- Do specific rules apply for some medicines (orphan drugs, end-of-life drugs, etc.)?

Because policy documents and guidelines sometimes differ from what happens in practice, the study authors decided to look at assessment reports for 12 sample products marketed between 2004 and 2011 (figure 16). The drugs were selected in order to illustrate the impact of a variety of factors and situations (severity, efficacy, cost-effectiveness, social impact, size of target population, etc.) and are therefore not representative of the whole market. The sample included cancer drugs with multiple indications of very different therapeutic value. It also included drugs for hepatitis C, macular degeneration, multiple sclerosis, and diabetes, as well as one orphan drug. Some of them were very costly.

Figure 13: Twelve sample pharmaceutical products examined in the OECD study

Bevacizumab: cancer, several indications (breast, colorectal, lung, kidney) with different therapeutic value

Cetuximab: cancer, two indications (colorectal, head and neck)

Sunitinib: cancer, several indications (GIST, renal cell, pancreas)

Cabazitaxel: prostate cancer

Dabigatram: anticoagulant and prevention of stroke

Fingolimod: multiple sclerosis

Eculizumab: orphan drug

Boceprevir and Telaprevir: hepatitis C

Ranibizumab: age-related macular degeneration

Sitagliptin, Sitagliptin-metformin: type 2 diabetes

Source: Paris, V., 2014

The study analyzed reimbursement and pricing processes in 14 countries, grouping them into two categories:

- a) Countries using formal pharmaco-economic assessment (cost-effectiveness analysis, cost-utility analysis, cost-benefit analysis) to make and inform decisions on reimbursement and/or pricing
  - Australia, Belgium, Canada (public plans), Denmark, Korea, the Netherlands, Norway, Sweden, UK (England and Scotland)
- b) Countries using formal assessment of the added therapeutic value of new products over comparators, to determine or negotiate price premiums with pharmaceutical companies
  - France, Germany (a new situation, because, in the past, pharmaceutical companies set prices in Germany), Italy, Japan, Spain

HOW DO COUNTRIES ASSESS “VALUE?”

The study examined how value is assessed by looking at guidelines produced by bodies in charge of HTA.

The concept of value is primarily based on therapeutic advantages procured by new products or indications over existing products. If a new product or indication has no added therapeutic benefits for patients, payers usually agree to pay for it only if it reduces the cost of treatment (or at the very least, does not increase it).

Many of these guidelines are very detailed and specify what companies are expected to submit in terms of data.

Countries use the following variables to determine the value of new medicines:

(i) Clinical outcomes: Countries prefer final endpoints (i.e., survival), but they accept intermediate and surrogate outcomes (e.g., reduced cholesterol) if information on survival is not yet available. This may, however, constitute a source of a fundamental type of error, when surrogate or intermediate outcomes do not translate into improvement in survival.

(ii) Utility weights: These are used to estimate quality-adjusted life years (QALYs) gained, which capture both gains from reduced morbidity and reduced mortality. Countries' guidelines for economic evaluation often indicate the use of cost-effectiveness utility analysis and the use of utility weights to compute and estimate the number of QALYs gained. They often have a preference for multi-attribute utility (MAU) "generic" instruments used in randomized clinical trials. Several countries use the Euro QoL 5D instrument (EQ-5D). EQ-5D consists of five items relating to mobility, self-care, main activity, pain/discomfort, and anxiety/depression.

Interestingly, countries do not always agree on the level of "innovativeness" of new products. For example, for the same drug, one country found added therapeutic value over what was available, while another found the opposite—no added value.

Assessment bodies use whatever data is available at the time of assessment (this is quite uniform across countries). In practice, assessment reports often rely on data provided by pharmaceutical companies, which use both generic MAU instruments developed by international societies as well as very disease-specific instruments, which are more sensitive to specific outcomes for the treatments received. This method is biased, since it allows

the companies to play with utility weights (as reported in Australia and the UK). If the drug in question is very close to the cost-effectiveness threshold, the use of different utility weights can **change the decision to fund** the drug.

HOW DO OECD COUNTRIES SET COST-EFFECTIVENESS THRESHOLDS TO MAKE REIMBURSEMENT DECISIONS?

The issue of cost-effectiveness thresholds is only relevant in countries using economic evaluation. The use of economic evaluation makes more sense if there is some indication of a level beyond which a technology will not be considered cost-effective; however, most countries have been reluctant to set and publish an explicit incremental cost-per-QALY threshold (or range) beyond which they will not pay for any drug. Exceptions are England, where a range of £20,000–30,000 per QALY has been published by NICE, and the Netherlands, where a threshold of €80,000 per QALY was tentatively announced.

Nonetheless, past decisions in published papers tend to reveal "implicit thresholds." The threshold (or threshold range) varies considerably across therapeutic areas, in that, countries following more or less explicit rules (e.g., Australia, UK) pay more for life-threatening diseases and end-of-life and orphan drugs, and they reimburse

well beyond explicit or implicit thresholds. Oncology products tend to be accepted at higher incremental cost-effectiveness ratios (ICERs) than treatments for other diseases (e.g., Australia, Canada, Sweden, Scotland, and England).

Several countries consider budgetary impact assessment to be an integral part of the evaluation and decision-making processes. Significant budgetary impact can lead to delayed entry of a drug onto the market or referral to a higher level of decision-making, but this is not always the case. Recommendations not to fund a medicine were more common in countries using economic evaluation than in countries founding their recommendations on clinical benefit only; however, negative recommendations were often followed by re-submissions of the application with a restricted set of indications, a lower price, or new evidence, and were eventually accepted.

IS THE PRICE OF DRUGS IN OTHER COUNTRIES TAKEN INTO ACCOUNT WHEN PRICING A PHARMACEUTICAL PRODUCT?

International benchmarking, along with therapeutic referencing, is widely used, especially in European countries, to regulate prices of pharmaceuticals. In 11 of the studied countries, international benchmarking (“external reference price”) is used as the main

criterion or as supportive information for price-setting. Australia, Sweden, and the UK do not use it, while Belgium, Germany, Italy, and Japan use it as supportive information only.

HOW DO COUNTRIES USE PRODUCT-SPECIFIC AGREEMENTS TO BETTER ALIGN THE VALUE AND PRICE OF DRUGS?

Product-specific agreements (risk-sharing agreements, price-volume agreements, non-confidential agreements, etc.) are agreements between the drug manufacturer and the payer regarding a specific product, aiming to ensure that the payer does not overpay for the product, while facilitating market access and ensuring the highest possible returns for the manufacturer. On the one hand, countries want to be sure that they do not overpay for a given product, but they realize that just setting or negotiating a price and/or reimbursement conditions does not guarantee this if a given drug is eventually found to underperform. Pharmaceutical companies, on the other hand, are interested in product-specific agreements that are likely to allow or speed market access while maintaining their “list price.”

Figure 14: The use of international price benchmarking in OECD countries

Case countries	Australia	Belgium	Canada	Denmark	France	Germany	Italy	Japan	Korea	Netherlands	Norway	Spain	Sweden	United Kingdom
Basket of countries														
Austria		•		•		•					•			
Belgium		-		•		•				•	•			
Cyprus		•												
Czech Republic		•				•								
Denmark		•		-		•					•			
Estonia		•												
Finland		•		•		•					•			
France		•	•		-	•		•		•				
Greece														
Germany		•	•	•	•			•		•	•			
Hungary		•												
Ireland		•		•		•					•			
Italy		•	•		•	•	-							
Latvia		•												
Lithuania		•												
Luxembourg		•												
Malta		•												
Netherlands		•		•		•				-	•			
New Zealand				•										
Norway														
Poland		•												
Portugal		•				•								
Slovak Republic		•				•								
Spain		•			•	•								
Sweden		•	•	•		•					•		-	
Switzerland			•											
United Kingdom		•	•	•	•	•		•		•	•			-
United States			•					•						

Source: Paris, V., 2014

Since the 1990s, payers and companies have been using product-specific agreements to address a number of issues. In the survey sample of countries and medications, more than 20 non-confidential agreements were signed and used to address the following issues:

- (i) *Uncertainty about clinical efficacy, effectiveness, or cost-effectiveness. Some product-specific agreements (such as coverage with evidence development (CED) schemes) do not include performance-based provision. They link the inclusion of a drug in the HBP to supplementary data collection, with the aim to*

reduce uncertainties about health outcomes obtained in clinical trials (efficacy) or in real life (effectiveness). These agreements aim to inform coverage and pricing decisions in case new data come to light but are not necessarily explicitly linked to the product's performance ;

- (ii) *Uncertainty about cost-effectiveness (ICER). Performance-based agreements link price to actual performance of a given drug (for individuals or groups of patients treated, for cancer medicines where the ICER varies according to the indication for which it is used,*

i.e., value-based pricing). These agreements are used when there is a high level of uncertainty about the benefits claimed by the manufacturer. When benefits are potentially high, the payer agrees to fund the new drug but with the provision of a refund by the manufacturer if the benefits are not observed in real life. An elevated ICER often leads to price negotiation;

- (iii) *Uncertainty about budgetary impact.* Financial agreements aiming to control/limit budgetary impact typically link price reductions or rebates to volumes sold or to evidence of inappropriate use.

In the sample of drugs examined, product-specific agreements were signed because the initial price was not considered to be cost-effective by the assessment body, which then led to price negotiation. These types of agreements were used for cancer medicines with several indications with very different cost-effectiveness (e.g., a drug that is cost-effective for breast cancer, but not so for brain cancer); agreements can be used for just one indication, leading to price discrimination across indications. Interestingly, drugs/indications subject to agreements are not always similar across countries.

Most of the 14 countries surveyed use product-specific agreements, with the exception of Denmark, Norway, and Spain. Italy and the UK prefer using non-confidential agreements, whereas France and Belgium use confidential agreements almost exclusively.

WHAT IS THE PRICE PREMIUM FOR ADDED THERAPEUTIC VALUE?

All case study countries have systems in place to assess a pharmaceutical's added value, with the objective to allow a price premium for medicines with added therapeutic value. Countries/markets reward added therapeutic value in a variety of ways. For instance, drugs perceived as more therapeutically valuable are priced higher relative to a competitor drug, and they are excluded from reference price clusters (e.g., Germany) or priced higher than competitors (e.g., France). In some countries, the most innovative products are "entitled international price," while others are priced relative to competitors' price in the internal market (e.g., France, Canada [federal maximum price regulation], Germany, etc.)

Although there seems to be a link between the price premium granted and added therapeutic value, it is impossible to say what value countries give to a QALY. Variation exists not only between countries, but also within a given country, because the price of a QALY (or accepted ICER) varies across therapeutic areas. Generally, international benchmarking and volumes are important determinants of prices.

In summary, it is not clear whether value-based purchasing (VBP) makes a difference in the prices paid for medicines, because the practice of VBP appears to be more of an art than a science, and in the end, pricing processes involve other parameters.

SUMMARY

Important differences in how countries define their HBPs can be observed, depending on the way their health systems are financed. Countries with national health systems (government-funded and operated) tend to not define the contents of their HBPs explicitly, whereas countries with health insurance systems tend to rely on positive, negative or mixed lists established at the central level in order to define their HBPs. There is, however, one notable exception to the previous statement: drug coverage is most often defined at the central level via positive lists, irrespective of the type of health system.

The mechanisms used to decide whether a drug, device or procedure will be included in the HBP vary greatly among OECD countries, with most countries relying on a health technology assessment (HTA) to evaluate drugs to be included; however, far fewer countries use this methodology to evaluate procedures or devices. And while most countries conduct an economic assessment as part of the HTA process, fewer than half of them examine budgetary impact.

Cost-sharing arrangements for medical services, devices and drugs included in an HBP, as well as other ways of limiting access to care, have an impact on effective coverage. Cost-sharing for outpatient medical care through copayments, deductibles, or co-insurance is widespread among OECD countries. ;however, most countries reduce copayments and other cost-sharing mechanisms for certain populations, such as low-income groups, the chronically ill, children, etc. Health accounts data affords a clearer picture of the actual coverage, as compared to that stipulated in laws.

Countries use a number of factors to determine the price they are willing to pay for a drug, but the process is inconsistent from country to country and does not appear to be entirely

systematic. Most countries rely on international benchmarking and therapeutic referencing and include economic evaluation in the decision-making process, but they avoid setting explicit cost-per-QALY thresholds beyond which they will not pay for a drug. In cases where implicit or explicit thresholds exist, these vary depending on the therapeutic area or disease. The few countries that routinely assess budgetary impact more frequently tend to make a negative decision on funding a drug. The majority of countries use product-specific agreements with the manufacturers to mitigate risks due to uncertainties about efficacy, effectiveness, cost-effectiveness or budgetary impact.

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