VARIATIONS IN PRICES AND REIMBURSEMENT OF MEDICINES IN THE EUROPEAN UNION

Survey Methodology

A snapshot of data on amoxicillin, budesonide, losartan and salbutamol in eight European Union Member States

hai EUROPE

COUNTRIES

The sample of the eight selected European Union (EU) Member States must be comprised by old and new Member States (year of EU entry prior to, and in or after, 2004, respectively).

The gross domestic product (GDP) per capita, as well as the private pharmaceutical expenditure[1] as a share of GDP and global health expenditure, must be considered when shortlisting the countries. The sample is, therefore, intended to be a balanced mix of countries with different GDPs per capita and out-of-pocket expenditure, and to provide a fair representation of the various sub-regions of Europe and different economic contexts (including Member States receiving external financial assistance).

All selected countries must have a reliable local data collector.

Table 1: *GDP per capita and out-of-pocket pharmaceutical expenditure*

	West	North West	Central West	South West		North East		Central East
	France	Sweden	Germany	Greece	Portugal	Latvia	Estonia	Czech Republic
GDP/capita[§]	42.999,968	57.909,292	44.999,496	21.857,28	20.727,588	15.205,424	19.031,941	18.857,914
OOP/GDO[‡]	0.30%	0.51%	0.28%	N/A	0.71%*	0.96%***	0.62%*	0.59%*
OOP/HE[¥]	2,66%	5.68%	2.54%	N/A	7%	15.43%***	9.87%	7.41%

[§] GDP per capita 2013, current prices (U.S. dollars). International Monetary Fund, World Economic Outlook Database, April 2014 (updated data from April 2014 was included in the original methodology as an amendment). [‡] Expenditure of pharmaceuticals and other medical non-durables by private household out-of-pocket, as a percentage of GDP. Eurostat, 2010; [¥] Expenditure of pharmaceuticals and other medical non-durables by private household out-of-pocket, a share of total current health expenditure. Eurostat, 2010.

Provisional; ** 1998; * 1999*

SAMPLE FAMILY

Household: 2 adults + 12-year-old child

Household income: Minimum wage x 1

Health insurance: No private (voluntary) health insurance

[1] It was not possible to retrieve updated data on out-of-pocket pharmaceutical expenditure; therefore, data on out-of-pocket pharmaceutical expenditure plus other medical non-durable was taken into consideration as indicative data.

MEDICINES

The selected medicines must be first-line treatments for common diseases that are most likely to affect a wider range of the population and, therefore, represent a greater burden for both individuals and society. The three selected conditions are an acute disease and two chronic diseases: pneumonia, asthma and hypertension[2].

European and non-European guidelines[3] were consulted to identify the medicines recommended as first-line treatments. If discrepancies were found between the two types of guidelines, priority was given to the European guidelines because they are more likely to consider the European epidemiological profile and be in line with local guidelines.

Finally, the chosen medicines are expected to hold a marketing authorisation that is valid in all countries included in the study. The medicines must also be likely to be sold in community pharmacies.

Adult 1: Hypertension

Raised blood pressure is a major risk factor for cardiovascular diseases, which are responsible for 7.5 million deaths—12.8 per cent of all deaths—worldwide, and represent 57 million disability adjusted life years (DALYs)—3.7 per cent of total DALYs (**1, 2).** In the European region, high blood pressure is responsible for 42 per cent of all deaths annually **(3)**.

In 2008, the global prevalence of hypertension in adults aged 25 or more was 40 per cent, with men registering a statistically significant higher prevalence than women in the Americas and Europe **(1).**

Cardiovascular disease is the greatest cause of death and premature death in the European Region (**4, 5, 6)** and amongst the leading cause of death in the EU, alongside cancer and respiratory diseases (**7).** Globally, it represents the single-largest cause of death, accounting for nearly 30 per cent of all deaths and 50 per cent of deaths from non-communicable diseases **(8).**

Physicians can choose the most appropriate pharmacological treatment to their patients from a large list of medicines, representing several therapeutic classes.

Clinical guidelines on hypertension management from the United Kingdom's National Institute for Health and Care Excellence (NICE), dating from 2011, recommend the use of either angiotensin-converting enzyme (ACE) inhibitors or angiotensin-II receptor blocks (ARBs) for people aged under 55 **(9).**

More recently, in 2013, a task force for the management of arterial hypertension from the European Society of Hypertension (ESH) and the European Society of Cardiology (ESC) stated that anti-hypertensive treatment benefits arise from lowering blood pressure regardless of the class of drug used **(10)**. The task force therefore reconfirmed that diuretics, beta-blockers, ACE inhibitors, ARBs and calcium antagonists are all appropriate choices for the initiation and maintenance of hypertension treatment. **(10)**

[2] Hypertension is not a disease, but rather a major risk factor for coronary heart disease and ischemic and hemorrhagic stroke. Other complications associated to hypertension include heart failure, renal impairment, peripheral vascular disease, retinal hemorrhage and visual impairment.
[3] The guidelines can be consulted following references 9, 10, 16, 18, 19, 22, 23, 27 and 28.

Both ACE inhibitors and ARBs are amongst the most widely used anti-hypertensive medicines **(10),** but ARBs are associated with higher levels of persistence[4] compared with ACE inhibitors **(11).** This may lead to increasing prescription rates.

Taking into account the recommendations by the consulted clinical guidelines (9, 10) and the data on patient persistence with anti-hypertensive treatment, it was agreed to include the ARB, losartan, in the study.

Losartan

Strength:	50 mg
Dosage form:	Tablets/capsules
Pack size:	56 tablets/capsules
Frequency dosing:	1 tablet/capsule per day
Originator brand name:	Cozaar® MSD

Adult 2: Community-acquired pneumonia

Pneumonia is an acute respiratory infection that affects the lungs. Community-acquired pneumonia (CAP) refers to pneumonia acquired outside of hospitals or extended-care facilities.

Although it can be caused by several microorganisms, bacteria—particularly, *Streptococcus pneumoniae* and *Haemophilus influenza* type b (Hbi)—is the leading cause of pneumonia.

CAP, along with bronchitis, is the most common lower respiratory infection (LRI). Globally, LRIs are the second-leading cause of global death, and third-leading cause of premature death. In 2010, they accounted for the second-highest loss of DALYs—115, 227, 000—worldwide**. (12)**

In the United States, for instance, despite the existing therapeutic treatments, pneumonia (and influenza) was the ninth-leading cause of death in 2010. **(13)** In 2005, there were over 60, 000 deaths from pneumonia in persons 15 years of age and older. The economic burden associated with the disease was over $17 billion per year. **(14)**

In Europe, pneumonia is also a common condition, affecting many people **(15).** In the 2012 European Health Report, diseases of the respiratory system are the fourth cause of death in females, and fifth in males behind external causes of injury and poisoning. The main causes of death amongst this group of diseases were pneumonia, influenza, chronic obstructive pulmonary disease (COPD) and asthma. **(5)** Pneumonia and COPD are also the main causes of premature death from respiratory diseases in Europe. **(5)**

Given that bacteria is the leading cause of pneumonia, it must be treated with antibiotics. To establish the most appropriate therapeutic regimen, a number of guidelines produced in the United States and Europe were consulted. The two regions differ substantially in the classes of antibiotics recommended as first choice to treat non-severe CAP. The American Thoracic Society, the Infectious Diseases Society of America and the Canadian Thoracic Society recommend the use of advanced-generation macrolides and respiratory quinolones. **(16, 17)** Meanwhile, the European Respiratory Society and the British Thoracic Society defend the use of β-lactams as first-line therapy. **(17, 18, 19)** The reasons for these differences are related to distinct

[4] Persistence is defined as the time interval between initiation of the therapy to its discontinuation and correlates with the risk for a first hypertension related event.

resistance patterns, but may also be related to a more defensive European approach towards medicines with more limited experience. **(17, 18)**

Due to the fact that this study includes European countries, priority was given to the recommendations provided by the European guidelines **(18, 19)**. Hence, taking into account the medicines recommended in the consulted guidelines, the selected therapeutic regimen is:

Amoxicillin

Strength:	500 mg
Dosage form:	Tablets/capsules
Pack size:	16 tablets/capsules
Frequency dosing:	500mg tid, 5 days
Originator brand name:	Amoxil®, GlaxoSmithKline

Child: Asthma

According to the World Health Organization (WHO), 235 million people worldwide suffer from asthma, a chronic respiratory disease (CRD) with major public health implications. **(20)** While affecting millions of adults, asthma is the most common chronic disease amongst children in both high- and low-income countries. **(20, 21)** Its prevalence is increasing in most countries, especially amongst children, narrowing the gaps once observed across the world. **(21, 22)**

In the past 30 years, the burden of asthma has been growing. **(21)** From 1990 to 2010, the number of DALYs lost from asthma increased by 4.6 per cent. Currently, 22,459,000 DALYs are lost worldwide due to the condition, ranking asthma the 14th leading cause of disability globally. **(12)**

Although asthma is not responsible for as many deaths as other CRDs, such as COPD, it can also be fatal causing an estimated 250,000 deaths annually (1 in 250 deaths worldwide). **(20, 21)**

Available medicines are effective in achieving and maintaining clinical control and, therefore, in reducing acute exacerbations, visits to the emergency room, hospitalisations, school and work absenteeism, and improving overall quality of life. Nonetheless, two major barriers impair access to it, especially in low- and middle-income countries. One is poor availability; another is the price, given that many medicines are simply unaffordable for patients who have to purchase them out-of-pocket. **(21)**

In Europe, socioeconomic aspects also seem to play an important role in the effective control of the disease. In the UK for example, confidential enquires into more than 200 asthma deaths concluded that behaviour and adverse psychosocial factors, such as income and employment problems, were recorded in the majority of patients and played a role in their deaths. **(23)** These results seems to be in line with those reported in case-control studies where patients admitted to hospital with asthma who died, compared with control patients who were also admitted to hospital with asthma, were significantly more likely to have financial, employment, or other problems. **(23)**

Although often perceived as high, the cost of treating asthma is largely surpassed by the cost of not treating it. Poorly controlled asthma poses a disproportionate burden on health care systems that may already be facing financial challenges. **(21)** In Europe, for instance, the total annual cost of asthma care is approximately €17.7 billion, of which

more than half represents lost work days: €9.8 billion due to productivity losses, €3.8 billion due to outpatient care and €0.5 billion due to inpatient care. **(24, 25)**

Moreover, the treatment of persistent asthma is considered to be a cost-effective intervention to tackle the immense burden of non-communicable diseases. **(2)**

In the EU, chronic respiratory diseases, including asthma and chronic obstructive pulmonary disorder, are amongst the leading causes of death, alongside cardiovascular diseases and cancer. **(7)**

The prevalence of asthma varies across EU countries, with Western Europe recording higher rates than Eastern Europe. In fact, asthma prevalence in some Western European countries, such as the United Kingdom, is amongst the highest in the world. **(26)**

The aim of asthma drug treatment is to control symptoms, optimise lung function and prevent exacerbations using the lowest effective dose.

Medicines used to control asthma can be classified as controllers or relievers. Controllers are intended to keep asthma under clinical control chiefly through their anti-inflammatory effects; therefore, they must be taken daily on a long-term basis. Relievers, on the other hand, quickly relieve bronchoconstriction associated with, for example, asthma exacerbations, or to prevent exercise-induced asthma. They should, therefore, be taken on an as-needed basis. Patients with persistent asthma must be prescribed both classes of medications**. (22, 23, 27, 28)**

Inhaled corticosteroids (controllers) and short-acting β_2 agonist (relievers) are considered the mainstay of asthma management. After taking into account the recommended medicines in the consulted guidelines, the selected therapeutic regimen is: **(22, 23, 27, 28)**

Budesonide

Strength:	200µg per dose
Dosage form:	Dry powder
Pack size:	200 doses
Frequency dosing:	200µg per day
Originator brand name:	Pulmicort Turbuhaler® AstraZeneca

Salbutamol (also known as Albuterol)

Strength:	100µg
Dosage form:	Pressurised suspension for inhalation in a pressurised meter-dose inhaler (pMDI)
Pack size:	200 doses
Frequency dosing:	As needed[5]
Originator brand name:	Ventolin ™ GlaxoSmithKline (GSK)

[5] To calculate the affordability of the medicine, and taking into account the difficulty in establishing a universally accepted frequency dosing, the price of one canister will be used.

PHARMACIES

Limited human resources are available to perform data collection in the field. Convenience sampling will, therefore, be the most adequate method to adopt. Given that only one pharmacy per country will be visited, the data obtained cannot be considered as representative of the situation in a particular country. Instead, it will provide a snapshot of the retail selling price and affordability of a set of medicines in a particular pharmacy and on a particular day.

DATA COLLECTION PROTOCOL & SURVEY

The person responsible for the data collection should visit a local pharmacy with a hard copy of the data collection form (Annex I). The data must be recorded with a high degree of accuracy, bearing in mind the following aspects:

- The active ingredient, strength and dosage form of each medicine cannot be changed by any means. All formulations are for immediate release; therefore, retarded/prolonged/modified release formulations must be excluded. The same applies to dispersible tablets.

- In the data collection form, the identification of the medicine in the second column follows this order: 1st international common denomination of the active ingredient (e.g., budesonide), 2nd dosage form (e.g., pressurised solution in a metered-dose inhaler) and 3rd strength (e.g., 200µg).

- Originator brand name: the originator brand is the original product that was first authorised for marketing, usually as a patented medicine. The originator brand name may vary across countries. As a result, this information will be previously obtained from the marketing authorisation holder and must not be modified.

- Lowest-priced generic: for the purpose of this study, the lowest-priced generic is the product other than the originator brand with the same active ingredient, strength and dosage form, regardless of whether it is marketed under another brand or generic name. This product will be identified at the pharmacy at the time of data collection. Film coated tablets and capsules are considered interchangeable for immediate release; the same applies to solutions and suspensions.

- When choosing the lowest-priced generic, attention must be paid to the pack size. The lowest-priced generic is the product with the lowest unit price for different pack sizes. Whenever possible, the selected pack size must be the same for the originator brand and for the lowest-priced generic.

- There is a recommended pack size for each medicine. Data must be collected on the recommended pack size or higher (the next largest pack) to avoid price differences derived from pack size differences (i.e., unit price may vary with pack size, with lowest prices being offered for larger packs).

- Some product presentations may not be reimbursed. Reimbursed presentations must always be preferred.

- The retail selling price refers to the price printed on the medicine package or displayed on the pharmacy's computer database before applying the different modalities of cost-sharing.

- The percentage co-payment refers to the price actually paid by the patient, in possession of a valid medical prescription, after applying the reimbursement rate (i.e., the retail price minus the reimbursement rate value). In addition to percentage co-payment, the patient might be asked to pay for a fixed-fee (fixed co-payment):
    - Fixed-fee per prescription – the fee is paid only once, regardless of the number of prescribed medicines.
    - Fixed-fee per prescribed medicine – the fee is paid per each medicine prescribed, regardless of the number of prescribed packs per medicine.
    - Fixed-fee per pack – the fee is paid per each pack on the prescription.

- Whereas a system of deductibles is applicable, the first scale of the system will be taken into account.[6]

- In case there is a multi-payer health insurance system, the healthcare services covered by the basic package will be taken into account.[7]

- Data collectors should mention, when collecting data for the asthma medicine, that it is intended for use by a 12 year-old person. (In some countries, the reimbursement rate is also age-specific.)

[6] The question on the deductibles was included in an amendment in the original methodology/instructions to data collectors.
[7] The question on single payer or multi-payer health insurance system was included as an amendment in the original methodology/instructions to data collectors.

DATA ANALYSIS

Measuring affordability

Affordability can be expressed as a percentage of income or as the number of working days needed to purchase the medicines. For the purpose of this study, affordability will be expressed as a **percentage of the family's monthly income** that must be allocated to pay for the standard treatment cost[8]. The income of the lowest-paid, unskilled worker must, therefore, be retrieved.

Table 2: *Minimum wages*

Country	Monthly gross minimum wage €[9]	Monthly gross minimum wage national currency	Exchange rates on 28 June 2013[10]
Czech Republic	308	8008 CZK	26.00120
Estonia	320	-	-
France	1430	-	-
Germany[11]	1131	-	-
Greece	586	-	-
Latvia	285	200LVL	0.70230
Portugal	485	-	-
Sweden[11]		SEK 21 062	-

[8] The standard treatment cost was computed using the unit patient price in national currency and according to the following treatment schemes: Budesonide – 1 dose/day/month; Amoxicillin – 1 tablet (capsule)/3xday/5 days; Losartan – 1tablet(capsule)/day/month. For salbutamol, due to the difficulty in establishing a common standard treatment, we considered the use of one canister per month to calculate the standard treatment cost, while recognising that this may not be the treatment generally in use. The unit patient price corresponds to the value paid by the patient, in possession of a valid medical prescription, after applying the different modalities of cost-sharing.

[9] Monthly gross minimum wages in Bulgaria, Czech Republic, Estonia, France, Greece, Latvia and Portugal were retrieved from Eurostat's minimum wage statistics dating from the second semester of 2013. For Greece and Portugal, due to changes in the salary payment over 14 months per year, the monthly minimum wage used to compute affordability corresponds to the salary paid over 12 months.

[10] The exchange rate indicated in Eurostat to convert the salaries in local currency to euros was used to reverse the conversion.

[11] Germany and Sweden do not have a statutory minimum wage. In Germany, there are only binding minimum wages for individual economic branches and occupations; therefore, the monthly minimum wage used is merely indicative. In Sweden, minimum wages are agreed through collective agreements; therefore, the monthly minimum wage used to compute affordability is merely indicative. For both Germany and Sweden, the salary of the lowest-paid manual worker was retrieved. Sources: The Swedish Trade Union Confederation at http://www.lo.se/english/startpagehttp, Statistisches Bundesamt at https://www.destatis.de/EN/Homepage.html. Information about monthly salaries in Sweden is dated from 2012; therefore, the selected lowest-paid salary was adjusted for inflation.

Price comparison

To allow price comparison across countries, prices will be converted from local currencies to American dollars. The exchange rate will be that of the average weekly exchange rate from the period of data collection 29/09/13 – 15/12/13.

Table 3: *Market exchange rates*

Country	Average market exchange rate[12]
Czech Republic	CZK -$ 0.0514
Estonia	€ - $ 1. 3585
France	€ - $ 1. 3585
Germany	€ - $ 1.3585
Greece	€ - $ 1.3585
Latvia	LVL - $ 1.9238
Portugal	€ - $ 1.3585
Sweden	SEK - $ 0.1538

Source: Oanda, currency converter. Available at http://www.oanda.com/currency/converter/

Theoretically, currencies should trade at the rate that would make the price of goods the same in each country. Purchasing power parity (PPP) is a good indicator of how expensive goods are in relative terms. In fact, where the price in terms of PPP is greater than the price at market exchange rate, the goods can be considered to be high priced in that country. Likewise, when the price in terms of PPP is less than the price at market exchange rate, the goods can be considered to be low in price.

For adjusted price comparison amongst countries, prices in national currency will be adjusted by using the following PPP conversion factor.

[12] The used market exchange rate corresponds to the weekly average from 30/09/13 to 12/12/13, corresponding to the period of data collection.

Table 3: Market exchange rates

Country	PPP conversion factor
Czech Republic	13.568
Estonia	0.619
France	0.905
Germany	0.847
Greece	0.685
Latvia	0.421
Portugal	0.677
Sweden	9.158

Source: World Economic Outlook Database April 2014, International Monetary Fund (updated data on PPP factor has been included in the original methodology as an amendment.

ANNEX I: DATA COLLECTION FORM

HAI Europe pilot study on access to medicines in Europe:

Identifying inequalities in affordability and pricing of medicines across EU Member States

Data Collection Form

Date: ___ / ___ / ___ **Country: _____** **City/town/village: _____**

Pharmacy name: _____ **Pharmacy phone number: _____**

Data provider (pharmacist/technician) name: _____

Data collector name: _____

Part I

A	B	C	D	E	F	G	H
Patient	**Medicine**[1]	**Medicine type**	**Brand/Generic name**	**Manufacturer**	**Pack size recommended**	**Pack size found**	**Retail price**
12-year-old child; asthma	Budesonide Dry Powder in a DPI[2] 200µg	**Originator brand**	Pulmicort Turbuhaler®	AstraZeneca	200 doses		
		Lowest-priced generic			200 doses		
Adult on minimum wage; acute infection	Amoxicillin tab/cap 500mg	**Originator brand**	Amoxil®	GSK	16 tab/cap		
		Lowest-priced generic			16 tab/cap		
12-year-old child; asthma	Salbutamol pressurized suspension in a MDI[3] 100µg/dose	**Originator brand**	Ventolin™	GSK	200 doses		
		Lowest-priced generic			200 doses		
Adult on minimum wage; hypertension	Losartan tab/cap 50mg	**Originator brand**	Cozaar® 50	MSD	56 tab/cap		
		Lowest-priced generic					

[1] All formulations must be of immediate release; retarded/prolonged/modified release formulations must **not** be considered, the same applies to dispersible tablets. [2] Dry powder inhaler. [3] Metered-dose inhaler.

Part II

				I	J	K	L	M
Patient	**Medicine**	**Medicine type**	**Brand/Generic name**	**%Co-payment**	**Fixed-fee per prescription**	**Fixed-fee per medicine**	**Fixed-fee per pack**	**Total**
12-year-old child; asthma	Budesonide Dry Powder in a DPI[1] 200µg	**Originator brand**	Pulmicort Turbuhaler®					
		Lowest-priced generic						
Adult on minimum wage; acute infection	Amoxicillin tab/cap 500mg	**Originator brand**	Amoxil®					
		Lowest-priced generic						
12-year-old child; asthma	Salbutamol pressurized suspension in a MDI[2] 100µg/dose	**Originator brand**	Ventolin™					
		Lowest-priced generic						
Adult on minimum wage; hypert.	Losartan tab/cap 50mg	**Originator brand**	Cozaar® 50					
		Lowest-priced generic						

Comments:

Instructions for completing the data collection form

General instructions

The data collector is expected to visit one pharmacy, whose choice will be based on his/her best convenience.

Once in the pharmacy, the data collector must provide a short explanation about the study rationale and its purpose, and assure that both the pharmacy ID and data provider ID will remain confidential.

The collecting data form is divided in two parts. The first one, which includes columns from A to H, characterises the patients, identifies the medicines, and is intended to collect data on the retail price, and pack size for both the originator brand and the lowest-priced generic. The second part, comprised by columns I to M, is intended to collect data on the actual value paid by the patient: percentage co-payment plus fixed co-payment.

For each medicine, it is recommended to complete part I and part II consecutively.

When it is not possible to collect the data, the field must be filled in with **n/a** (not available). Don't leave it blank or it will look like oblivion.

The 'Comments' section can be used to report on any subject deemed relevant.

The active ingredient, dose and dosage of the selected medicines cannot be changed by any means.

The fields filled with **'-'** must be ignored; it means that the originator brand is not available on the market.

Please make sure the collecting data form is legible, accurate and complete before leaving the pharmacy.

Completing the Collecting Data Form

Column A
Column A describes the patient who the medicine was prescribed for. The patient income, age and type of disease must be referred to the person providing the data, as it may influence the final price paid by the patient, e.g. different reimbursement rates for different income or age-groups.

Column B
Column B identifies the medicine. Its identification follows this order: 1st international common denomination of the active ingredient (e.g. budesonide), 2nd dosage form (e.g. pressurized solution) and 3rd strength (e.g. 200µg). The active ingredient, dosage form and strength cannot be changed by any means.

Attention must be paid to the fact that all formulations are for immediate release, therefore retarded/prolonged/modified release formulations must **not** be considered. The same applies to dispersible tablets.

Please note that tablets and capsules are interchangeable, i.e., data can be collected on either tablets or capsules, for a given medicine, depending on what dosage form is available. The same applies to solutions and suspensions.

Columns C and D
Data must be collected on both the originator brand and the lowest-priced generic available on the market.

The **originator brand** is the original product that was first authorized for marketing, usually as a patented medicine; because its name may vary across countries, this information has already been obtained from the Marketing Authorization Holder, and therefore mustn't be modified.

The **lowest-priced generic**, for the purpose of this study, corresponds to any product other than the originator brand, with the same active ingredient, strength and dosage form as indicated in column B, regardless of whether it is marketed under another brand name or generic name. This product will be identified at the pharmacy at the time of data collection. Please, remember that tablet↔capsule and solution↔suspension are interchangeable.

When picking the lowest-priced generic, attention must be paid to the pack size. Therefore, the lowest-priced generic is the product with the **lowest unit price** (price per tablet (tab), capsule (cap) or dose for different pack sizes. To find the unit price the retail price must be divided by the number of tablets, capsules or doses.

It can happen that the originator brand is no longer available on the market; in this case data must still be collected on the lowest-priced product available.

Columns F and G
For each medicine, there is a recommended pack size. Data must be collected on the recommended pack size or larger (if available), in order to avoid price differences derived from pack size differences, i.e., unit price may vary with pack size, with lowest prices being offered for larger packs.

Some product presentations may not be reimbursed. Reimbursed presentations must always be preferred.

Column H
The retail selling price refers to the price printed on the medicine package or displayed on the pharmacy's computer database, before applying the different modalities of cost-sharing.

Column I
The percentage co-payment refers to the price paid by the patient, in possession of a valid medical prescription, after applying the reimbursement rate. If the reimbursement rate is of 100%, the percentage co-payment must be recorded as 0 (zero); don't leave it blank or it will look like an oblivion.

Column J, K and L
Sometimes, in addition to the percentage co-payment, the patient might be asked to pay for a fixed-fee (fixed co-payment):

- **Fixed-fee per prescription** – the fee is paid only once, regardless of the number of prescribed medicines. In case the pharmacist asks whether this is starting or repeated prescription, please mention **starting prescription**.

- **Fixed-fee per prescribed medicine** – the fee is paid per each medicine prescribed, regardless of the number of prescribed packs per medicine.

- **Fixed-fee per pack** – the fee is paid per each pack on the prescription.

Column M
Refers to the final price actually paid by the patient after applying the different modalities of cost-sharing.

Other
If there is a system of deductibles, the first trench of the system will be taken into account when reporting about the patient price[13].

If there is a multi-payer health insurance system, the healthcare services covered by the basic package will be taken into account when reporting about the patient price.[14]

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Its content represents the views of the author only and is his/her sole responsibility; it cannot be considered to reflect the views of the European Commission and/or the Consumers, Health, Agriculture and Food Executive Agency, or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.

[13] The question on the deductibles was included as an amendment in the original methodology/instructions to data collectors.
[14] The question on single payer or multi-payer health insurance system was included as an amendment in the original methodology/instructions to data collectors.

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