# The pharmaceutical system of the Netherlands

A comparative analysis between the Dutch out-patient pharmaceutical system, in particular the pricing and reimbursement characteristics, and those of the other European Union Member States, with a special focus on tendering-like systems

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# Executive Summary

The European Union has 27 unique pharmaceutical systems. However, looking to the brief document of the Dutch system and the comparative analysis between the Netherlands and the other EU Member States, there can be stated that the Dutch pharmaceutical system is in a lot of ways the same organised as other European systems. Of course there are always remaining some differences. Just like the whole pharmaceutical system also tendering like systems in different countries are unique, because every country shapes them to their needs. The case studies on tendering like systems showed that the system in the Netherlands has similarities to the tendering like systems of Germany, Belgium and Denmark as well.

## Pricing policies

In the Netherlands, and in seven other European countries, there is no direct price control on manufacturer level. For this reason a pricing policy on this level is not the case, except free pricing of course.

External price referencing (EPR) is applied on the pharmacy purchasing price (PPP) of prescription-only medicines. In four other countries the EPR is done on the PPP as well (Slovenia, Ireland, Finland, Cyprus) and additionally in Austria. The Dutch basket consists of the four other European countries France, UK, Belgium and Germany. In comparison to the other countries the number of states in the basket is relatively low. The price calculation is based on the average, as is the case in many EU Member States.

Table I: Executive Summary - External price referencing in the EU countries, as of 2010 or latest available data

| | |
|---|---|
| **Existence** | |
| In place, as price criterion | AT, BE, BG, CY, CZ, EE, EL, ES, FR, HU, IE, LU, LV, **NL**, PL, PT, RO, SI, SK |
| In place, not as direct price criterion (e.g. only for additional info) | FI, IT, LT |
| Plans to implement | MT |
| Never introduced | DE, SE, UK |
| Abolished | DK |
| **Country basket[1,2]** | |
| > 20 countries | AT, CZ (for reimb.price), EL, FI, LV, SK |
| 10-20 countries | ES, HU, PL, RO |
| 5-10 countries | BG, CZ (for price setting), IE, LT |
| < 5 countries | CY, FR, LU, **NL**, PT, SI |

reimb.= reimbursement

Source: PPRI (2007-2009), ÖBIG and GÖG reports, additional information provided by country experts employed by GÖG

1 Country basket of Belgium is not available
2 Country baskets of Estonia and Italy are not specified

## Mark-ups and Value added tax

The Dutch system has no statutory mark-ups on wholesale level like four other EU countries. The pharmacy remuneration is arranged by fixed fees. This is rather rare; the most countries use linear or regressive mark-ups for remuneration.

Table II: Executive Summary - Price policies at distribution level in the EU countries, as of 2010 or latest available data

| Wholesale remuneration | | Pharmacy remuneration | |
|---|---|---|---|
| Linear | CY, EL, IE, IT, MT, PL, PT | Linear | CY, DK, EL, IE, IT, MT, PT |
| Regressive | AT, BE, BG, CZ, DE, EE, ES, FR, HU, LT, LV, RO, SI, SK | Regressive | AT, BE, BG, CZ, EE, ES, FI, FR, HU, LT, PL, RO, SE, SK |
| Fee-for-service | - | Fee-for-service | IE, **NL**, SE, SI, UK |
| Mix | LU [1] | Mix | DE [2] |
| No statutory mark-ups | DK, FI, **NL**, SE, UK | No statutory mark-ups | - |

Source: PPRI (2007-2009), ÖBIG and GÖG reports, additional information provided by country experts employed by GÖG

1 LU: There are linear and regressive mark-ups present. Differences depend on the origin of the medicine.
2 DE: Prescription-only-medicines have a flat fee of €8.10 plus a linear mark-up. Reimbursable over-the-counter-medicines have a regressive mark-up.

In the Netherlands there is, just as in the most European countries, a value added tax (VAT) rate specifically for medicines. This one is lower than the standard VAT rate. No split VAT rates on medicines are applied in the Dutch system.

Table III: Executive Summary - Value added tax (VAT) rates in the EU countries, as of 2010 or latest available data

| VAT rates on medicines | |
|---|---|
| Same rate as standard rate | BG, DE, DK |
| Lower rate than standard rate | AT, BE, CY, CZ, EE, EL, ES, FI, FR, HU, IE, IT, LT, LU, MT, LV, **NL**, PL, PT, RO, SE, SI, SK, UK |
| Split rates for medicines | FR, IE, LT, RO, SE, UK |

Source: National country sources, PPRI (2007-2009), additional information provided by country experts employed by GÖG

## Reimbursement

The Dutch system has a product-specific reimbursement scheme like 18 other European countries have. The reimbursement rate used in the Netherlands is 100% (or there is no reimbursement). This is only the case in six other Member States. In the Netherlands there is, as in nearly all European countries, a positive list present.

Table IV: Executive Summary - Reimbursement in the EU countries: Lists, rates and schemes, as of 2010 or latest available data

| | |
|---|---|
| **Reimbursement lists** | |
| Positive list(s) | AT, BE, BG, CY, CZ, DK, EE, FI, FR, HU, IE, IT, LT, LU, LV, MT, **NL**, PL, PT, RO, SE, SI (2 lists), SK |
| Negative list(s) | DE (2 lists), EL (only legal basis[1]), ES, HU, UK (2 lists) |
| **Reimbursement rates** | |
| Only 100% | AT, DE[2], IE, IT, MT, **NL**, UK |
| 100% and further rates | BE, BG, CY, CZ, DK, EE, EL, ES, FI, FR, HU, LT,LU, LV, PL, PT, RO, SE, SI, SK |
| **Main reimbursement scheme** | |
| Product | AT, BE, BG, CZ, DE, EL, ES, FI, FR, HU, IT, LU, **NL**, PL, PT, RO, SI, SK, UK |
| Disease | EE, LT, LV |
| Consumption | DK, SE |
| Population-group | CY, IE, MT |

product = product-specific scheme, eligibility based on product. disease = disease-specific scheme, eligibility based on disease of a patient. consumption = consumption specific scheme, eligibility based on the expenses for medicines of a patient. population-group= population-group-specific scheme, eligibility based on the population or group to which a patient belong.

Source: PPRI (2007-2009), ÖBIG and GÖG reports, additional information provided by country experts employed by GÖG

1 EL: There is a legal basis for a negative list, but this is not yet implemented. The reintroduction of positive list is still ongoing
2 DE: Basically there is 100% reimbursement, but through the mandatory co-payment of 10% of the medicines' price (minimum €5, maximum €10) the rate could become lower

## Reference price system

Like in the most EU Member States a reference price system is in place in the Netherlands. For grouping the medicines a mix of ATC levels is used. This is only done in two other countries. The calculation of the reference price is based on the average price of the group. This calculation differs from most EU countries, since they often use the lowest price for calculating the reference price.

Table V: Executive Summary - Reference price systems in the EU countries, as of 2010 or latest available data

| | |
|---|---|
| **Existence** | |
| In place | BE, BG, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IT, LT,LV, **NL**, PL, PT, RO, SI, SK |
| Abolished | SE |
| Never introduced | AT, CY, IE, LU, MT, UK |
| **Clustering of reference groups** | |
| At ATC 5 level | BE, DK, EE, EL, ES, FI, FR, IT, LT, PT, RO, SI |
| At ATC 5 and 4 level | BG, CZ, HU, SK |
| At a mix of ATC 5, 4 and 3 or/and at different criteria | DE, LV, **NL**, PL |
| **Calculation of reference price** | |
| Lowest price of products in the group | BG, CZ, DK, EE, FR, HU, IT, LT, LV, PL, RO, SI, SK |
| Below average of prices of products in the group | DE, ES, FI[1] |
| (Around) average | EL, **NL** |
| Above average | PT, BE[2] |

ATC= anatomic therapeutic chemical (classification system)

Source: PPRI (2007-2009), GÖG 2010, additional information provided by country experts employed by GÖG

1 FI: For price calculation the lowest price is taken plus a flat amount of €1.50 or € 2.
2 BE: Reference price is 30% below the price of the original product.

## Out-of-pocket payments and mechanisms for vulnerable groups

In the Netherlands patients do not have to co-pay for reimbursable medicines. This is the case in two other EU counties, Ireland and Malta. Exceptions are the co-payments due to the reference price system, which are in each country with a reference price system.

Table VI: Executive Summary – Co-payments in the EU countries, as of 2010 or latest available data

| Out-of-pocket payments | |
|---|---|
| Fixed co-payment | AT, DK, EE, FI, FR, HU, IT (in some regions), PL, SK, UK |
| Percentage co-payment | BE, BG, CY (public sector[1]), CZ, DE, DK, EE, EL, ES, FI, FR, HU, LT,LU, LV, PL, PT, RO, SE, SI, SK |
| Deductible | DK, SE |
| No co-payments | IE, MT, **NL** |

Source: PPRI (2007-2009), GÖG reports, additional information provided by country experts employed by GÖG

1 Full out of pocket spending in private sector

In every EU country there are mechanisms for vulnerable groups. Each country has its own criteria. The most common are income and age. The only criterion in the Dutch system is income. People with a low income get a financial compensation of the state. Furthermore that there are some financial arrangements in place for patients who spend more than a certain percentage of their income on medicines.

## Generic promotion

Regarding generic promotion the Dutch system is the same organised as those of the most European countries: prescribing by the international non-proprietary name (INN) and generic substitution are allowed, but not obligatory. The Netherlands has, compared to some other countries, a developed electronic prescribing system in which the brand name on a prescription is automatically changed into the generic name. This indirectly causes INN prescribing.

Table VII: Executive Summary – Generic promotion in the EU countries, as of 2010 or latest available data

| INN prescribing | | Substitution | |
|---|---|---|---|
| Obligatory | CY (public sector), EE, LT, PT, RO | Obligatory | CY (public sector), DE, DK, FI, MT, SE, SK |
| Indicative | BE, BG, CZ, DE, ES, FI, FR, HU, IE, IT, LU, LV, MT, **NL**, PL, SI, SK, UK | Indicative | CZ, EE, ES, FR, HU, IT, LT, LV, **NL**, PL, PT, RO, SI |
| Not allowed | AT, CY (private sector), DK, EL, SE | Not allowed | AT, BE, BG, CY (private sector), EL, IE, LU, UK |

Source: GÖG reports (mainly 2010d-e), PPRI (2007-2009), additional information provided by country experts employed by GÖG

## Tendering like systems

Case studies were performed to have a closer look at tendering like systems in the out-patient sector (cf. Table VIII). The included countries were the Netherlands, Germany, Belgium and Denmark.

The tendering like systems were introduced in each country to reduce costs. The tendering like systems differ between the four case countries. Especially the included number of active ingredients vary. The product price is the most important criterion used in all countries. Besides that the ability to supply is important. The majority of the tendering includes generic medicines.

Information about the effects of the introduction of tendering like systems is not for every country available, e.g. there could not be found information about the consequences of the Danish system. In Belgium, Germany and the Netherlands the systems have caused cost savings. Although it is argued or the cost savings in Belgium are real savings, because of the many switches to other, more expensive, active ingredients.

Table VIII: Overview case studies, data as of 2010 or latest available data

| Country | Year of introduction | System | Main goal | Main actors in tendering process | Scope | Criteria | Effects |
|---|---|---|---|---|---|---|---|
| **NL** | 2005 | Health care insurers apply generic preference policy allowing them to limit reimbursement to lower priced labels of off-patent active ingredients. | Stimulating price competition, lower pharmaceutical expenditure | Insurances and manufacturers | - generics<br>the number of active ingredients vary by insurer ( one insurer include >50 active ingredients) | - price<br>- ability to supply | - savings (not sure who makes the profit)<br>- manufacturers with low mark share becoming really big |
| **DE** | 2003 | Sickness funds negotiate individual rebate agreements with pharmaceutical industry. Substitution by pharmacies. | Lower prices of medicines, lower pharmaceutical expenditure | Insurances and manufacturers | - mostly generic (also biosimilars)<br>AOK [1]tender for > 90 active ingredients | - price<br>- product portfolio<br>- ability to supply | - no direct cost savings, but lower prices<br>- lot of insecurities at manufactures |
| **BE** | 2008 | Price competition for certain active substances according the "KIWI Model"[2] to lower co-payment for patients. | Lower the pharmaceutical expenditure | Social Health Insurances (SHI) and manufacturers | - two active ingredients (simvastatin, amlodipin[3]) | - price<br>- ability to supply | - millions of direct savings [4] |
| **DK** | 1991 | Prices can be lowered every two weeks. Winners take almost full reimbursement market | Cost savings, lower pharmaceutical expenditure | National Health Service (NHS) and manufacturers | - generics and their original product | - price | n.a. |

n.a. = not available

Source: Kanavos 2009 (not published), GÖG 2008b-d, PW 2008-2010, CPB 2008, Ministry of VWS 2006-2008, additional information provided by country experts employed by GÖG

1 Allgemeine Ortskrankenkassen (AOK), one of the largest sickness funds in Germany.

2 Kiwi model: Model for reimbursement of medicines, in which the government performs public tenders whereby the lowest priced medicine, wins the tender. The system is named after the experience of New Zealand in implementing this model.

3 Winner of tender had no capacity to procure; tender was abandoned.

4 It could be argued whether the increase in consumption of other medicines neutralized the savings.

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# List of abbreviations

| | |
|---|---|
| AOK | General Health Insurance (Germany) / *Allgemeine Ortskrankenkassen* |
| ATC | Anatomic Therapeutic Chemical (classification system) |
| CBG | Medicines Evaluation Board (the Netherlands) / *College ter beoordeling van geneesmiddelen* |
| CEE | Central and Eastern European (- countries) |
| CFH | Pharmaceutical Care Committee (the Netherlands) / *Commissie farmaceutische hulp* |
| CVZ | Health Care Insurance Board (the Netherlands) / *College voor zorgverzekeringen* |
| DDD | Defined Daily Dose |
| EPR | External Price Referencing |
| EU | European Union |
| GÖG | Austrian Health Institute / Gesundheit Österreich (GÖG) |
| GVS | Pharmaceutical Reimbursement System (the Netherlands)/ *Geneesmiddelen-vergoedingssysteem* |
| HSE | Healh Service Executive (Ireland) |
| INFARMED | Medicines Agency (Portugal) / Instituto Nacional da Farmácia e do Medicamento |
| INN | International non-proprietary name |
| KNMP | Royal Dutch Pharmaceutical Society / *Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie* |
| NHS | National Health Service |
| NRT | Nicotine Replacement Therapy |
| NZa | Dutch Healthcare Authority / *Nederlandse Zorg Autohoriteit* |
| OECD | Organisation for Economic Co-operation and Development |
| OPP | Out-of-pocket payment |
| OTC | Over-the-counter (products) |
| PE | Pharmaceutical expenditure |
| PHIS | Pharmaceutical Health Information System |

| | |
|---|---|
| POM | Prescription-only medicine(s) |
| PPP | Pharmacy Purchasing Price |
| PPRI | Pharmaceutical Pricing and Reimbursement Information |
| PRP | Pharmacy Retail Price |
| PW | *Pharmaceutisch Weekblad* (Dutch magazine for pharmacists) |
| RPS | Reference Price System |
| SFK | Foundation of Pharmaceutical Statistics (the Netherlands)/ *Stichting Farmaceutische Kengetallen* |
| SHI | Social Health Insurance |
| VAT | Value Added Tax |
| VWS | (Ministry of) Health, Welfare and Sport (the Netherlands) / *Volksgezondheid, welzijn en sport* |
| WGP | Price of Drugs Act (the Netherlands) /*Wet Geneesmiddelprijzen* |
| WHO | World Health Organisation |
| WTG | Health Care Tariffs Act (the Netherlands) / *Wet tarieven gezondheidszorg* |
| Zvw | Health Insurance Act (the Netherlands) / *Zorgverzekeringswet* |

# List of countries

| | |
|---|---|
| AT | Austria |
| BE | Belgium |
| BG | Bulgaria |
| CY | Cyprus |
| CZ | Czech Republic |
| DE | Germany |
| DK | Denmark |
| EE | Estonia |
| EL | Greece |
| ES | Spain |
| FI | Finland |
| FR | France |
| HU | Hungary |
| IE | Ireland |
| IT | Italy |
| LT | Lithuania |
| LU | Luxembourg |
| LV | Latvia |
| MT | Malta |
| NL | Netherlands |
| PL | Poland |
| PT | Portugal |
| SE | Sweden |
| SI | Slovenia |
| SK | Slovakia |
| UK | United Kingdom |

# List of used currencies

| | |
|---|---|
| GBP | British Pound |
| DKK | Danish Krone |
| EUR (€) | Euro |
| HUF | Hungarian Forint |
| PLN | Polish Zloty |
| SEK | Swedish Krona |

# 1 Introduction and objectives

Every country has its own of historical developments, traditions and cultures. For that reason each country has developed a unique pharmaceutical system with a matching reimbursement and pricing system. A comparative analysis between those systems could be very useful. It will contribute to increased transparency, provides information and it can be used by policy-makers on national and European levels.

PPRI (Pharmaceutical Pricing and Reimbursement Information) is a project originally commissioned by the European Commission[1]. This project aims at providing knowledge and promoting information-exchange on pharmaceutical pricing and reimbursement policies in de European Union (EU) Member States. Part of the project were the PPRI meetings where countries share information about their system. Nowadays the PPRI network consist of members of almost 60 institutions (mainly competent authorities and third party payers) from the whole European Union. Also countries outside the European Union became part of this network to share information about their system en learn from each other.

Each PPRI country produced its own so-called *PPRI Pharma Profile*, a document with information about pricing and reimbursement in a set template. Unfortunately, the Netherlands have to this day no complete PPRI Pharma Profile and knowledge is missing about the Dutch pharmaceutical system. As a consequence, a complete comparison between the pharmaceutical systems in the EU is not possible. For this reason, a report that contains information of the Dutch system and makes a comparison between the Netherlands and the other EU Member States could be really interesting and useful.

The aim of this report is to provide more knowledge about the Dutch pharmaceutical system, in particularly about the pricing and reimbursement characteristics. Besides that a comparative analysis will be accomplished between the Dutch pharmaceutical system and those of the other EU countries. Another objective of this report is to create a special focus on tendering like systems through case studies. It will be interesting to know more about these systems because it is a hot topic in the policy field nowadays. In this whole report, only the out-patient sector will be considered.

According the aim of the report, the following research question was defined:
*How is the out-patient pharmaceutical system, in particular the pricing and reimbursement system, in the Netherlands organized compared to the other EU countries, with a special focus on tendering-like systems?*

[1] Today it is an EU Member States driven initiative, with the PPRI secretariat located at the Austrian Health Institute (GÖG)

# 2 Methodology

This report consists of three main parts. It starts with a brief document about the Dutch pharmaceutical system. Then there will be a comparative analysis between the pharmaceutical system of the Netherlands and those of the other EU countries. In order to compare the information of the European pharmaceutical systems indicators were set in the beginning. At the end four case studies are focusing on tendering like systems in Europe. All these parts consider only the out-patient sector. A glossary is added to this report to make clear all the terms used.
The different parts will be explain more in detail on the next pages.

## 2.1 Indicators

The list of indicators is defined after a literature search. There was searched for relevant literature with a special focus on pricing and reimbursement indicators on PubMed with the terms: health care system(s), reimbursement, indicator(s) and pricing. Internal documents of the Gesundheit Österreich (GÖG) were consulted as well. To establish the reliability of the literature sources there was a closer look at the sources of evidence used.

There wasn't much evidence based literature about comparisons of pharmaceutical systems and indicators in peer-reviewed journals found on PubMed. The most value was given to the PPRI Pharma Report and Pharmaceutical Health Information System (PHIS) Project and the associated indicators. These indicators had a lot of evidence; those were used in previous research on indicators for example in WHO reports, OECD data and reports of GÖG. Besides that these indicators were set following a large-scale needs assessment among policy makers and interest groups in European countries. The final list of indicators can be found in the result section of this report.

## 2.2 Information the Netherlands

A brief document of the Dutch pharmaceutical was written to get a clear overview of the Dutch system. This document was written in line with the set indicators of pricing and reimbursement. There was already a draft PPRI document of the Netherlands from 2006. A lot of parameters were not filled out in this document and information was missing. The information about the Dutch system was for that reason mainly gathered from Dutch government documents and from the Dutch Health Care Insurance Board (CVZ). Besides these sources also relevant documents of GÖG were used and the Dutch trade journal of pharmacists (*Pharmaceutisch Weekblad, PW*) was consulted. There was also contact with the Dutch Ministry of Health via a GÖG country expert.

## 2.3 Information EU countries

For the comparative analysis, country specific information was needed of all EU Member States. These data was collected per individual indicator. The most important sources were the published PPRI Report and the PPRI Pharma Profiles of the countries. Most country profiles were from 2007 or 2008. There were some countries which has no (updated) PPRI Pharma Profile. For these countries published GÖG reports about their pharmaceutical system were used to gather the relevant information. Information from the PPRI network meetings was used as well for verifying the data and getting the most up-to-date facts.

The country specific characteristics were checked per country by experts of the health economics team employed by GÖG. These experts have close contact with the different countries and are informed of the latest changes in the pharmaceutical systems.

## 2.4 Case studies

The case studies were performed on four European countries: the Netherlands, Germany, Belgium and Denmark. The countries were chosen on advice of experts in health economics. In the case studies the following questions were addressed:

» When was the tendering like system introduced?
» What were the main goals?
» How is the system organized?
» Who are the main actors in the tendering process?
» What is the scope of the included medicines?
» What are the criteria for tendering?
» What are the effects of the policy?

Different sources were used. Most of them were GÖG documents about tendering systems and information of PPRI network meetings. Another source was from a report from the London School of Economics. They have written a document about tendering like systems in Belgium, the Netherlands and Germany. This report is not (yet) published, but the information is included in the case studies. Relevant government documents were consulted as well. There was also a small research on PubMed (used terms: (preference) pricing, tendering, medicines) but unfortunately this provided no useful literature.

## 2.5 Terms and definitions

There are a lot of terms concerning pricing and reimbursement. It is important to have clear definitions of them. For that reason a glossary can be found applicable to this report in the annex.
The glossary is developed by the author, in consistence with the terminology provided by the PHIS Glossary[2].

The term EU Member States and EU countries are used interchangeably in this report. These terms refers to the 27 countries that were members of the European Union as of 2010[3]: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Germany, Greece, Finland, France, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Spain, Sweden, Slovenia, Slovakia, the Netherlands and the United Kingdom.

## 2.6 Outline of this report

This report consists of three important parts:

» Brief document about the Dutch pharmaceutical system
» Comparative analysis between the Netherlands and the other EU countries

[2] PHIS Glossary, accessible on http://phis.goeg.at
[3] The official website of the European Union, http://europa.eu/

» Case studies focusing on tendering like systems of four countries (the Netherlands, Germany, Belgium and Denmark)

Chapter 1 gives a brief introduction and describes the objectives of the report.

Chapter 2 is a description of the methodology used for producing this report. Besides the methodology of the three important parts of the report mentioned above, it explains more about the used indicators and their setting. This chapter also gives a description about the terms and definitions used in the report.

Chapter 3 covers all the results. It contains a part about the set indicators, the brief document of the Dutch system, the comparative analysis between all the EU countries and the results of the performed case studies.

Chapter 4 provides the discussion and summarises the lesson learned during this research subject.

Chapter 5 is the concluding chapter. It defines the conclusions of the report.

Chapter 6 provides a list of all the used literature and web links.

The annex contains a glossary applicable to the report.

# 3 Results

## 3.1 Indicators

All the indicators which were classified under the category pricing or reimbursement in the PPRI report and the PHIS Pharma Profiles are included in the list of indicators. Besides them a few other ones were included which were related to the (pharmaceutical) system and generics because they could be interesting for the comparative analysis as well. Unfortunately it appeared that there was no up-to-date data available for the set quantitative indicators. For this reason, it was decided not include them in further analysis and in the final table of indicators.

The final indicators (cf. Table 3.1) were classified in three categories: pricing, reimbursement and generics. The set indicators will be explained more detailed in the result section of the comparative analysis.

Table 3.1:
Set indicators

| | |
|---|---|
| | **Pricing** |
| P1 | Price policies |
| P2 | External price referencing |
| | *External price referencing – general* |
| | *External price referencing – methodology* |
| P3 | Statutory mark-ups |
| | *Wholesale mark-up* |
| | *Pharmacy mark-up* |
| P4 | Value Added Tax (VAT) |
| | **Reimbursement** |
| R1 | Reimbursement list |
| R2 | Reimbursement scheme |
| R3 | Reimbursement rate |
| R4 | Reference price system |
| R5 | Out- of pocket payments |
| R6 | Mechanism for vulnerable groups |
| | **Generics** |
| G1 | Generic promotion |

Source: Compilation by the author, based on the PPRI and PHIS indicators

## 3.2 Brief document of the Dutch pharmaceutical system

### 3.2.1 Pricing

#### 3.2.1.1 Organisation and price control

The legal basis of setting medicine prices is the Price of Drugs Act (Wet Geneesmiddelprijzen, WGP). The law was established in 1996 as the prices of medicines in the Netherlands were far higher than the prices in the adjacent states. All prescription-only medicines (POM), including generics and parallel imported medicines, dispensed by pharmacies and dispensing doctors are subject to the WGP.

According to the WGP, the Ministry of Health, Welfare and Sport (VWS) has to fix the maximum wholesale price (pharmacy purchasing price, PPP) of all POM. Hence, there is no control at the ex-factory price on manufacturer level. In case a manufacturer sells medicines to a pharmacy directly, without intervention of a wholesaler, the manufacturer has to restrict the prices to the maximum wholesale price set by the Ministry of VWS. At pharmacy level prices are regulated via dispensing fees.

Within 90 days after having received the application of the manufacturer, the Ministry of VWS has to fix the maximum wholesale price. The Ministry is allowed to prolong this time period with 60 days in case of an extraordinary number of applications.

Maximum prices are revised every six months, taking into account changes in the prices of medicines in reference countries and fluctuations in the exchange rate of the Euro and the British pound (cf. section 3.2.1.2.1). The maximum prices are published twice a year in the official bulletin (*Staatscourant*). Manufacturers are allowed by law to appeal against the decision concerning the maximum price of a medicine.

For over-the-counter (OTC) products there is free pricing. Prices of OTC products at pharmacy retail level are officially free as well, but in practice they are always sold according to the price mentioned in the *taxe* (except from a few supermarket-related drugstores*)*. The taxe is a list that contains recommended pharmacy retail prices for all available pharmaceutical products on the Dutch market. The price list is monthly published by the Z-index and regularly updated by manufacturers and wholesalers. The prices must be equal to or below the maximum price according to the WGP (cf. section 3.2.1.2.1).

Table 3.2:
Price policies in the Netherlands, as of 2010

| | Free pricing | Statutory pricing |
|---|---|---|
| POM, mostly reimb. | Manufacturer level | Wholesale and pharmacy level |
| OTC, mostly not reimb. | - | All levels 1 |
| Legal basis | Prices of Drugs Act (*Wet Geneesmiddelprijzen*, WGP) | |

Source: Farmatec 2010 (www.farmatec.nl), ÖBIG 2006

1 Officially is there free pricing also on pharmacy level, but in practice prices are as mentioned in the taxe

## 3.2.1.2 Pricing procedures

The only procedure that is used by the Dutch Ministry of Health to establish the maximum wholesale price of all prescription-only-medicines (POM) is external price referencing, which legal basis is the WGP. The prices are calculated as the average wholesale price of similar medicines in the European countries Belgium, France, the United Kingdom (UK) and Germany. Similar means in this case: a medicine with the same active ingredient, the same strength and the same pharmaceutical form (including generics).

However when setting the reimbursement price, different procedures are applied. A tendering like procedure is taking place for different reimbursable medicines between manufactures and insurance companies; this is called the preference policy. Only low-priced products will be eligible for reimbursement. More details about this procedure could be found in section 3.2.2.7.

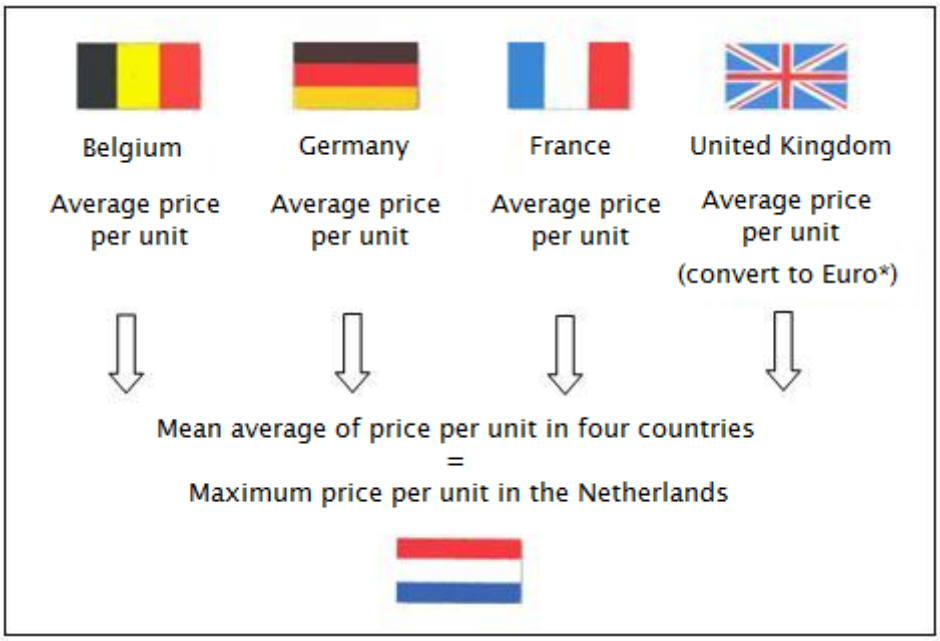
### 3.2.1.2.1 External price referencing

Farmatec, an executive body of the Ministry of VWS, is the responsible authority for determining the maximum prices of medicines in the Netherlands. As said before, the prices are calculated as the average wholesale price of similar medicines in Belgium, France, the UK and Germany (cf. Figure 3.1). The prices of the medicines abroad are acquired from the followed institutes[4]:

» Algemene Pharmaceutische Bond (Belgium)
» Informationsstelle für Arzneispezialitäten (Germany)
» Société d'Éditions Medico-pharmaceutiques (France)
» Dictionary of Medicines and Devices (UK)

Maximum prices can only be calculated if at least two of the four countries have a comparable medicine on the market. For each country the prices are divided by pack to get the price per unit and an average is calculated. The mean average of the four countries is the maximum price per unit of the comparable medicine in the Netherlands.

Figure 3.1:
External price referencing in the Netherlands, as of 2010




* The conversion to euro is based on the average exchange rate, valid on the date of which the price list is published

Source: Compilation by the author, based on GÖG surveys

### 3.2.1.3 Pharmacy remuneration

On the basis of the Health Care Tariffs Act (Wet Tarieven Gezondheidszorg, WTG), the government defines the tariffs of prescription-only-medicines (POM). The maximum rates/ fees which a pharmacy

[4] www.farmatec.nl

may charge to the patient or to the insurance of the patient are set. This amount that a pharmacist can declare consists of three parts: the wholesale price, a fixed fee and the value added tax.

The wholesale price is in fact the price of the dispensed medicine as listed in the *taxe* (cf. section 3.2.1.1). Pharmacists are receiving discounts from the industry with buying medicines. To forward this favor to the patients, the so-called clawback percentage was introduced. This percentage is deducted from the fee that health insurance will pay for the medicines costs. Just like the dispensing fee, the clawback percentage is set every year by the Dutch Healthcare Authority (NZa)[5]. For 2010 the clawback percentage was defined at 8.53% of the gross purchasing price with a maximum of € 6.80 per prescription. Insurance companies and pharmacists are allowed to agree a lower the clawback percentage.

Dispensing fees are remunerations for the service provided by the pharmacy, which are charged per dispensed prescribed medicine. Till July 2008 there was a fixed dispensing fee without regard to the kind of dispensing (e.g. a special preparation or a periodical delivery). Nowadays there is a standard dispensing fee and there are separate dispensing fees for special deliveries (e.g. a first prescription or a dispensing after opening hours).

The standard dispensing fee is based on the practice costs and the norm income of a pharmacist as specified by the government. The NZa defines this amount every year and adjusts the fee if needed (from 2004 till 2006 the fee remained stable). Insurance companies are allowed by the NZa to make agreements with a pharmacist to pay more in return for a higher quality of service.

Value added tax (VAT) is applied in the Netherlands in two rates, the so called low and the high rate. The low VAT rate is applied to all medicines, also for OTC products, and is set on 6%. The standard VAT, high rate, is set on 19%.

## 3.2.2 Reimbursement

### 3.2.2.1 Organisation

Until 1991, all prescribed medicines were eligible for reimbursement. The reimbursement system changed greatly by the introduction of the reference price system and the positive list in 1991 (cf. section 3.2.2.2 and 3.2.2.6) and to minor extent by the introduction of the new Health Insurance Act (*Zorgverzekeringswet,* Zvw) in 2006 and the accompanying Decree of Health Insurance and Regulation on Health Insurance.

According the Health Insurance Act (Zvw) an insured patient has the right to obtain medicines as designated by the Ministry of VWS in the Decree on Health Insurance.

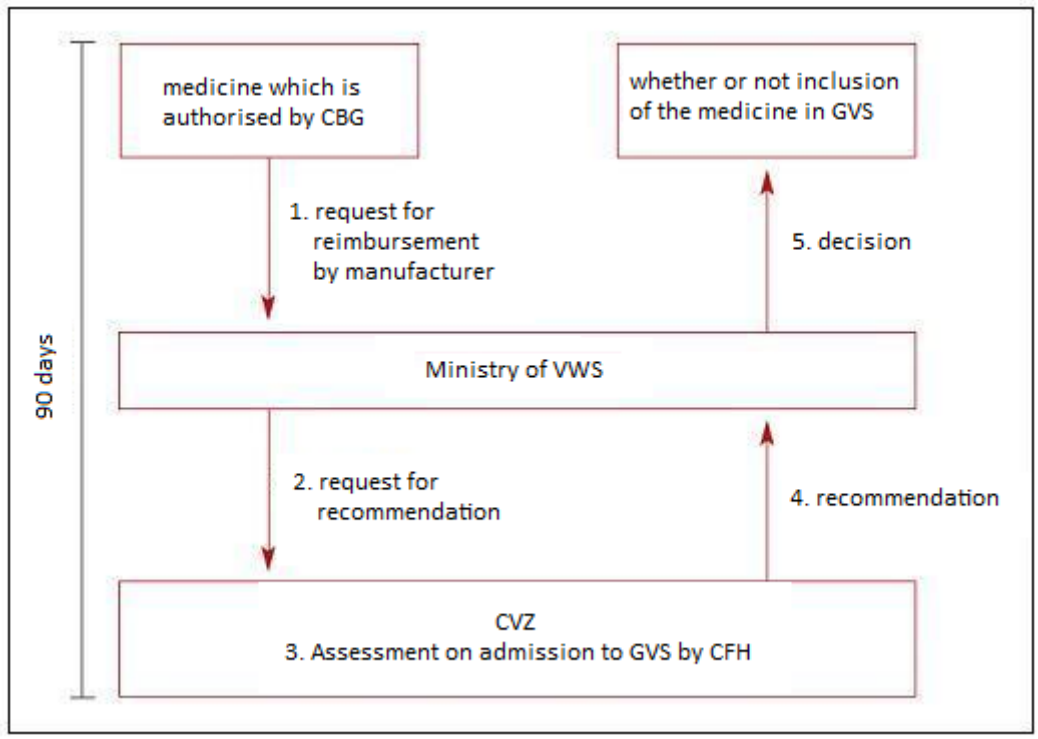
Manufacturers have to submit reimbursement applications for authorised medicines to the Ministry of VWS. The only requirement for a manufacturer to apply for reimbursement status for a medicine is that the medicine has to be registered with the Medicines Evaluation Board (*College ter Beoordeling van Geneesmiddelen*, CBG). Manufacturers do not have to prove cost effectiveness.

[5] The NZa is the supervisory body for all the healthcare markets in the Netherlands.

The Ministry will send the application to the Health Care Insurance Board (*College voor Zorgverzekeringen*, CVZ). On the basis of the recommendations of the Pharmaceutical Care Committee (*Commissie Farmaceutiche Hulp,* CFH), a subcommittee of the CVZ, the Ministry of VWS has to determine within 90 days after receiving the application whether a medicine will be included in the pharmaceutical reimbursement system (*Geneesmiddelenvergoedingssysteem,* GVS) or not (cf. Figure 3.2). Extension of the period of 90 days is possible if additional information is necessary.

For generics, parallel imported medicines and new dosages of medicines that are already in reimbursement list Annex 1A (cf. section 3.2.2.3 ), there is a shortened procedure possible. In the case of a shortened procedure the Ministry decides about including in the GVS without input of the CVZ. The reimbursement price for generics is based on the lowest priced generic that could theoretically supply the whole market. Parallel imported medicines are reimbursed according the cheapest price per the country of origin.

Figure 3.2:
Dutch procedure for reimbursement request, as of 2010




Source: Based on brochure *Een zorgvuldige afweging.* (CVZ 2006), additional information from CVZ-website (www.cvz.nl)

## 3.2.2.2 Reimbursement list

In case it is decided that a medicine is reimbursable, it is included in the reimbursement list, the positive list. In this list there can be searched for active ingredients, ATC codes or trade names. Most of the medicines on the list are POM. Only a few OTC products are eligible for reimbursement (cf. section 3.2.2.8).

The positive list is updated on a continuous basis and is publishing on the internet[6]. Communication to doctors, pharmacists and patients about changes in the positive list takes place via umbrella organisations/associations like the Royal Dutch Pharmaceutical Association (KNMP).

### 3.2.2.3 Reimbursement categories

Reimbursable medicines on the positive list are divided in three different categories, the so-called Annexes:

» Annex 1A: Therapeutically interchangeable products reimbursed according to the reference price system (cf. section 3.2.2.6).

» Annex 1B: Unique products (no clustering possible). Not reimbursed according to the reference price system and no reimbursement limits exist.

» Annex 2: Medicines only reimbursed under specific circumstances, for example if prescribed by a specialist, if administered within a specialised healthcare centre (e.g. for cancer treatment), or after approval by the health insurer.

The CFH classifies, on behalf of the CVZ, the medicines into the different annexes. The CFH consists of twenty external, independent experts (e.g. pharmacists, doctors, scientists and also mathematicians). As said before the Ministry of VWS is responsible for the final decision to include the medicine on the reimbursement list or not.

In the Netherlands there is 100% reimbursement for all medicines which meet the eligible criteria.

### 3.2.2.4 Eligibility scheme and criteria

The Dutch eligibility scheme is product-specific; eligibility for reimbursement depends on the medicine in question.

To be included in Annex 1A of the reimbursement list, a medicine must be therapeutically equivalent to one of more other medicine(s) already in the list (i.e. same indications, same route of administration, and used by patients in the same age category). Medicines which comply with the mentioned criteria are interchangeable unless there are differences in quality between the medicines.

Conditions for including a medicine in Annex 1B are based on an assessment of the therapeutic value and cost-effectiveness. If the therapeutic value of the medicine is too low, it will not be eligible for reimbursement. The CFH assesses medicines' therapeutic value based on:

» Efficacy
» Effectiveness
» Side effects
» Experience
» Applicability
» Easiness of use for the patient

[6] Available on http://www.farmatec.nl/geneesmiddelen/prijzenenlimieten/vergoedingssysteem/Vergoedingslimieten.aspx

Including a medicine in Annex 2 can be used as an instrument to limit the use of the medicine. By placing the medicines in Annex 2, the government tries to ensure that a medicine is used for those patients for whom they think it is most efficient. To be eligible for reimbursement of Annex 2-medicines, the patient has to fulfil specific criteria, e.g. have a specific indication or already have another specific treatment before.

### 3.2.2.5 Reimbursement price

Prices of Annex 1-medicines are set according to the reference price system (cf. section 3.2.2.6). This is done by the Ministry of VWS. The products of Annex 1A only require co-payments if the medicine has a price above the maximum reimbursement price. 90% of the medicines in this category are fully reimbursed.

For the unique medicines from Annex 1B, which cannot be clustered with other medicines, maximum wholesale prices are the only cap on reimbursement price. These wholesale prices are set by external price referencing as the average of the wholesale prices in the Belgium, Germany, France and the UK (c.f. section 3.2.1.2.1). This is also the case for medicines in Annex 2.

Parallel imported medicines and combination products are not included in the calculation of the reimbursement price. In practice their prices are lower than those of other (non-imported) medicines. Although the reimbursement list has been updated on continuous basis, reimbursement prices have not been recalculated since 1999.

A lot of health insurance companies are now, as this is allowed with the new health insurance legislation, offering the possibility to reimburse above the set limit as part of their addition insurance package.

### 3.2.2.6 Reference price system

A reference price system was introduced in the Netherlands in 1991. It is used for setting maximum reimbursement price levels for medicines in Annex 1A from the positive list.

The different medicines are clustered into groups of interchangeable medicines (including generics). Since June 2002, medicines have been considered interchangeable in the Netherlands if they are used for the same indications, have the same pharmaceutical form and are used for patients in the same age category. Having the same clinical characteristics is important as well. The clustering is done according to the ATC code (a mix of 3, 4 and 5).

The reference price (or the maximum reimbursement price level) is calculated using the costs of the defined daily dose (DDD) set by the WHO. When this dose is higher or lower than the common used dose in the Netherlands, the standard Dutch dose will be used. The reimbursement price is set as the price of the medicine equal to or directly below the average of the prices of all medicines in the group. Under this system, at least one medicine in each group is fully reimbursed. Medicines priced above the reference price are only partially reimbursed and the patient must pay the difference between the reimbursement price and the pharmacy retail price.

## 3.2.2.7 Preference policy

### 3.2.2.7.1 General

An important development in the Dutch pharmaceutical system is the introduction of the preference policy. The main goal of the preference policy is to obtain more price competition and as a consequence lower prices.

With this policy insurance companies determine one or a limited number of product(s) per product category or medicine cluster (medicines with the same active ingredient, dosage form and strength) as preferred, each time for a fixed period. A patient is, based on the basic insurance, entitled to the preferred medicines. The preference medicines must be admitted to the GVS.

The Ministry of VWS still decides whether a medicine is eligible for reimbursement or not, but the health insurance companies may narrow the range of medicines in a cluster for which their company will pay.

Insurance companies are allowed to exclude generic products from a specific supplier/manufacturer from reimbursement on condition that there is at least one product of every active ingredient available for an insured patient. Insurers are not obliged to have a preference policy.

One legal exception is the situation of a medical need for a medicine. In this case, the insurance is obligated to reimburse the non-preferred product as well.

### 3.2.2.7.2 History

On July the 1th in 2005, five Dutch insurance companies started a joint preference policy. These companies had together a market share over 50% of all the insured persons in the Netherlands. In January 2006 two other companies also joined this policy. The reason for the joint policy was the possibility to offer suppliers a substantial market share.

In the beginning, the policy was applied for only three active ingredients: simvastatin, pravastatin and omeprazol. The insurance companies reimbursed only the medicines (-labels) which they have preferred. A medicine became preferred for a six-month period when the price in the price list (*taxe*) was maximal 5% above the lowest price of the cluster on the set date. Exceptions are products of manufacturers who don't have the capacity to supply the whole market or medicines of which the price increase during the time of the preference policy.

Since the introduction of the Health Insurance Act (Zvw) in 2006, the insurers had a legal basis for starting an individual preference policy. In July 2008 four insurers have started the first individual policy. The scope of the policy and the time that a medicine is preferred differed, but the date of starting was equal for every insurance company (July 2008).

### 3.2.2.7.3 Current situation

Currently the preference policy is applied for commonly used generic medicines and for generics with a high charge for the insurer. The number of included active ingredients is widely extended since the individual preference policies. Some insurers have a preference policy on more than 50 active ingredients, in different dosages.

The preference policy has led to cost savings. Through this policy some manufacturers with a small market share have expanded their share a lot.

Now there is generic substitution in place. There are some plans for the introduction of therapeutic substitution. With the current substitution plan a medicine is substituted by another product from the same therapeutic class. This other product could have a different active ingredient. Before it will be allowed, the Health Insurance Act needs to be adjusted.

## 3.2.2.8 Changes in reimbursement list

Changes in the reimbursement list are possible. They occur when a medicine is removed from the positive list, when a medicines' reimbursement status is changed or when a new product has introduced to the GVS.

In 2004, the self-medication pharmaceuticals were removed from the positive list. On 1 January 2005, reimbursement for five clusters of OTC medicines (laxative products, calcium tablets, allergy products, anti-diarrhea products and antacids) was reinstated if the medicine is prescribed by a doctor for chronic use and if the patient uses the self-medication pharmaceutical for longer than six months. In 2009, it was decided that benzodiazepines will be eligible for reimbursement for only five indications.

No set procedure is in place to switch pharmaceuticals from POM to OTC status. The Medicines Evaluation Board (CBG) is responsible for evaluating the status of medicines, but only the market authorisation holder is permitted to apply for a change in status, as the legal status is part of the market authorisation. Since 2006 the Ministry of VWS has also the authority to request the switching of certain categories of medicines to OTC status.

Medicines can be removed from Annexes 1A or 1B if alternatives show better efficacy, safety or cost-effectiveness. At the moment when a medicine is introduced in the GVS which is interchangeable with a product of Annex B, the status of the medicine concerned in Annex 1B will be changed and the medicine is clustered to Annex 1A. This can also be the case if the patent of a medicine expires and other manufacturers develop generic variants; the status and clustering will switch from 1B to 1A.

## 3.2.2.9 Out of pocket payments

Under the reimbursement scheme, only prescription only medicines (POM) listed in Annex 1A of the positive list can require to make a co-payment. Even in Annex 1A, patients receive medicines free of charge unless the medicine is priced above the maximum reimbursement level: these co-payments are due to the reference price system (cf. section 3.2.2.6). If the medicine is priced above the reference price, the patient must pay the difference between the reimbursement price and the pharmacy retail price.

### 3.2.2.10 Mechanism for vulnerable groups

There are fiscal arrangements for vulnerable groups, when the medicines costs exceed a specific percentage of the patients' income.

Another mechanism is the so called *Zorgtoeslag* (Health fee) for people with low income. This is a compensation mechanism. The amount may reach a maximum of € 735 for people who live alone and € 1.548 for multi-persons households.

## 3.3 Comparative analysis

### 3.3.1 Pricing policies

Pricing refers to setting a price for a medicine at the thereby legally defined price level, often the manufacturer level. Pricing policies are regulations or procedures used by government authorities to set or limit the amount paid by purchasers or the amount received by sellers.

Two different way on how to set a price are free pricing and price control. In the **free pricing** system, pharmaceutical prices may be freely set by the manufacturer (or wholesaler, if the controlled price type is the pharmacy purchasing price). When there is **price control**, the authorities determine the pharmaceutical prices.

The authorities could control the prices on different levels; on manufacturer level, on wholesale level and on pharmacy level. This involves respectively the following controlled price types: the ex-factory price, the pharmacy purchase price and the pharmacy retail price. Pricing is often controlled directly on manufacturer level. Despite a present free pricing on manufacturer level, the ex-factory price could still be **indirectly controlled** by the agreed wholesale price or by the set reimbursement price.

Figure 3.3 on the next page shows in which countries there is **direct price control** on manufacturer level.

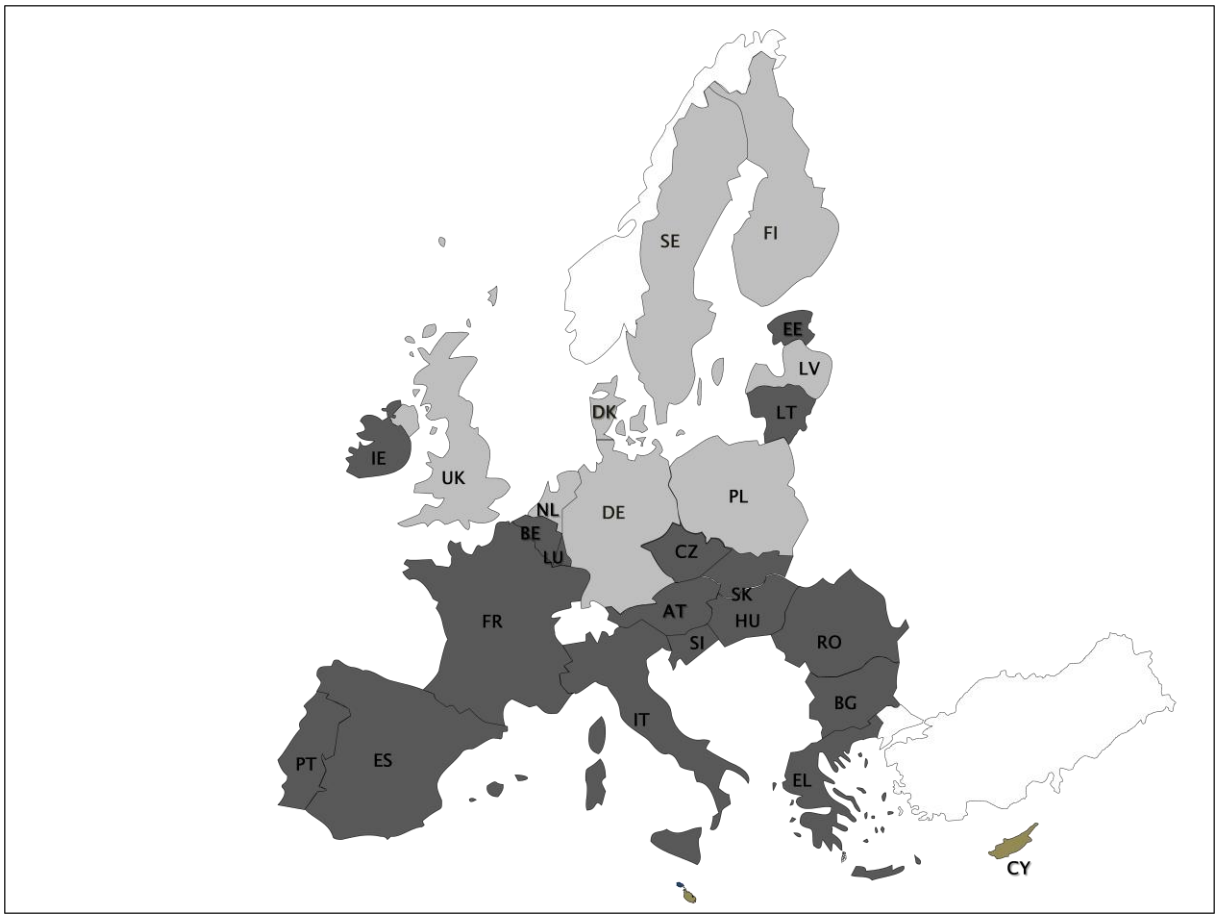
Eight EU countries have no direct price control in place (Germany, Latvia, Denmark, Finland, the Netherlands, Poland, Sweden and the United Kingdom). In Cyprus and Malta there is limited price control. In Malta is this only the case in the public sector and in Cyprus the control is only on locally produced medicines.

In the European countries which have price control, the most common policy is statutory pricing (cf. Table 3.3). Through statutory pricing, the medicine prices are set on a regulatory basis (e.g. by a law or decree). In Italy and France there are negotiations between the manufacturer and the government about the prices. Other Member States have besides negotiations also statutory pricing as their policy, if the negotiation falls then statutory pricing takes place. It could also be the other way, e.g. in Estonia statutory pricing is the main policy. But negotiations can be started after the preliminary statutory pricing decision if the manufacturer is not able to justify the price according to the decision made by the government.

In most European countries the price control is applied on reimbursable medicines. In five countries the policy is even applied to all medicines (e.g. in Greece).

In the Netherlands there is, like in seven other European countries, no direct price control on manufacturer level. For this reason a pricing policy on this level is not the case.

Figure 3.3:
Price control on manufacturer level in the EU countries, as of 2010 or latest available data




Source: PPRI (2007-2009), ÖBIG and GÖG reports, additional information provided by country experts employed by GÖG

Table 3.3:
Price policies on manufacturer level in the EU countries, as of 2010 or latest available data

| Country | Price policy on manufacturer level[1] | | |
|---|---|---|---|
| | Scope | Main policy | Other possible policy |
| AT | Reimb. | Statutory pricing | Additionally price negotiations |
| BE | All | Statutory pricing | Price negotiations (reimb.) |
| BG | POM | Statutory pricing | Price negotiations (reimb.)<br>Tendering (medicines paid by the Ministry of Health) |
| CY | Locally produced pharmaceuticals | Statutory pricing | Tendering |
| CZ | All | Statutory pricing | Price negotiations (reimb.) |
| DE | _ | _ | _ |
| DK | _ | _ | _ |
| EE | Reimb. | Statutory pricing | Price negotiations |
| EL | All | Statutory pricing | _ |
| ES | Reimb. | Statutory pricing | _ |
| FI | _ | _ | _ |
| FR | Reimb. | Price negotiations | Statutory pricing: in case of failure negotiations |
| HU | Reimb. | Price negotiations (in addition statutory pricing criteria) | _ |
| IE | Reimb. and those supplies to the HSE (medicines under price agreements) | Price based on agreements between HSE and industry | Price negotiations |
| IT | Reimb. | Price negotiations | |
| LT | Reimb. | Statutory pricing [2] | Price negotiations [1] |
| LU | All | Statutory pricing | _ |
| LV | _ | _ | _ |
| MT | All medicines in public system | Tendering | _ |
| NL | _ | _ | _ |
| PL | _ | _ | _ |
| PT | POM | Statutory pricing | _ |
| RO | POM | Statutory pricing | _ |
| SE | _ | _ | _ |
| SI | Reimb. | _ | _ |
| SK | Reimb. | Statutory pricing [3] | _ |
| UK | - | - | _ |

HSE: Health Service Executive (Irish National Health Service authority), all = all medicines, reimb.= reimbursable medicines

Source: PPRI (2007-2009), GÖG reports, additional information provided by country experts employed by GÖG

1 Price notification is not included as a price policy while at the moment there is a EU-wide discussion about the right definition of it
2 LT: the reference declared manufacturer price should not exceed 95% of the average manufacturer's price in the six reference EU countries (Latvia, Estonia, Poland, Czech Republic, Slovakia, and Hungary). Negotiations are only for medicines which price exceeds 95% of the average price in reference countries.
3 SK: Pricing Committee sets 'agreed price' based on price proposal by manufacturers.

## 3.3.2 External price referencing

A very common price pricing procedure is **external price referencing** (EPR). This is an international price comparison with various country baskets (reference countries) to derive a reference price for the purposes of setting or negotiating the price of the product in a given country. For example, statutory pricing is often based on external price referencing procedures.

As seen in Table 3.4 below, most EU Member States apply external price referencing (all except Germany, Denmark, Sweden, the United Kingdom and Malta). However, in Malta there are plans to implement EPR. Some countries use EPR only as additional information (e.g. Italy) or just as a procedure instead of a criterion (e.g. Latvia and Finland).

Every country has its own methodology for the **price calculation**. Some take the lowest price per group (e.g. Spain and Hungary), others take the average (e.g. Austria and Ireland) and there are also countries which use a mix of the average and the lowest (e.g. Slovakia and Bulgaria). Of course also other calculations exist, e.g. in Latvia where they take the third lowest price of the prices in all EU countries as the reference price.

The **country basket** varies between the countries. This is due to economic, geographic and historical considerations. For instance Central and Eastern European (CEE) countries refer to other CEE countries (e.g. Lithuania has a lot of other Baltic states included as reference countries). Also the average price level can be a criterion for selecting the reference countries; lower income countries tend to refer to other well-resourced states and more wealth countries might choose other high-price countries. Sometimes there a mixture can be seen between low- and high price countries in a basket (e.g. Hungary). The amount of countries in the basket differs per state, from three (Slovenia) till all other EU Member States (Slovakia).

The most European countries apply external price referencing on the ex-factory price of reimbursable medicines and/or prescription-only-medicines (POM).

Table 3.4:
External price referencing in the EU countries, as of 2010 or latest available data

| Country | External price referencing | | | | |
|---|---|---|---|---|---|
| | Y/N | Year of intr. | Scope | Price level | Calculation and reference country |
| AT | Y | 2004 (published in 2005) | Reimb. | Ex-factory price resp. PPP for selected countries | Average of the prices in EU-24 (all, except RO and BG) |
| BE | Y | n.a. | All | Ex-factory price | Head-to-head to prices of the product in all EU-26 |
| BG | Y | 2000 | POM | Ex-factory price | Average of 3 lowest prices in reference countries (RO, RU, CZ, SK, HU, PL, PT, ES, AT), since 2010. |
| CY | Y | n.a. | Imported POM and OTC (in private sector) | PPP | Average of the countries SE, AT, FR, EL plus 3% to cover transport costs |
| CZ | Y | n.a. | All | Ex-factory price | P: average price of reference countries (EE, EL, ES, FR, HU, IT, LT, PT)<br>R: lowest price of reference countries (EU-26) |

| Country | External price referencing | | | | |
|---|---|---|---|---|---|
| | Y/N | Year of intr. | Scope | Price level | Calculation and reference country |
| DE | N | – | – | – | – |
| DK | N [1] | _ | _ | _ | _ |
| EE | Y | 2003 | Innovative reimb. | Ex-factory price | Referencing to LV, LT, HU and country of origin; sometimes also to other EU MS |
| EL | Y | n.a. | All (excl. generics) | Ex-factory price | Average of the three lowest prices among the reference countries (all EU countries excl. DK, EE, MT, SE, EL) |
| ES | Y | n.a. | Innovative ph. | Ex-factory price | Lowest price per group of the reference countries (DE, AT, BE, DK, FR, NL, IE, IT, LU, UK, SE) |
| FI | (Y)[2] | 2004 | Reimb. (POM and OTC) | PPP | _ [3] |
| FR | Y | 2003 | Innovative ph. | Ex-factory price | Price similar to the price submitted by the company in reference countries (DE, ES, IT and UK) |
| HU | Y | 2004 [3] | Reimb. | Ex-factory price | Lowest price of the reference countries (FR, IE, DE, ES, PT, IT, EL, PL, CZ, SL, SK, BE, AT, one additional country) |
| IE | Y | n.a. | POM (including generic) | PPP | Average of reference countries (BE, DK, FR, DE, NL, ES, UK, FI, AT) |
| IT | (Y) [4] | (1994) | Reimb. | Ex-factory price | Average of the reference countries (not specified) |
| LT | Y | 2003 | Reimb. (POM and generics) | Ex-factory price | If the declared price exceeds the 95% of price of reference countries ( LV, EE, PL, CZ, SK, HU) , base price is average price in reference countries |
| LU | Y | n.a. | All | PRP | Lowest price in country of origin (DE, FR, BE) |
| LV | Y | 2005 | Reimb. | Ex-factory price | Third lowest price EU-26 (EU countries minus LV) |
| MT | N [5] | _ | _ | _ | _ |
| NL | Y | n.a. | POM | PPP | Average of the mean prices per unit of the reference country (BE, DE, FR, UK) |
| PL | Y | 2002 | Reimb. | Ex-factory price | Lowest price of the reference countries (BE, UK, IE, FR, DE, NL, SE, DK, ES, PT, IT, EL, CZ, HU, LU, LT, CH) |
| PT | Y | n.a. | POM and reimb. OTC (excl. generics) | Ex-factory price, PRP | Average price of reference countries (EL, ES, FR, IT) |
| RO | Y | n.a. | POM | Ex-factory price | Lowest price per group of reference countries (AT, BG, BE, CZ, DE, EL, ES, HU, IT, LT, PL, SK)[6] |
| SE | N | _ | _ | _ | _ |

| Country | External price referencing | | | | |
|---|---|---|---|---|---|
| | Y/N | Year of intr. | Scope | Price level | Calculation and reference country |
| SI | Y | n.a. | Reimb. | PPP | 95% of the average of the reference countries (AT, DE, FR)[7] |
| SK | Y | 2003 | Reimb. | Ex-factory price | Average of six lowest prices in EU-26 (EU countries minus SK) |
| UK | N | _ | _ | _ | _ |

all = all medicines, excl. = exclusive, n.a. = not available, OTC = over-the-counter medicines, PPP = pharmaceutical purchasing price, PRP = pharmaceutical retail price, POM = prescription-only-medicines, P =pricing, R =reimbursement, reimb. = reimbursable medicines

Source: PPRI (2007-2009), ÖBIG and GÖG reports, additional information provided by country experts employed by GÖG

1 DK: EPR is used to be mandatory until 2005
2 FI: There is no formal international price comparison (i.e. arithmetic average or similar) in place, but according to the law prices in other European Economic Area-countries (EU countries plus Norway and Liechtenstein) may be considered when determining the approved wholesale price
3 HU: In 2004 the law about the ref. countries was set
4 IT: EPR is only used as additional information during the negotiation procedure (there was EPR from 1994-2004)
5 MT: Plans to implement it in 2010 (not yet implemented)
6 RO: Reform plans for 2010
7 SI: Plans for 2010; The wholesale price of a pharmaceutical may in general not exceed 85% of the average price determined by the price comparison. For imported products an extra 0.5% is added.

In the Netherlands external price referencing is applied on the pharmacy purchasing price (PPP) of POM. In four other countries is the EPR done on the PPP as well (Slovenia, Ireland, Finland, Cyprus) and – in addition to the ex-factory price – in Austria. The basket in the Netherlands consists of the four other European countries France, UK, Belgium and Germany. In comparison to the other countries the number of states in the basket is relatively low. The price calculation is based on the average, as is the case in many EU Member States.

### 3.3.3 Statutory mark-ups

Price policies are not only relevant on manufacturer level. They are also on a distribution level present (wholesale and retail), i.e. the **wholesale and pharmacy mark-ups**. When there is a controlled mark-up, it is called a statutory mark-up. The associated schemes could be **linear** or **regressive**. The mark-up schemes can cover all medicines, but also only a selected group of medicines e.g. reimbursable medicines. It is possible that a country has different schemes for different medicines' groups. Sometimes there are other ways for remuneration as well, e.g. a fixed fee or fee-for-service remuneration (cf. Table 3.5).

Five EU countries don't apply a wholesale mark-up (Denmark, Finland, the Netherlands, Sweden and the United Kingdom). Cyprus and Malta only have wholesale mark-ups in the private sector (in Cyprus the mark-up is only applied on locally produced medicines). If there is no wholesale mark-up applied, it is possible that the mark-ups are freely negotiated between manufacturer and wholesaler like in Finland and Sweden.

Pharmacy mark-ups are regulated in all EU member states, but to a different extent.

In the most European countries the mark-up schemes cover all medicines, whereas in some countries e.g. Romania and Germany it is only applied on a selected group of medicines (e.g. POM). In some countries (e.g. Latvia) there are different schemes for different kind of products. Regressive schemes are more commonly than linear schemes. On pharmacy level six countries use fixed fees or fees-for

services (the Netherlands, Germany, Slovenia, Ireland, Sweden and the United Kingkom). Sweden uses only for generics a fixed fee.

Table 3.5:
Price policies at distribution level in the EU countries, as of 2010 or latest available data

| Country | Wholesale remuneration | | | Pharmacy remuneration | | |
|---|---|---|---|---|---|---|
| | Y/N | Scope | Type of mark-up | Y/N | Scope | Type of mark-up |
| AT | Y | All | Regressive[1] | Y | All | Regressive[1] |
| BE | Y | All | Regressive[2] | Y | All | Regressive[2] |
| BG | Y | POM | Regressive | Y | POM | Regressive |
| CY | Y | Locally produced medicines in private sector | Linear | Y | All medicines in private sector | Linear |
| CZ | Y | All | Regressive[3] | Y | All | Regressive [3] |
| DE | Y | POM, reimbursable OTC | Regressive | Y | POM, reimbursable OTC | Different [4] |
| DK | N | _ | _ | Y | All, except OTC products sold outside the pharmacy as well | Linear [5] |
| EE | Y | All | Regressive | Y | All | Regressive |
| EL | Y | All | Linear | Y | All | Linear |
| ES | Y | All | Regressive [6] | Y | All | Regressive |
| FI | N [6] | _ | _ | Y | All, except NRT sold outside the pharmacy as well | Regressive |
| FR | Y | Reimb. | Regressive | Y | Reimb. | Regressive |
| HU | Y | All | Regressive | Y | All | Regressive |
| IE | Y [7] | Reimb. | Linear | Y [7] | Reimb. | Linear, fees |
| IT | Y | Reimb. | Linear | Y | Reimb. | Linear [8] |
| LT | Y | Reimb. | Regressive | Y | Reimb. | Regressive |
| LU | Y | All | Different [9] | Y | All | Different [9] |
| LV | Y | All | Regressive [10] | Y | All | Regressive [10] |
| MT | Y | All in private sector | Linear | Y | All in private sector | Linear |
| NL | N | _ | _ | Y[11] | POM | Fees |
| PL | Y | Reimb. | Linear | Y | Reimb. | Regressive |
| PT | Y | All | Linear | Y | All | Linear |
| RO | Y | POM | Regressive | Y | POM | Regressive |
| SE | N [12] | _ | _ | Y | POM | Regressive, fees [13] |
| SI | Y | All, except non-reimb. OTC | Regressive | Y | All, except non-reimb. OTC | Fees |
| SK | Y | Reimb. | Regressive | Y | Reimb. | Regressive |
| UK | N | _ | _ | Y | Reimb. (NHS medicines) | Fees |

Y = yes, N = no, all = all medicines, reimb. = reimbursable medicines, NHS, National Health Service, non-reimb. = non reimbursable medicines, NRT = nicotine replacement therapy, OTC = over-the-counter medicines, POM = prescription-only- medicines

Source: PPRI (2007-2009), ÖBIG and GÖG reports, additional information provided by country experts employed by GÖG

1 AT: Two whoslesale mark-up schemes depending on reimbursement category; two pharmacy mark-up schemes depending on customers - one scheme for privileged customers (e.g. sickness funds) and one for private customers
2 BE: Different schemes for reimb. (mark-ups and flat-fees) and non-reimb. (mark-ups with a maximum)
3 CZ: Combined regressive maximum mark-up for wholesalers and pharmacies
4 DE: POM: flat fee of €8.10 plus a linear mark-up. Reimbursable OTC products: regressive mark-up
5 DK: Mark-up has variable elements, modified in average twice per year
6 FI: Mark-ups are freely negotiated between manufacturer and wholesaler

7 IE: Wholesale and pharmacy mark-ups are not statutory. There are different mark-ups (resp. fees) for different reimbursement schemes

8 IT: The pharmacy mark up for products reimbursed by the NHS is linear, but it has been made regressive due to a "statutory discount" granted by pharmacists to the NHS, calculated according to a regressive method.

9 LU: Linear and regressive mark-ups, difference depends on origin of the medicine

10 LV: different schemes for reimbursable and non-reimbursable medicines

11 NL: The standard fees are determined by the NZa (supervisory body for all the Dutch healthcare markets), not directly by the government

12 SE: Mark-ups are freely negotiated between manufacturer and wholesaler

13 SE: There is an extra fee of SEK 10,- for generics

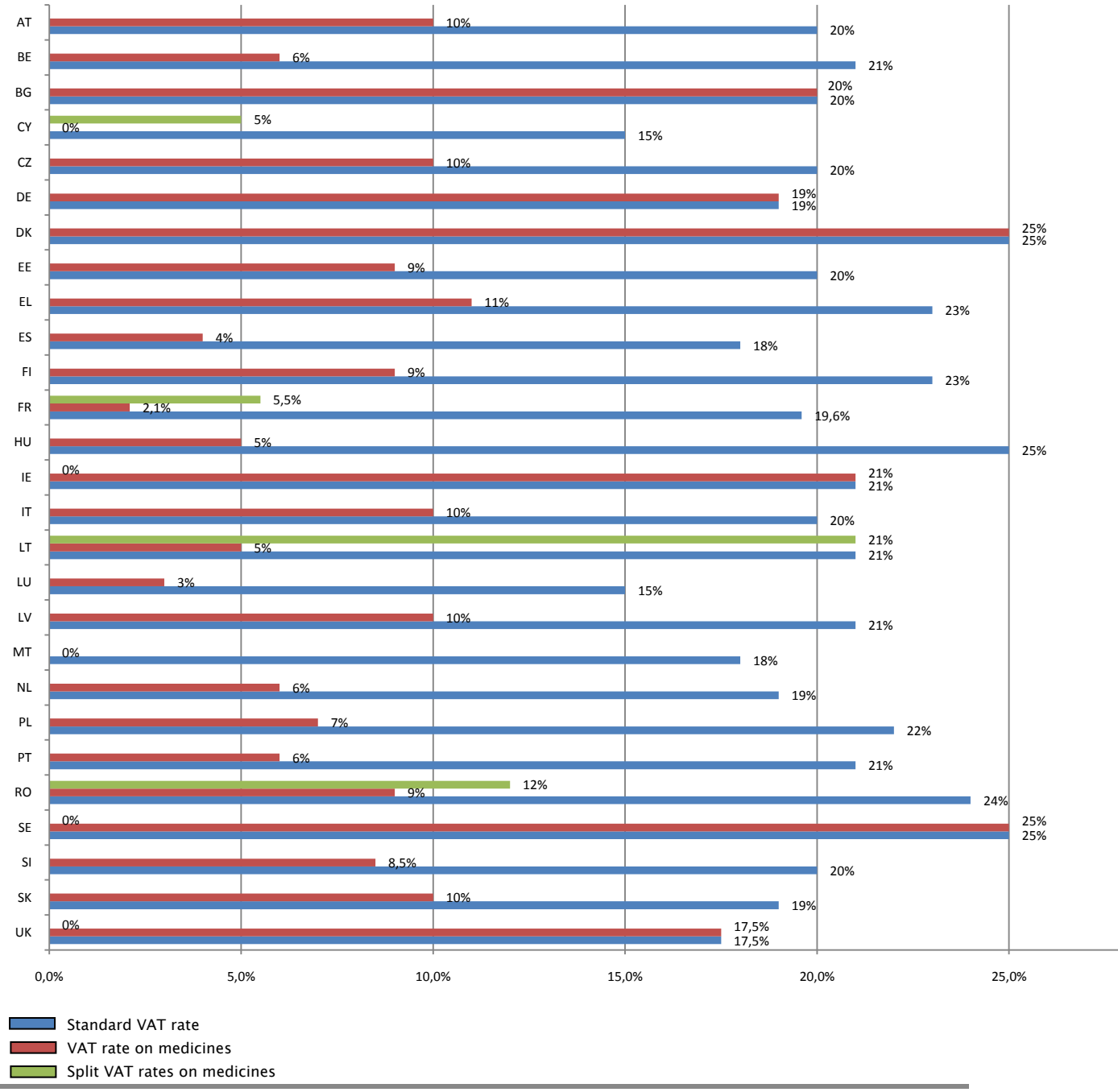
The Dutch system has no statutory mark-ups on wholesale level like a few other countries. The pharmacy remuneration is arranged by fixed fees. This is not the most common way for remuneration in Europe.

### 3.3.4 Value added tax

Beside the mark-ups another important element of the final pharmacy retail price are the taxes, in particular the **value added tax** (VAT). This is a sales-tax which is added at each stage of production based on the value added to the product at that stage.

As seen in Figure 3.4 most of the countries have a **special VAT rate for medicines**, which is lower than the standard VAT. Exceptions to this are Bulgaria, Denmark and Germany. In these countries the VAT for medicines is equal to the standard VAT rate. Six countries have spit VAT rates (e.g. France and Lithuania); for specific groups of medicines there is a lower rate or no VAT in charge. Only one country, Malta, has no VAT at all on medicines.

Figure 3.4:
VAT rates in the EU countries: standard rate and rates for medicines, as of 2010




Source: National country sources, PPRI (2007-2009), additional information provided by country experts employed by GÖG

| | |
|---|---|
| CY | VAT of 5% for diagnostic agents, otherwise no VAT on medicines |
| EL | Since July 2010 VAT has been changed: 11% on medicines, 23% standard VAT (before 10 resp. 21%) |
| FR | Split VAT rates on medicines: 2.1% for reimbursables, 5.5% for non-reimbursables |
| IE | Split VAT rates on medicines: 21% for non-oral medicines, 0% for oral medicines |
| LT | Split VAT rates on medicines: 5% for reimbursables, 19% for non-reimbursables, no VAT for medicines produced from human tissues |
| RO | Split VAT rates on medicines: 9% for POM, 19% for OTC |
| SE | Split VAT rates on medicines: no VAT for POM, 25% for OTC |
| UK | Split VAT rates on medicines: no VAT for NHS medicines, 17.5% for OTC, non-reimbursed and private prescriptions |

In the Netherlands there is, just as in the most European countries, a value added tax rate which is lower than the standard VAT especially for medicines. No split VAT rates on medicines are applied.

### 3.3.5 Reimbursement schemes and rates

In the out-patient sector **different reimbursement schemes** regarding to eligibility for reimbursement could be distinguished, e.g. the product-specific scheme, the disease-specific scheme, the population-group-specific scheme and the consumption-based eligibility.

At a **product-specific** scheme the eligibility for reimbursement depends on the medicine in question: The medicine is either considered as reimbursable or as non-reimbursable. There will be an evaluation of different aspects of the product (e.g. therapeutic benefit, comparison to other alternatives, costs etc.). This assessment, which is generally performed by experts, not only influences the inclusion on the positive list (cf. section 3.3.6) but also the reimbursement rate.

Under the **disease-specific** scheme, getting a reimbursement status and specific reimbursement rates is linked to the underlying disease which should be treated. One medicine may be reimbursed at different reimbursement rates for the treatment of different diseases.

The level of reimbursement in the **consumption-based** eligibility scheme depends on the expenses for medicines of a patient in a certain period of time, e.g. a year. The amount of reimbursement increases with a higher pharmaceutical consumption. This way favours patients in need for more pharmaceutical care (e.g. elderly people). The decision to grant reimbursement to a medicine is made on a product level.

Another example of a reimbursement scheme is the **population-group-specific** one where only specific population groups are eligible for reimbursement (e.g. children or people with a low income), while others are not. Meaningful to say is that nearly every reimbursement scheme has elements of a population-group eligibility, e.g. a disease-specific scheme in which elderly people with specific long term disease are eligible for reimbursement. Also the mechanisms for vulnerable groups, which every country has (cf. section 3.3.9), can acquire special reimbursement rates for specific populations. For this reason it is decided only to classify a scheme in a country as a population-group-specific scheme if the reimbursement rate(s) explicit refer to patient or population characteristics (cf. Table 3.6).

The reimbursement categories are based (or linked to) on the reimbursement scheme. This can also be seen in Table 3.6. The number of categories and rates differs per country.

The reimbursement scheme of the most EU Member States (19 countries) is product-specific. In many cases there is a sub scheme which is disease-based. Notable are the schemes of Denmark and Sweden, these are the only two schemes in the EU which are consumption-based. Population-specific schemes are the case in Ireland, Malta and Cyprus.

In most of the countries the different reimbursement categories have **different reimbursement rates**. Usually the rates are defined in percentages and is there a special rate for medicines for chronic diseases (e.g. Latvia and Greece). Often the added therapeutic value of the product and the severity of the disease play an important role in the categorizing (this could be related to the product and disease-specific schemes). Seven EU countries have only one rate (Italy, Ireland, Malta, Germany, the United Kingdom, the Netherlands and Austria), a reimbursement rate of 100%.

Despite there is only one rate of 100% in these seven countries, real coverage is only done in five countries because Malta and Ireland have population-group-specific schemes. Full coverage in Ireland is only for a specific group of the population, and in Malta only in the public sector. Other people in Ireland have to co-pay, and in Malta they have to pay fully out-of pocket.

Table 3.6:
Reimbursement schemes and rates in the EU countries, as of 2010 or latest available data

| Country | Reimbursement | | |
|---|---|---|---|
| | Scheme | | Rates |
| | Main | Sub | |
| **AT** | Product | _ | **100%** |
| **BE** | Product | Disease | **100; 75; 50; 40; 20%**<br>100%: vital medicines<br>75%: therapeutically important medicines<br>50%: medicines for symptomatic treatment<br>40%: influenza vaccines and antihistamines<br>20%: contraceptive medicines |
| **BG** | Product | Disease | **No fixed reimbursement rates defined**<br>Up to 100%: medicines for common chronic disease<br>Up to 75%: medicines for diseases with low morbidity and mortality leading to significant deterioration of the health status and disability |
| **CY** | Population | disease, product | **100; 50%** (public sector)<br>100%: different statuses (e.g. pensioners)<br>50%: people with low income<br>**0%** (private sector) |
| **CZ** | Product | Disease | **No fixed reimbursement rates defined**<br>exception: 50% for immunostimulantia |
| **DE** | Product | _ | **100%** [1] |
| **DK** | Consumption | Disease | **100; 85; 75; 50%**<br>Rate is depending on PE (higher PE means a higher rate) |
| **EE** | Disease | Product | **100; 75; 50%**<br>100%: serious or epidemic disease<br>75%: chronic disease<br>50%: general disease |
| **EL** | Product | Product | **100; 90; 75%**<br>100%: medicines for severe diseases<br>90%: medicines for chronic conditions<br>75%: standard rate of reimbursement |
| **ES** | Product | _ | **90; 60%**<br>90%: Medicines for chronic diseases<br>60%: Majority of POM |
| **FI** | Product | Disease | **100; 72; 42%**<br>100%: medicines for 34 severe chronic conditions/life-threatening diseases where drug treatment is necessary and effective<br>72%: medicines for 10 chronic diseases where drug treatment is necessary<br>42%: basic medicines with therapeutic value |
| **FR** | Product | Disease | **100; 65; 35%**<br>100%: severe chronic diseases<br>65%: medicines with major clinical benefit by serious disease<br>35%: medicines with less clinical benefit by serious disease and those for non-serious disease with a form of clinical benefit |
| **HU** | Product | Disease | **85; 55; 25%** or **100; 90; 70; 50%**<br>85, 55, 25%: medicines of positive list. Rate depends on therapeutic value of the medicine and severity and status of disease.<br>100, 90, 70, 50 %: medicines for specific diseases |

| Country | Reimbursement | | |
|---|---|---|---|
| | Scheme | | Rates |
| | Main | Sub | |
| IE | Population | product and disease (elements) | **100%**<br>100%: for a specific group of population.<br>The others have 100% reimbursement of medicines after having paid up-front a specific co-payment |
| IT | Product | Disease | **100%:** |
| LT | Disease | _ | **100; 90; 80; 50 %**<br>Rate is depending on severity of the disease (the more severe, the higher the rate) |
| LU | Product | _ | **100; 80; 40%**<br>100%: medicines. with precise indication of therapeutic application, which is generally medicines for chronic disease<br>80%: all other drugs without special destination, prescriptions prepared as directed by physician<br>40%: medicines with more limited indications |
| LV | Disease | Product | **100; 90; 75; 50%**<br>100%: chronic, life threatening diseases or diseases causing irreversible disability where medicines ensures and maintains the patient's life functions<br>90%: chronic diseases, which could be aggravated without medicines<br>75%: diseases where medicines maintain or improve the patient's health<br>50%: diseases where medicines are necessary to improve the patient's health, vaccines. |
| MT | Population | Product | **100%** (public sector)<br>**0%** (private sector) |
| NL | Product | _ | **100%** |
| PL | Product | Disease | **100; 70; 50%**<br>There are no specified inclusion criteria for each group:<br>100%: medicines for specific indications<br>70, 50%: supplementary medicines<br>Full lump sum of PLN 3.20: basic medicines |
| PT | Product | _ | **100; 95; 69; 37; 15%**<br>100%: life saving medicines<br>95%: essential medicines for chronic diseases;<br>69%: essential medicines for serious illnesses<br>37%: not priority medicines with proven therapeutic value<br>15%: new medicines with not yet proven therapeutic value |
| RO | Product | Disease | **100; 90; 50%**<br>100%: medicines for severe chronic diseases<br>90%: essential and cost effective medicines<br>50%: essential but less cost effective medicines |
| SE | Consumption | _ | **100; 90; 75; 50%**<br>Rate is depending on PE (higher PE means a higher rate) |
| SI | Product | _ | **75; 25%**<br>75%: medicines on positive list<br>25%: medicines on intermediate list |
| SK | Product | _ | **100% and partial reimbursement**<br>Categories not specified |
| UK | Product | _ | **100%** |

PE = pharmaceutical expenditure, PLN = Polish Zloty, POM = prescription-only-medicines

Source: PPRI (2007-2009), ÖBIG and GÖG reports, additional information provided by country experts employed by GÖG

1 DE: Basically there is a 100% reimbursement, but through the mandatory co-payment of 10% of the medicines' price (minimum €5, maximum €10) the rate could become lower

The Dutch system is product-specific like the 18 other European countries. The only reimbursement rate used in the Netherlands is 100% (or there is no reimbursement). This is not common in most other Member States.

## 3.3.6 Reimbursement list

Countries can produce different lists to define which medicines will be reimbursed (**positive list**) and which will be not reimbursed (**negative list**). It is even possible that a country has two positive lists, e.g. Slovenia. When a country has a disease-specific reimbursement, there is usually a list with 'reimbursable diseases'. The updating of these lists differs from country to country. Most regularly lists are updated on continuous basis, monthly or quarterly.

In nearly all EU countries, there is a positive list present (cf. Table 3.7). Slovenia even has two positive lists, the second one they call intermediate list. Only Germany, Greece and the United Kingdom have no positive lists in place. However there was a positive list in Greece till 2006. At the moment Greece is working on a reintroduction of the positive list again.

Hungary is the only country which has **both a positive and a negative list**. The United Kingdom, Spain and Germany have only a negative list. Spain and the United Kingdom even have two of them. In Finland and Greece, there is a legal basis for a negative list but these lists are not yet implemented.

Table 3.7:
Reimbursement lists in the EU countries, as of 2010 or latest available data

| Country | Reimbursement list | Country | Reimbursement list |
|---|---|---|---|
| AT | Positive | IT | Positive |
| BE | Positive | LT | Positive |
| BG | Positive | LU | Positive |
| CY | Positive | LV | Positive |
| CZ | Positive | MT | Positive |
| DE | Two negative[1] | NL | Positive |
| DK | Positive | PL | Positive |
| EE | Positive | PT | Positive |
| EL | _ [2] | RO | Positive |
| ES | Negative | SE | Positive |
| FI | Positive [3] | SI | Two positive [4] |
| FR | Positive | SK | Positive |
| HU | Positive, negative | UK | Two negatives |
| IE | Positive | | |

Positive = positive list(s), negative = negative list(s)

Source: PPRI (2007-2009), ÖBIG and GÖG reports, additional information provided by country experts employed by GÖG

1 DE: In addition, a small (positive) list issued by the Federal Joint Committee contains non-prescription drugs that are exceptionally reimbursed under the Social Health Insurance
2 EL: Negative list is not yet implemented (the legal basis is present). The reintroduction of positive list is still ongoing
3 FI: Negative list is not yet implemented, however the legal basis is there
4 SI: There a two positive lists, one called positive list and another is called intermediate list

In the Netherlands there is only one positive list present, as in the most European countries.

### 3.3.7 Reference price system

Besides external pricing, there is also internal price referencing. A way to apply this is the **reference price system (RPS)**. This system is usually not only applied as pricing procedure but also, even more often, for reimbursement purpose. As a consequence the scope is always reimbursable medicines. One condition for building a RPS is to have interchangeable medicines, in particular generics, available on the market.

In a reference price system (RPS) interchangeable medicines are grouped (**reference groups**). Usually this happens on basis of the same active ingredient (ATC 5) or medicines' groups (ATC 4), but other groups exist as well. For each reference group a maximum price is determined, the reference price, which is the basis for reimbursement. An insured patient must pay the difference between the set reference price (plus, if applicable, co-payments on the reference price) and the actual retail price for a medicine under the RPS.

A reference price system is present in 20 of the 27 EU Member States. The first country was Germany which implemented it in 1989. The Netherlands followed in 1990. The Swedish RPS was abolished in 2002 after it had existed nearly for ten years.

As seen in Table 3.8 all European countries with a RPS are clustering medicines by ATC code (5,4 and/or 3). The Netherlands, Poland and Latvia even use a mix of different ATC levels. Germany also uses groups which cannot be assigned to an ATC level.

Nearly all EU Member States take the lowest price of the group as the reference price. The average (e.g. the Netherlands), or a mix of the average, and the lowest (e.g. Spain) are also taken. Some countries have a more complex methodology for determining the reference price, e.g. Germany. Notable is Portugal which uses, as only European country, the highest price of the group as the reference price.

The RPS is updated regularly, e.g. every year (e.g. Estonia), every six months (e.g. Belgium and Slovenia) or even every two weeks like in Denmark. Yet for a lot of countries it is not known how often the reference price system is updated.

Table 3.8:
Reference price systems in the EU countries, as of 2010 or latest available data

| Country | Reference price system | | | | |
|---|---|---|---|---|---|
| | Y/N | Year of introduction | Meth. of clustering | Price calculation | Updates |
| AT | N | _ | _ | _ | _ |
| BE | Y | 2001, in 2005 and 2007 extended | ATC-5 | 30% below the price of the original product | Every six months |
| BG | Y | _ | ATC- 5 and 4 (only for some products) | Lowest price | n.a. |
| CY | N | _ | _ | _ | _ |
| CZ | Y | 1995 | ATC-5 and 4 | Lowest price | Every six months |
| DE | Y | 1989 | ATC-5 and two other levels [1] | Max. the highest price of the lowest third interval of the lowest and the highest price | Once a year minimal, in practise more often |
| DK | Y | 1993 | ATC-5 | Lowest price | Every two weeks [2] |
| EE | Y | 2003 | ATC-5 | Lowest price [3] | Quarterly |
| EL | Y | 2006 | ATC 5 | Average price or directly below | n.a. |
| ES | Y | 2000 | ATC-5 | Average of the three lowest prices | n.a. |
| FI | Y | 2009 | ATC 5 | Lowest price plus a flat amount (€1.5 or €2) | n.a. |
| FR | Y | 2003 | ATC-5 | Lowest price | n.a. |
| HU | Y | 1991 | ATC-5 and 4 (only for some products) | Lowest price | Annually |
| IE | N | _ | _ | _ | _ |
| IT | Y | 2001 | ATC-5 | Lowest price | Monthly |
| LT | Y | 2003 | ATC-5 | Lowest price | n.a. |
| LU | N | _ | _ | _ | _ |
| LV | Y | 2005 | Mix ATC-5,4 and 3 | Lowest price | n.a. |
| MT | N | _ | _ | _ | _ |
| NL | Y | 1991 | Mix ATC-5, 4 and 3 | Average price or directly below | (Last measure was in 1999) |
| PL | Y | 1998 | Mix ATC-5,4 and 3 | Lowest price | n.a. |
| PT | Y | 2002 | ATC-5 | Highest price | Quarterly |
| RO | Y | 1997 | ATC-5 | Lowest price | n.a. |
| SE | N [4] | _ | _ | _ | _ |
| SI | Y | 2003 | ATC-5 | Lowest price | Every six months |
| SK | Y | 1995 | ATC-5 and 4 | Lowest price | Quarterly |
| UK | N | _ | _ | _ | _ |

Y = yes, N = no, ATC =anatomic, therapeutic, chemical classification, max. = maximal, meth. = methodology, n.a. = not available

Source: PPRI (2007-2009), GÖG 2010, additional information provided by country experts employed by GÖG

1 DE: Three levels based on other criteria than the ATC classification of the WHO.
1: all medicines with the same active ingredient
2: therapeutically and pharmacologically comparable (different active ingredients possible)
3: medicines with several active ingredients (combinations of active ingredients), if considered therapeutically comparable

2 DK: often with the market authorisation of new off-patent medicines

3 EE: If more than two pharmaceuticals of the same pharmaceutical form and duration of effect from different marketing authorisation holders are available in the reference price group, the next cheapest average price of the pharmaceutical is taken for the reference price.

4 SE: There was a RPS between 1993 and 2002 which was then abolished. Within the system for generic substitution substitutable medicines are still grouped together.

In the Netherlands a reference price system is in place. It was one of the first European countries which introduced the system. For grouping the medicines a mix of ATC levels is used. This is only done in two other countries. The calculation of the reference price is based on the average price of the group. This is opposite to the most EU countries, which use the lowest price for calculating the reference price. Remarkable to say is that the system is not updated since 1999.

### 3.3.8 Out-of-pocket payments

Not all costs are paid by the health insurer or another third party payer like the Social Insurance. Sometimes patients have to co-pay even for reimbursable medicines. In case of self-medication and non-reimbursed medicines they have to pay the total costs out-of pocket. These payments are all mentioned out-of-pocket payments (OPP).

There are **different co-payments**:

» *Fixed co-payments* are, as the name already says, fixed amount of money which the patient has to pay, e.g. for each prescribed medicine that is dispensed to him/her (prescription fee).

» *Percentage co-payments* are results of the different reimbursement rates on medicines. The patient has to co-pay for example the other 40% when the reimbursement rate is 60%,

» *Deductibles* consist of a fixed amount which the patient needs to pay before the costs are fully or partially reimbursed. Especially in the consumption-based reimbursement systems these payments can be found (e.g. Denmark and Sweden).

Other co-payments are **payments due to the reference price system** (RPS). In the 20 EU countries where a RPS is applied, patients have to co-pay for products priced above the set reference price (cf. section 3.3.7). The amount of this payment is the difference between the retail price and the reimbursed amount. This type of co-payments is not included in Table 3.9.

The most applied out-of-pocket payment in the European Union is the percentage co-payment (cf. Table 3.9). It is applied in 21 of the 27 EU Member States; only Austria, Ireland, Malta, the Netherlands, Italy and the United Kingdom don't have them.

In 10 European countries is a prescription fee applied. Most of these countries charge a fixed fee per prescribed medicine, varying from €0.50 (France) till €8.54 (United Kingdom). Some countries (e.g. Finland and Poland) have only a prescription fee in specific reimbursement categories. Next to the prescription fee another example of a fixed co-payment can be seen in Estonia; at a specific reimbursement rate all costs above a set amount of €12.78 have to be paid by the patient.

The deductible is hardly used in the European countries. Only countries with consumption-based reimbursement systems, Denmark and Sweden, use deductibles.

Table 3.9:
Co- payments in the EU countries, as of 2010 or latest available data

| Country | Out-of pocket payments | | |
|---|---|---|---|
| | Fixed co-payments | Percentage co-payments | Deductibles |
| **AT** | Prescription fee of €5.10 (2010) | – | – |
| **BE** | – | 25, 50, 60 or 80%, depends on reimbursement rate | – |
| **BG** | – | Up to 90 %, depends on reimbursement rate | – |
| **CY** | – | 50% for specific population groups (in public sector) [1] | – |
| **CZ** | – | Different co-payments rates (not defined) | – |
| **DE** | – | 10% of the medicines' price (min. €5 and max. €10) [2] | – |
| **DK** | Prescription fee of 10 DKK (€1.34) | 100, 50, 25 or 15%, depends on personal PE, decreases with rising PE (Max. annual co-payment is DKK 3,490.- ) | Reimbursement for adults starts after OPP of DKK 850.- |
| **EE** | Prescription fee of €1.28 or €3.20 depends on reimb. category<br><br>In the 50% category: all costs above €12.78 per prescr. have to be paid | 10, 25, 50%, depends on reimbursement rate | – |
| **EL** | – | 10 or 25% for specific products, depends on the disease | – |
| **ES** | – | 10 or 40% (Max. €2.64 for medicines for chronic disease) | – |
| **FI** | Purchase fee of €3.- (in reimb. category 100%). or €1.50 (above annual ceiling) | 28% or 58%, depends on reimbursement rate | – |
| **FR** | € 0.50 for each medicine pack (ceiling of €50) | 35 or 65% , depends on reimbursement rate | – |
| **HU** | 300 HUF = €1.20 (in specific categories) | 10, 15, 30, 45, 50 or 75%, depends on reimbursement rate | – |
| **IE** | – | – | – |
| **IT** | In some regions: prescription fee of €1-2 per prescription or pack | – | – |
| **LT** | – | 10, 20 or 50%, depends on reimbursement rate | – |
| **LU** | – | 20 or 60%, depends on reimbursement rate | – |
| **LV** | – | 10, 25 or 50%, depends on reimbursement rate | – |
| **MT** [8] | – | – | – |
| **NL** | – | – | – |
| **PL** | Prescription fee of €0.80 (in some reimb. categories) | 30 or 50%, depends on reimbursement rate | – |
| **PT** | – | 5, 31, 63 or 85 %, depends on reimbursement rate: | – |

| Country | | Out-of pocket payments | |
|---|---|---|---|
| RO | - | 10 or 50%, depends on reimbursement rate | - |
| SE | - | 100, 50, 25 or 10%, depends on personal PE, decrease at rising PE. (Max. annual co-payment is SEK 1,800.- ) | Reimbursement for adults starts after OPP of SEK 900.- |
| SI | - | 25 or 75%; depends on reimbursement rate. | - |
| SK | Prescription fee of €0.13. | Up to 13% (in law 20%) | - |
| UK | Prescription fee of GBP 7.10 per medicine | - | - |

PRP = pharmacy retail price, PE: pharmaceutical expenditure, reimb. = reimbursable, OPP = out-of-pocket-payment, prescr.= prescription, min.= minimal max. = maximal, DDK = Danish Krone, SEK = Swedish Krona, GBP = British Pound, HUF = Hungarian Forint

Source: PPRI (2007-2009), GÖG reports, additional information provided by country experts employed by GÖG

1 CY: Out of pocket spending in private sector
2 DE: Drugs priced 30% below reference price: exempt from this co-payment.
3 MT: Full out-of pocket spending in private sector

In the Netherlands patients don't have to co-pay for reimbursed medicines. This is similar in Ireland and Malta (in the public sector). Exceptions are the co-payments due to the reference price system. These co-payments are observed in 19 other EU countries.

### 3.3.9 Mechanism for vulnerable groups

The affordability of medicines for the whole population is of great relevance for public health. For this reason countries introduced mechanisms for vulnerable groups (e.g. for children, persons with low income or chronically ill patients).

Mechanisms to protect vulnerable groups are affecting the reimbursement rate and/or the co-payments. A **higher or full reimbursement rate** can be provided or the co-payment can be limited. An **exemption of co-payments** is also possible. **Limiting the co-payments** can be done on several ways, e.g.:

» Determining a maximum co-payment per prescription

» Defining a ceiling for a given time period (a maximum payable out-of-pocket amount). This is especially the case in a consumption-based system.

» Giving financial support, e.g. in the form of a budget

There are different **criteria** which could include a person to a vulnerable group, e.g. age, income, specific disease, disabilities, consumption and status (veterans, orphans, widows, pregnant etc.). Another criterion is the presence of a 'specific disease'. Some countries take hereby also into account the stage of the disease, whether the disease is chronically and how severe the disease is.

Looking to the European Member States (cf. Table 3.10), every country has specific mechanisms for protecting vulnerable groups, one country more than another. Exemption from co-payment is the most applied mechanism, e.g. in Austria, France and Italy. A combination of different mechanisms is also possible. This is for example the case in Denmark, where there are mechanisms in place for four different vulnerable groups. Medical budgets, e.g. in Latvia and Hungary, are hardly observed in EU countries.

Age and income are the most used criteria in the different EU countries. Sometimes the criteria overlap each other, which might make it difficult to define individual different vulnerable groups and there mechanism, e.g. in Portugal retired people with low income are seen as a vulnerable group.

Table 3.10:
Mechanism for vulnerable groups in the EU countries, as of 2010 or latest available data

| Country | Mech. of vulnerable groups | |
|---|---|---|
| | Criteria | Mechanism |
| AT | - age<br>- income<br>- specific disease | - Exemption of co-payment<br>(no prescription fee) |
| BE | - age<br>- disabilities<br>- income<br>- status | - Higher reimbursement rate |
| BG | - specific disease<br>- status | - Exemption from co-payment |
| CY | - specific disease<br>- income<br>- age<br>- (consumption) | - Lower co-payment<br>- Exemption from co-payment |
| CZ | - income | - Exemption of co-payment<br>(no prescription fee) |
| DE | - chronic disease<br>- age | - Lower ceiling, exemption from co-payment<br>Total cost-sharing under SHI (excluding direct payments) is limited to 1% of income for a chronic condition instead of 2%. Children below the age of 18 years are excluded from co-payments.<br>For children or terminally ill patients as well as for socially less privileged persons different rules and thresholds are applicable. |
| DK | - consumption<br>- disability<br>- income<br>- age<br>- specific disease | - Higher reimbursement rates (disabled people and low income people)<br>- Limited co-payment (pensioners)<br>- Exemption of co-payment (terminally ill patients)<br>- Ceiling - a maximum limit of €472.37 per 12 months per patient (patients with a large consumption) |
| EE | - age<br>- disabilities<br>- consumption | - Higher reimbursement rate |
| EL | - income | - Higher reimbursement rate |
| ES | - age<br>- specific disease | - Lower co-payment<br>people with chronic disease: 10%<br>- Exemption from co-payment<br>retired people: 0% |
| FI | - income<br>- age<br>- disability | - Exemption of co-payments (pensioners, children and people with disabilities)<br>- Financial compensation (people with low incomes) |
| FR | - specific disease<br>- age<br>- income | - Exemption from co-payments (prescription fee, access to specific reimbursement lists) |
| HU | - income | - Special (higher) reimbursement levels<br>- Individual, monthly drug budgets. |
| IE | - age<br>- chronic disease | - Exemption from co-payment<br>persons > 70 year: free general medical service<br>patient with chronic disease: medicines and appliances for free |
| IT | - specific disease<br>- disabilities<br>- pregnancy<br>- income<br>- age | - Exemption from co-payment<br>i.e. the prescription fee which is charged in some regions do not have to be paid |

| Country | Mech. of vulnerable groups | |
|---|---|---|
| | Criteria | Mechanism |
| LT | - age | Higher reimbursement rates |
| LU | n.a. | n.a. |
| LV | - income<br>- specific disease | - Annual budget from the state<br>persons with low income<br>- Exemption of co-payment<br>Diabetic people: free test strips (under conditions) |
| MT | - chronic disease<br>- income | Full reimbursement of the NHS medicines |
| NL | - income | Financial compensation and fiscal arrangements |
| PL | - status<br>- disability<br>- specific disease | - Higher reimbursement rate<br>- Exemption from co-payment |
| PT | - income<br>- age | - Higher reimbursement rates<br>15% higher, for generics full reimbursement (pensioned people with low income) |
| RO | - age<br>- status<br>- specific disease | Full reimbursement |
| SE | - consumption<br>- age | Higher reimbursement rates |
| SI | - disease | - Full reimbursement<br>100% reimbursement for certain patient groups |
| SK | - income | Co-payment ceiling (for partially reimbursable medicines) |
| UK | - income<br>- age<br>- disease | Lower co-payment |

NHS = National Health Insurance, PE = pharmaceutical expenditure, reimb. = reimbursement, SHI = Social Health Insurance,

Source: PPRI (2007-2009), GÖG reports, additional information provided by country experts employed by GÖG

In the Netherlands the only criterion is income. People with a low income get a financial compensation of the state. Besides that there are some financial arrangements for patients who spent a set percentage of their income on medicines. This specific mechanism cannot be seen in other EU countries.

### 3.3.10 Generic promotion

Generics play an important role in cost-containment. The use of generics can cause a high amount of cost savings, because they are (in most cases) less expensive than the original products. This could be a reason for a country to promote the use of generic medicines.

There are **different tools for generic promotion**. The key elements are prescribing by INN (international non-proprietary name/ the generic name) and generic substitution. With generic substitution a medicine, whether marketed under a trade name or generic name, is substituted by a medicine which contains the same active ingredient(s), often a cheaper one.

Sometimes these tools are used alone, sometimes in parallel. INN prescribing goes often hand-in-hand with generic substitution. Other promotions could vary from fast track procedures for generics to information campaigns for patients and doctors. The tools for generic promotion can be **indicative or obligatory**. In specific cases there is a possibility for prescribers to exclude generics substitution even when this is mandatory (e.g. if there is a medical necessity).

**INN prescribing**, also called generic prescribing, is allowed in all EU Member States except in the four countries Austria, Denmark, Spain and Sweden. In Cyprus prescribing the INN is only allowed in the public sector. Only in five countries (Estonia, Lithuania, Portugal, Romania and Cyprus.) the generic prescribing is a mandatory. In some countries INN prescribing is widely practiced although it is indicative (e.g. the United Kingdom and the Netherlands). A reason for this could be the strong encouragement and/or the supporting electronic systems which make generic prescribing easier.

**Generic substitution** is allowed in 20 EU countries. The United Kingdom foresees the introduction of (obligatory) generic substitution as well. In more than half of the Member States where generic substation is allowed, the substitution is indicative. The year of introduction of the generic substitution is not always known. But looking into the available data, Denmark seems one of the first countries which started with generic substitution (1991). In 1997 this substitution became mandatory.

There are several **other promotions** to stimulate the use of generics. In nearly every country information activities are performed. In some countries (e.g. Portugal and Hungary) electric systems are developed to support generic prescribing.

Table 3.11:
Generic promotion in the EU countries, as of 2010 or latest available data

| Country | INN prescribing | | Generic substitution | | | Other promotion |
|---|---|---|---|---|---|---|
| | Allowed, Y/N | ind/obl | Allowed, Y/N | Year of intro. | ind/obl | |
| AT | N | - | N | | - | Various pilot projects, e.g. lower prescription fee for generics in one of the Austrian sickness funds |
| BE | Y | ind. | N | _ | - | Information activities targeted at general public |
| BG | Y | ind. | N [1] | _ | - | n.a. |
| CY | Y/N [2] | obl. (in public sector) | Y/N [2] | n.a. | obl. (in public sector) | n.a. |
| CZ | Y | ind. | Y | n.a. | ind. | Fast-track mechanism envisaged for generic pricing/ reimbursement |
| DE | Y | ind. | Y | 2004 [3] | obl. | Information activities targeted at general public |
| DK | N | - | Y | 1991 (mandatory in 1997) | obl. | Information activities targeted at general public |
| EE | Y | obl. | Y | n.a. | ind. | Information activities targeted at general public |
| EL | N | - | N | _ | - | n.a. |
| ES | Y | ind. | Y | 1997 | ind. | - Information activities targeted at general public<br>- Development of electronic system (in some regions) |
| FI | Y | ind. (in practice not used) | Y | 2003 | obl. | Information activities targeted at general public |

| Country | INN prescribing | | Generic substitution | | | Other promotion |
|---|---|---|---|---|---|---|
| | Allowed, Y/N | ind/obl | Allowed, Y/N | Year of intro. | ind/obl | |
| FR | Y | ind. | Y | 1999 | ind. | Social health insurance representatives visits prescribing, advertising campaigns on television |
| HU | Y | ind. | Y | 1995 | ind. | - Information campaigns<br>- Electronic system to indicate the preferred product |
| IE | Y | ind. | N | _ | - | Information activities targeted at general public |
| IT | Y | ind. | Y | 2001 | ind. | Information activities targeted at general public |
| LT | Y | obl. [4] | Y | 2004 | ind. | Information activities targeted at general public |
| LU | Y | ind. | N | _ | - | n.a. |
| LV | Y | ind. | Y | 2006 | ind. | Analysis of prescription information |
| MT | Y | ind. | Y | 2003 | obl. | n.a. |
| NL | Y | ind. [5] | Y | n.a. | ind. | - Information activities targeted at general public |
| PL | Y | ind. | Y | n.a. | ind. | n.a. |
| PT | Y | obl. | Y | 2000 | ind. | - Information campaign, promotion of switch of copy products to generics.<br>- Development of electronic tools to support the prescription |
| RO | Y | obl. | Y | n.a. | ind. | Rebates for generics are very common practice. |
| SE | N | - | Y | 2002 | obl. | - Incentive agreements (e.g. rewards)<br>- Committees point out first choice medicines (e.g. simvastatin)<br>- Information activities targeted at general public |
| SI | Y | ind. (not applied in practice) | Y | n.a. | ind. | Analysis of prescription information |
| SK | Y | ind. | Y | 2004 | obl. | Website where patients can check availability of generic versions of their medicines and verify co-payment levels |
| UK | Y | ind.[6] | N | _ | _ | Information activities targeted at general public |

ind. = indicative, obl. = obligatory, intro = introduction, n.a. = not available, INN = international non propriety name, reimb. = reimbursable medicines

Source: GÖG reports (mainly 2010d-e), PPRI (2007-2009), additional information provided by country experts employed by GÖG

1 BG: Generic substitution is discussed and there are plans for introduction
2 CY: INN prescribing and generic substitutions are not allowed in the private sector, but obligatory in the public sector
3 DE: Until 2002, pharmacists were only allowed to substitute drugs if explicitly indicated by physicians on the prescription. From 2002 on pharmacists were requested to substitute non-patented pharmaceuticals above a certain substitution price line by other products
4 LT: INN prescribing obligatory, but doctors can mark the trade name additionally
5 NL: Brand name is automatically changed to INN through an electronic prescribing system
6 UK: INN prescribing is indicative, although encourage and widely practiced

In the Netherlands both INN prescribing as generic substitution is allowed. They are widely used, though there is no obligatory for it. The brand name on Dutch prescriptions is automatically changed to the generic name through the present electronic prescribing system, which causes indirectly generic prescribing and as a consequence more use of generics. As in most other EU Member States there are information activities targeting the general public to promote generic use by another way than INN prescribing and generic substitution.

## 3.4 Case studies

### 3.4.1 The Netherlands

In the Netherlands there is a tendering like system in the form of a preference policy. Health care insurers use this policy to limit the reimbursement to lower priced labels of off-patent active ingredients. A tendering like process takes place between the insurer and the manufacturers.

#### 3.4.1.1 Goal

The Dutch preference policy was introduced to lower the pharmaceutical expenditure on generics through more competition on the market. Another objective was to get a more normal market with less space for discounts and bonuses and to lower the prices for patients. As said before insurers use the policy to limit the reimbursement to lower priced medicines.

#### 3.4.1.2 Introduction of the policy

Since July 1th 2005, five insurance companies (dominating 50% of the insurers' market) have decided to implement a joint preference policy; they only reimbursed the labels/manufacturer which they made preferable in a cluster, unless there was a medical need for a specific label. One year later two other insurance companies joined them as well. The main reason for setting up a preference policy together, was to guarantee the manufacturers a substantial market.

In July 2008, a couple of insurance companies have started an individual preference policy besides the joint policy. One of the reasons was the New Health Insurance Act in 2006, which leaved less space for collective agreements. Thereby the insurers became more convinced of the feasibility of an individual preference policy and the willingness of patients to switch to another generic medicine.

#### 3.4.1.3 Scope

The joint preference policy only applied for three products: simvastatin, pravastatin and omeprazol. All these products had high sales, the patent was expired and there were different generic variants on the market.

With the introduction of individual policies, the scope of medicines was extended. The number of products which are subject to a preference policy varies per insurer. In 2010 some insurance companies already included more than 50 active ingredients. This number is still increasing (the amount depends on the plans of the insurance companies).

The most products, which are subjected to a preference policy, are those with a lot of generic variants on the market. The policy does not exclude branded products, as these can be the lowest price label as well. No patented products are included, because these are no part of a cluster.

### 3.4.1.4 Criteria

The price is the most important criterion for choosing a preferred manufacturer. Besides that the ability of the manufacturer to supply the whole market is another one for most insurers.

### 3.4.1.5 Procedure

With the preference policy, insurers plan to cover at least one product (label) per active ingredient included in the positive list (e.g. the insurer limit reimbursement to simvastatin of label A and exclude other simvastatin labels)

A specific product by a selected manufacturer can become 'preferred' when they offer the lowest price in the national price list (*taxe*) of the cluster or fall within a price range of 5% with the lowest list price. With the individual policies some insurers narrowed the range to 3%, other left it at 5% but would only contract with a maximum of two preferred manufacturers.

The chosen products are preferred for the set period by the insurer; in the beginning this period was six months but currently it could also be three months. When the manufacturer of the preferred product does not have the capacity to supply the market or when the price will rise during the preference period, the medicine will not be preferred anymore. Of course the manufacturer may always decline the price in the preference period.

Pharmacists are not involved in the tendering process. The procedure is only between manufacturers and insurance companies. In the end pharmacists get from each insurer a list of the manufacturers who won the tender and became the preference. If the pharmacy delivers a non-preferred label to the patient, the patient has to pay for the difference between the price of the preferred label and the non-preferred label, except in case of medical need.

Some insurance companies have expressed the desire to expand their preference policy to therapeutic clusters of medicines with significant price differences, but small clinical differences. They would call it 'therapeutic tendering'. There are insurers which exclude already different formulations from reimbursement, e.g. controlled release products and fast-acting formulations.

### 3.4.1.6 Effects

The joint preference policy had no real consequences. The prices have barely decreased with the introduction of the policy. In the beginning only one label lowered the price to € 0.01 below the lowest cluster price. In the end all labels stayed between the set 5% rate. As a consequence every manufacturer was preferred.

On the other side, the individual preference policy led to a large price fall. Up to a reduction of 90% of the prices of the selected generic medicines could be observed. The total initial savings from the preference policies have exceeded expectations. The price cuts in 2008 alone projected annual savings

of 355 million euro of which 310 million came from generics. The other 45 million euro in savings were assumed to come from the shift from original brand products to generics. [7]

Through the preference policy, some generic market leaders lost their market present to smaller companies. It was possible for manufacturers with a low market share to become really big.

Apart from all the savings there are some negative effects as well. Some pharmacists were close to their had to close their pharmacy because they had a reduced income (e.g. discounts were no longer possible) or sell it to a pharmacy chain. To ensure a stable income the dispensing fee was increased. This resulted in an overall cost increase of 200 million euro. This development erodes the net value of originally projected saving, but the balance is still positive.

[7] Amount of cost savings extracted from Kanavos 2009

### 3.4.2 Germany

In Germany there is a rebate system with elements of tendering. The sickness funds make individual rebate agreements with the pharmaceutical industry. The rebate system is used by the insurers to control the rising levels of pharmaceutical expenditure.

#### 3.4.2.1 Goal

The rebate system was introduced to lower the medicines' prices and as a consequence to decrease the pharmaceutical expenditure.

#### 3.4.2.2 Introduction of the policy

The rebate system had his introduction in 2003. The whole process was subject to juridical reviews due to the legal issues centred on the question if insurance companies were qualified as public contracting bodies. The decision of the European Court in 2009 has made an end of this discussion; the sickness funds were qualified to perform the tendering process.

#### 3.4.2.3 Scope

The majority of the tendering was performed on generic products; 98% of the tenders in 2008 were for generic products. Some of the sickness funds have ventured tenders for patent-protected medicines, which is accounted for 2.9% of the total rebate sales volume. One of the largest sickness funds, AOK, organize tenders for more than 90 molecules.

#### 3.4.2.4 Criteria

Most contracts are based on price and volume agreements. The lowest price is the main criterion during the tendering, but other factors have influence as well. Sickness funds also define the ability to provide a more or less complete range of that product portfolio (i.e. the number of product presentations based on dosage).

#### 3.4.2.5 Procedure

The tendering process in the rebating system takes place between manufacturers and sickness funds. The sickness funds 'invite' the pharmaceutical industries to reduce their price lists by providing a rebate on the price.

Most of the tenders are organized in two main ways; on molecule (active ingredient) level and on basis of the product's portfolio. The first way, the one on molecule level, is most commonly used; companies bid separately for each active ingredient. For portfolio contracts products are grouped and companies are assessed by the level of rebate they can offer.

### 3.4.2.6 Effects

The achieved discounts/rebates have induced a price fall of over 80%. Nevertheless, the continued challenges to the legal framework in which the system operates remain a problem in Germany. Nowadays the rebate system is one topic of the German healthcare reforms.

### 3.4.3 Belgium

The tendering in the Belgium system is relative small. The price competition is similar to the KIWI model (the New Zealand model), where government performs public tenders for medicines within certain classes.

#### 3.4.3.1 Goal

In Belgium a tendering procedure was designed for the modification of reimbursement conditions of medicines for budgetary reasons. The government wanted to achieve lower pharmaceutical expenditure with the introduction of the tendering.

#### 3.4.3.2 Introduction of the policy

Tendering in the out-patient sector has been allowed since 2005 in Belgium. In the middle of 2007 the Ministry of Social Affairs launched the first two procedures.

#### 3.4.3.3 Scope

The tenders took place for only two products, simvastatin and amlodipin. The tender for amlodipin was abandoned because the winner of the tender was a company with no capacity to supply the market. Currently there are no plans to include further active ingredients.

#### 3.4.3.4 Criteria

The price is the only criterion which is applied at the tender decisions.

#### 3.4.3.5 Procedure

The procedure is similar to the KIWI model, named after the New Zealand's tendering model, in which the government performs public tenders. The company which offers the lowest price wins the tender. As a reward, this product will get a higher reimbursement rate.

#### 3.4.3.6 Effects

The tendering procedure of simvastatin have resulted in lower co-payments for patients and in 15 million euro of direct savings. It is argued whether the increase in (or switch to) atorvastatin or rovustatin consumption neutralized the savings made on simvastatin. These increases or switches could be due to lack of incentives for prescribers to prescribe the most cost-effective product in a therapeutic class (i.e. simvastatin). At the time of writing there are no tendering procedures in place anymore in Belgium.

### 3.4.4 Denmark

The only system in Denmark that has tendering elements is the reference price system (RPS). Every two weeks the prices could be changed and there could be a new 'winner'. The RPS is closely related to (and based on) the generic substitution scheme – for reimbursable medicines the reimbursement groups are identical to the substitution groups.

#### 3.4.4.1 Goal

The main goal of the policy is to establish cost savings. Besides that lower co-payments for patients were desirable.

#### 3.4.4.2 Introduction of the policy

Since 1991 generic substitution has been mandatory in Denmark. The government wants to lower the pharmaceutical expenditure and for that reason a regulation of generic substitution (the so-called G-Scheme) was established, starting with the beta-blockers. Through the G-scheme, doctors are obligatory to show on their prescription whether a medicine could be substituted. In the pharmacy only the cheapest medicine (a price different of at least €0.67) may be delivered.

#### 3.4.4.3 Scope

The procedure is applied for generics and their original products.

#### 3.4.4.4 Criteria

In Denmark only the price is a criterion. The lowest price wins the tender.

#### 3.4.4.5 Procedure

The tender takes part between the National Health Service and the manufacturers. Every two weeks the prices of medicines may lower. The company with the lowest price, 'the winner', takes almost full reimbursement market as there is mandatory generic substitution.

#### 3.4.4.6 Effects

Unfortunately there could not be found any information about the effects of the tendering like process.

### 3.4.5 Country comparison of case studies

In all countries the ultimate goal of the tendering is the same; to obtain a lower pharmaceutical expenditure by lowering the prices of medicines through price competition. An additional aim was to reduce the co-payments for patients.

The tendering like system has different extents in the four countries. Especially the included number of molecules varies, e.g. there were tender plans for two molecules in Belgium and for more than 90 active ingredients in Germany. This might have something to do with the experience with the policy. When there is more (positive) experience with tendering, an insurer or NHS may extent the number of molecules for the tender. In the Netherlands this is seen as well. The amount of included active ingredients is still increasing.

The price is the most important criterion in all countries. In Germany the ability to provide a wide range of a product portfolio can also influence the decision. In the Netherlands it is, next to a low price, really important that a company can supply the whole market. In Belgium this also plays a role, the tendering for amlodipin was abandoned because the supplier had no capacity. The winner of the tender will be given a higher or full reimbursement. This is observed in every country.

The majority of the tendering includes generic medicines. Sometimes also the original product is part of the tender. In the Netherlands the medicines have to be part of an interchangeable cluster, for that reason patented products are not included.

The information about the effects of the introduction of tendering like systems differs per country. In Denmark there is no information about the consequences available. In Belgium, Germany and the Netherlands the systems have caused costs savings, although it is argued in Belgium whether the costs savings have been neutralized by switches to other active ingredients or not.

At the moment there are no tendering procedures in place anymore in Belgium. In the other three countries the tendering like systems are still there.

# 4 Discussion/lessons learned

Pharmaceutical systems are constantly subject to change (e.g. through decisions made by governments, insurance companies or manufacturers). This report aims to provide the most up-to-date data, as of 2010. Unfortunately this was not always possible due to changes in the systems during the writing of the report.

It became clear that it is really important to have clear definitions of the indicators and terms that will be used. An example was the indicator price policies where there was focussed on the present price control. It was important to explain this in more detail; that only direct price control on manufacturers level was meant and not an indirect one because of wholesale mark-ups. Some policies were even excluded, like price notification, because there was a European-wide discussion about the right definition.

The PPRI Pharma Profiles that were used as an important source of specific country information, were set up with the help of a template to collect all the information. Every country had its own way to fill in this template; some countries wrote really extensively and others more briefly. This caused sometimes differences in the amount of gathered information.

This lack of information became for example clear during the research of the scope of the different price policies and procedures. The scope could extended to all medicines, reimbursable medicines, but also POM, OTC and included or excluded generics. Unfortunately not every country explained their scope in detail. In this report as much information as known was provided in the tables. It would be interesting to do further research after the different scopes and provide a clear table with all the information on the same detailed level.

In every table there was degree of standardization which makes it possible to compare the indicators. Sometimes specific country information about the indicators was really complex, which made it hard to standardize. Nevertheless, it was standardized but important information to know was provided in footnotes.

The case studies were performed on basis of a literature research. During the research it became clear that the amount of available information differs per country. More information could be found about the Dutch and the German systems than for the two other countries, Denmark and Belgium. Probably this can be partly due to the fact that the Dutch and the German systems get more attention of policy makers. For further research a recommendation could be to personally contact the different countries for missing information.

The definition of tender, tendering and tendering like systems remains a critical aspect. For this report the definition of 'tender' according the PHIS Glossary was used. This set definition of 'tendering like systems' is still interpreted really broad. Hence, there could be still discussed in which degree e.g. the Danish system is really a tendering like system.

There are some important lessons learned from this research:

» Pharmaceutical systems are constantly subjected to change. For this reason authors constantly have to make sure that the information is still up-to-date.
» It is really important to have clear definitions.
» Comparability of information about pharmaceutical systems could be difficult.
» Templates should have a good review process to make sure that all the wanted information is given.
» Concerning case studies, it could be useful to personally contact countries to collect the missing information.

# 5 Conclusions

The aim of this report is to provide more knowledge about the Dutch pharmaceutical system in the out-patient sector, in particularly about the pricing and reimbursement characteristics. The associated research question was: *How is the out-patient pharmaceutical system, in particular the pricing and reimbursement system, in the Netherlands organised compared to the other EU countries, with a special focus on tendering-like systems?*

It became clear that the European Union has 27 unique pharmaceutical systems, with regard to pricing and reimbursement characteristics. However, looking on the brief document of the Dutch system and the comparative analysis between the Netherlands and the other EU Member States, there can be stated that the Dutch pharmaceutical system is in a lot of ways the same organised as other European systems. Of course there always remain some differences.

Just like pharmaceutical systems also tendering like systems in countries are unique. This is due to the fact that every country shapes these to their needs. The case studies on tendering like systems showed that the system in the Netherlands has similarities to the tendering like systems Germany, Belgium and Denmark as well.

Looking at the pricing characteristics key policies like external price referencing and reference price systems are used in the Netherlands just as in most other EU countries. Like in the most European countries, also in the Dutch system there is a special VAT rates for medicines which is lower. Remarkably to say is the fact that there is no direct control on manufacturer level. A difference with a lot of Member States is the absence of a wholesale mark-up and the present of the pharmacy fee, instead of linear or regressive mark-ups.

The Dutch reimbursement scheme is product-specific. A positive list in place as is common in the EU. More unique is that there is only one reimbursement rate (100%).

Unlike in most other EU countries, patients in the Netherlands normally do not have to co-pay for medicines. One exceptions is when co-payments are made due to the reference price system. Just like the other Member States the Dutch system has mechanisms for vulnerable groups. Unique in this are the fiscal arrangements which are taken for people with a low income.

The generic promotion is the same as in most European countries; INN prescribing and generic substitution are allowed but not mandatory and also other promotions are present. Interesting is the developed electronic prescribing system in the Netherlands which automatically changes the brand name into the generic name.

The Dutch tendering like system, the preference policy, has the same goal as those in other countries, but differs in extent - especially the included number of molecules varies. The main criterion 'product price' was also seen in the other case studies.

In short, it can be stated that the Netherlands has an unique pharmaceutical system, but that there are also similarities with the systems of the other European countries.

# 6 Literature

CVZ 2006
Een zorgvuldige afweging (Brochure)

CVZ 2010
Farmacotherapeutisch Kompas
Accessible at: http://www.fk.cvz.nl/

CPB 2008
Prijsvorming van generieke geneesmiddelen: forse prijsdalingen in het nieuwe zorgstelsel
Accessible at: http://www.cpb.nl/nl/pub/cpbreeksen/document/175/
CPB: Centraal Plan Bureau: Bureau for Economic Policy Analysis for the Netherlands

GÖG 2008a
Arzneimittelsysteme in Bulgarien und Rumänien. Vienna

GÖG 2008b
Referenzpreissysteme in Europa. Vienna

GÖG 2008c
Tendering of Pharmaceuticals in EU Member States and EEA countries. Vienna

GÖG 2008d
Steuerung des Arzneimittelverbrauches am Beispiel Dänemark. Vienna

GÖG 2010a
Pharmaceutical system in Luxembourg. Factsheet. Vienna (not published)

GÖG 2010b
Pharmaceutical system in Slovenia. Factsheet. Vienna (not published)

GÖG 2010c
Pharmaceutical system in Czech Republic. Factsheet. Vienna (not published)

GÖG 2010d
Rationale Arzneimitteltherapie in Europa. Vienna

GÖG 2010e
Rational use of medicines in Europe. Executive summary. Vienna

Ministry of VWS 2006
Letter of Minister: Evalutatie preferentiebeleid. The Hague
GMT/VDG 2709247

Ministry of VWS 2008
Letter of Minister: Stand van zaken preferentiebeleid en tarief apotheekhoudenden. The Hague
GMT/VDG 2709247

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# Annex – Glossary

Active ingredient

Ingredient that alone or in combination with one or more other ingredients is considered to fulfil the intended activity of a medicine.

Anatomical, Therapeutic, Chemical classification (ATC classification)

A classification system developed by the WHO for medicines, whereby the active ingredients are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. The ATC classification includes three important levels:

- ATC 3 (pharmacologic):
Describes a medicine group with a comparable pharmacologic action, e.g. A10B – oral anti diabetics
- ATC 4 (chemical):
Describes a chemical subgroup of medicines, e.g. A10BA – biguanids
- ATC 5 (active ingredient):
Describes a specific active ingredient or a combination of active ingredients, e.g. A10BA02 – metformin

Brand name

Name given for marketing purposes to any ready-prepared medicine placed on the market under a special name and in a special pack. A brand name may be a protected trademark.

Co-payment

Insured patient's contribution towards the cost of a medical service covered by the insurer. Can be expressed as a percentage of the total cost of the service or as a fixed amount.

Deductible

Amounts required to be paid by the insured under a health insurance contract, before benefits become payable. Usually expressed in terms of an "annual" amount. Once the deductible is reached, the third party payer then pays up to 100% of approved amounts for covered services provided during the remainder of that benefit year.

Defined Daily Dose (DDD)

The DDD is a unit of measurement defined as the assumed average maintenance dose per day for a medicine used for its main indication in the adult. DDDs for plain substances are normally based on monotherapy. The DDD does not necessarily reflect the recommended or Prescribed Daily Dose.

Ex-factory price

The manufacturer's posted price. Discounts or other incentives offered by manufacturers result in an effective price that is lower than the ex-factory price.

External price referencing / international price referencing

The practice of using the price(s) of a medicine in one or several countries in order to derive reference price for the purposes of setting or negotiating the price of the product in a given country.

Fee-for service

Payments to a provider (e.g. a pharmacist) for each act or service rendered. Two common ones are the dispensing fee and the prescription fee.

*Prescription fee* The fixed fee that the patient has to pay for each prescription item dispensed on the expense of a third party payer, i.e. a form of fixed co-payment.

*Dispensing fee* Normally a fixed fee that pharmacies are allowed to charge per prescribed item instead of or in addition to a percentage mark-up. The dispensing fee could be paid by the third party payer.

Fixed Co-payment

An out-of-pocket payment in the form of a fixed amount (like for example a prescription fee) to be paid for a service, a medicine or a medical device.

Free Pricing

Pricing system, where medicine prices may be freely set.

Generics

Medicines which have the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product have been demonstrated by appropriate bioavailability studies.

Generic promotion

Any policy in place to promote the use of generics and/or (licensed) off-patent products. It includes generic substitution, international non-proprietary name (INN) prescribing or a range of other measures.

Generic substitution

Practice of substituting a medicine, whether marketed under a trade name or generic name (branded or unbranded generic), by a medicine, often a cheaper one, containing the same active ingredient(s).

Indicators

A parameter that aims to describe, in a few numbers as much detail as possible about a system, to help understand, compare, predict, improve, and innovate. .Indicators serve two major functions: They reduce the number of measurements and parameters that normally would be required to give a accurate picture of a situation, and they facilitate the communication process for providing the reader with the results of measurement.

Interchangeable pharmaceutical product

An interchangeable pharmaceutical product is one which is therapeutically equivalent to a comparator product and can be interchanged with the comparator in clinical practice.

International Non-proprietary Name (INN) prescribing

INN prescribing refers to physicians prescribing medicines by its INN, i.e. the active ingredient name instead of the brand name. INN prescribing may be indicative or required (mandatory INN prescribing).

List Price

The prices that purchasers display as the prices at which they are prepared to sell their products and/or regulated by legislation. The prices of products as quoted in the purchaser's price list, catalogue, internet site, advertisements, in a national price list/formulary etc.

Mark-up

The mark-up is the percentage of the purchasing price added on to get the selling price.
A mark-up is added on to the total cost incurred by the producer of a good in order to create a profit.

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|---|---|
| *Wholesale mark-up* | The gross profit of wholesalers, expressed as a percentage add-on to the ex-factory price. |
| *Pharmacy mark-up* | The gross profit of pharmacies expressed as a percentage add-on to the wholesale price (or pharmacy purchasing price). |

National Health Service (NHS)

The system of social security and health services, which is financed through general taxation (central or regional), usually covering all inhabitants/residents. The scope of services rendered is identical for every person covered and most services are offered by public institutions. In some countries people may opt for a complementary voluntary health insurance for services, which are not covered through the NHS.

Over-the-counter (OTC) medicines

Medicines which may be dispensed without a prescription and which are in some countries available via self-service in pharmacies a/o other retail outlets (e.g. drug stores). Selected OTC products may be reimbursed for certain indications in some countries.

Out-of Pocket Maximum (Annual Ceiling)

The maximum amount (e.g. a certain percentage of income) that an insured person has to pay for all covered health care services for a defined period (often a year).

Out-of-pocket payments (OPP)

The amount a person has to pay for all covered health care services for a defined period (often a year). It includes:

| | |
|---|---|
| *Fixed co-payments* | Out-of-pocket payments in the form of a fixed amount (e.g. the prescription fee) to be paid for a service, a medicine or a medical device. |
| *Percentage co-payments* | Cost-sharing in the form of a set proportion of the cost of a service or product. The patient pays a certain fixed proportion of the cost of a service or product, with the third party payer paying the remaining proportion. |
| *Deductibles* | Initial expense up to a fixed amount which must be paid out-of pocket for a service or over a defined period of time by an insured person; then all or a percentage of the rest of the cost is covered by a third party payer. |

Out-patient sector (ambulatory sector)

Sector which contains all possibilities of care which do not require an overnight stay. This sector is the opposite of the in-patient (hospital) sector.

Parallel imported medicines

Medicines which are purchased in one Member State, typically where income levels are relatively low, and sold into other Member States, where income levels and hence prices are higher (although there are exceptions to this, when high prices are being charged in lower income Member States).

Pharmaceutical system

A pharmaceutical system comprises the following elements: regulatory (marketing authorisation, market surveillance, vigilance), pricing, funding & reimbursement, supply chain / distribution and consumption of medicines.

Pharmacy purchasing price (PPP, wholesale price)

The price charged by wholesalers to the retailers (usually pharmacies). It includes any wholesale mark-up.

Pharmacy retail price (PRP)

The price charged by retail pharmacies to the general public. It includes any pharmacy mark-up or dispensing fee.

It can be a Gross PRP (including VAT) or a Net PRP (excluding VAT).

Prescription-only-medicines (POM)

Medicines which can be dispensed only on a prescription of a health professional.

Price negotiations

A form of pricing procedure, where medicine prices are discussed/negotiated (e.g. between manufacturer and third party payer).

Pricing

The act of setting a price for a medicine.

Pricing policies

Regulations or procedures used by government authorities to set or limit the amount paid by purchasers or the amount received by sellers (e.g. free pricing, statutory pricing, price negotiation and price control).

Pricing procedure

The method for determining the price of a medicine, e.g. internal price referencing, external price referencing, cost-plus pricing and profit control.

Reference Price System

The third party payer determines a maximum price (= reference price) to be reimbursed for certain medicines. On buying a medicine for which a fixed price / amount (the so-called reimbursement price) has been determined, the insured person must pay the difference between the fixed price / amount and the actual pharmacy retail price of the medicine in question, in addition to any fixed co-payment or percentage co-payment rates. Usually the reference price is the same for all medicines in a given ATC 4 level and/or ATC 5 level group.

Reimbursement

Reimbursement is the percentage of the reimbursement price (for a service or a medicine) which a third party payer pays. So 100% reimbursement means that the third party payer covers 100% of the reimbursement price / amount of a medicine or service except a possible prescription fee.

Reimbursement list

List which contains medicines with regard to their reimbursement status.
It can either be a positive list or a negative list.

*Positive list* List of medicines that may be prescribed at the expense of the third party payer.
*Negative list* List of medicines which cannot be prescribed at the expense of the third party payer

Reimbursement price

This price is the basis for reimbursement of medicines in a health care system, i.e. the maximum amount paid for by a third party payer. The reimbursed amount can either be the full reimbursement price (like e.g. Austria) or a percentage share of the reimbursement price (e.g. in Denmark). In a reference price system the reimbursement price is lower than the full price of the medicine, leaving the patient to pay the difference privately (or through complementary voluntary health insurance).

Reimbursement scheme (eligibility scheme)

The reimbursement system which covers the majority of residents in a country, in some countries also referred to as "general" reimbursement. There are, in general, four types of eligibility schemes:

* *Product-specific* : Eligibility for reimbursement depends on the medicine in question

* *Disease-specific* : Eligibility for reimbursement is linked to the underlying disease which shall be treated

* *Population-specific* : Specific population groups (e.g. children, old-age pensioners) are eligible for medicines, while others are not.

* *Consumption-based* : The level of reimbursement depends on the expenses for medicines of a patient within a certain period of time (increasing reimbursement with rising consumption)

Reimbursement rate

The share (mostly in percentage) of the price of a medicine or medicinal service, which is reimbursed/subsidised by a third party payer. The difference to the full price of the medicine or medicinal service is paid by the patients.

Reimbursement category

Medicines eligible for reimbursement are often grouped according to selected characteristics, e.g. route of administration (oral, etc.), main indication (oncology, paediatric, etc.), ATC level, classification (hospital-only, etc.). In many countries different reimbursement rates are determined for different reimbursement categories.

Remuneration

The payment of a health care provider (individual or organisation) for the services provided.

The services may be paid directly by the patient or by a third party payer.

Statutory pricing

Pricing system, where medicine prices are set on a regulatory basis (e.g. law, decree).

Social Health Insurance (SHI)

Social health insurance is a type of health care provision, often funded through insurance contributions by employers and employees as well as state subsidies. In many countries there are obligatory schemes for (employed) persons whose income does not exceed a certain amount/limit (= insurance obligation) in place.

Third Party Payer (Payer, Insurer, Purchaser)

Public or private organisation that pays or insures health or medical expenses on behalf of beneficiaries or recipients.

Tender

Any formal and competitive procurement procedure through which tenders/offers are requested, received and evaluated for the procurement of goods, works or services, and as a consequence of which an award is made to the tenderer whose tender/offer is the most advantageous.

A tendering like system is a system which has elements of tender procedures.

Value added tax (VAT)

A sales-tax on products collected in stages by enterprises. It is a wide-ranging tax usually designed to cover most or all goods and services, including pharmaceutical products. The VAT rate of medicines in the EU is often lower than the standard VAT rate.

Vulnerable groups

Groups within a society facing higher risks of poverty and social exclusion compared to the general population. These vulnerable and marginalised groups include but are not limited to: people with disabilities, isolated elderly people and children, people with low income etc.

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Source: Made by the author, based on PHIS Glossary. Vienna 2009. Latest update as of May 2010. Vienna. Accessible at: http://phis.goeg.at → Glossary