Pharmaceutical Pricing and Reimbursement Information

Belgium

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BELGIUM

Pharma Profile

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PPRI Representatives
National Institute for Health and Disability Insurance (RIZIV/INAMI): André DeSwaef, Yoeriska Antonissen

Authors
National Institute for Health and Disability Insurance (RIZIV/INAMI): André DeSwaef, Yoeriska Antonissen

Editors
Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG: Sabine Vogler, Christine Leopold (editor-in-chief)

PPRI Secretariat
Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG / Austrian Health Institute (GÖG/ÖBIG)

Executive Summary

BACKGROUND

Health insurance is one of the seven pillars of the Belgian social security system, the other six being the old-age and survivors' pensions, unemployment insurance, insurance for accidents at work, insurance for professional diseases, family benefits (mostly child support) and yearly vacation. All pillars are based on the principles of intra- and intergeneration solidarity.

The legal framework for the Belgian health care system, which originates from 1944, is the Law of 14 July 1994.

There is no separate funding for the seven pillars of the social security system. Generally speaking, 67% of the total funding comes from social contributions, 19% from taxes and duties and approximately 10% from government funding (general taxes). The social contributions are paid both by the employee (3.55% of a person's gross salary) and the employer (3.80% of the salary).

In 2004, total health expenditure (THE) was € 27.9 billion or 9.6% of gross domestic product (GDP). Public health expenditure (HE) accounts for about two thirds of the total expenditure (71.1% in 2003) and private health expenditure (HE) (co-payments, co-insurance) for approximately one third (28.9% in 2003).

At the central level, the Belgian National Institute for Health and Disability Insurance (Rijksinstituut voor ziekte- en invaliditeitsverzekering / Institut national d'assurance maladie-invalidité, RIZIV/INAMI) is responsible for the organisation of reimbursement of health care expenses. At a more decentralised level, organisation is left to the sickness funds. All decisions concerning the scope of the health insurance are made at the central level in close collaboration with various actors, i.e. the sickness funds, professional bodies of health care providers and the Government.

Health insurance is compulsory for all employees and everybody has free choice of one of the seven sickness funds. Due to the compulsory nature of the system, almost everybody has health insurance. Certain groups (low-income, disability, etc.) receive extra benefits, e.g. lower co-payments.

A total of 42,176 medical doctors (in- and out-patient) provide in-patient and out-patient health care for the Belgian population. In 2005, 4 doctors (not including dentists) were available per 1,000 inhabitants, and patients are free to choose their doctor. Since 2006, general practitioners (GP) have a limited role as gatekeepers, so mostly patients have direct access to specialist care (specialist or hospital).

Physicians are paid on a fee-for-service basis and through out-of-pocket payments (OPP) by patients, which can be partially or fully reimbursed depending on the social status of the patient.

Generally speaking, hospitals have five main sources of funding: a fixed annual budget based on historical all patient refined diagnosis-related group (APR-DRG) data; fee-for-service funding for certain activities, e.g. 1-day clinics and dialysis; part of the fees of doctors working in hospitals; profits made on pharmaceuticals and medical devices; and patients' out-of-pocket payments (OPP). Funding is gathered from various levels, the most important being the health care budget. Other sources of funding include the federal and regional governments.

PHARMACEUTICAL SYSTEM

The Medicines Act of 25 March 1964 and the Royal Decree of 14 December 2006 form the legislative framework for the production, registration and distribution of pharmaceuticals. The Royal Decrees of 10 November 1967 and 25 September 1974 regulate the opening and transferring of public pharmacies. Rules regarding competition among pharmacists are not fixed by decree but through auto-regulation by the Order of Pharmacists (Orde der Apothekers). Statutory pricing is obligatory for all pharmaceuticals marketed in Belgium and is regulated by two Ministerial Decrees, both of 29 December 1989, one for reimbursable and one for non-reimbursable pharmaceuticals. The reimbursement of pharmaceuticals is regulated by the Law of 14 July 1994 (legal framework) and the Royal Decree of 21 December 2001 (practical aspects of reimbursement).

The pharmaceutical sector is regulated by two main players: the Federal Pharmaceuticals and Health Products Agency (Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten, FAGG), which is responsible for all public health aspects of pharmaceuticals, registration, vigilance, etc. and the National Institute for Health and Disability Insurance (RIZIV/INAMI), which is responsible for the reimbursement of pharmaceuticals. Both are independent organisations working under the political responsibility of the Minister of Public Health and the Minister of Social Affairs, respectively. Besides these two main players, the Ministry of Economic Affairs is responsible for the pricing of pharmaceuticals. The Budget Minister, however, has an advisory role.

According to Eurostat there are 97 companies in Belgium that manufacture pharmaceutical preparations (2004). On 1 January 2007 there were 5,158 pharmacies in Belgium, all of which are privately owned. Pharmaceuticals can only be distributed by pharmacies and hospital pharmacies. The total sales of pharmaceuticals (prescription-only medicine(s) (POM) and over-the-counter (OTC) pharmaceuticals) in pharmacies amounted to € 3,989 Mio. (€°382 per inhabitant) in 2005. These sales are increasing year on year, although the yearly increase is declining. Since 1995 the pharmaceutical expenditure (PE) has risen by 80%, which is probably due to demographic factors, e.g. the ageing population, and scientific progress.

PRICING

The Ministry of Economic Affairs is the competent authority for setting the maximum prices of all pharmaceuticals. There are two pricing committees, one for reimbursed and one for non-reimbursed pharmaceuticals. Both committees have an advisory role. After the maximum price has been set by the Minister of Economic Affairs, the Reimbursement Committee (Commissie Tegemoetkoming Geneesmiddelen, CTG) can negotiate with the pharmaceutical

company to determine the reimbursement level that will be proposed to the Minister of Social Affairs, who makes the final decision concerning reimbursement.

All pharmaceuticals are subject to statutory pricing by the Ministry of Economic Affairs. European average prices and the relative value of the pharmaceutical with regards to a set price level are taken into account. The price set by the Minister of Economic Affairs is a maximum price, thus a pharmaceutical can never be marketed at a higher price than this. Although the pricing process leaves no room for negotiation, the actual applied price is subject to negotiations during the reimbursement process.

There is no system of free pricing in Belgium. Officially, public procurement/tendering are not applied. However, for vaccines manufacturers negotiate a price directly with the competent authorities (regions).

At the end of 2006 the legal basis was established for a new procedure (designed for the modification of reimbursement conditions for pharmaceuticals for budgetary reasons) based on the principles of “public tendering”. In general terms, an indirect competitive benefit is offered to the pharmaceutical company, by means of a lower co-payment for the patients for its pharmaceutical(s), offering the lowest cost for the treatment (from the health insurance and patient perspective).

Price decisions are always made at manufacturer level. Both internal and external price referencing are currently applied in Belgium. External price referencing is applied for all pharmaceuticals, whereas internal price referencing is only used for those pharmaceuticals where a comparable product is marketed in Belgium.

Both wholesale and pharmacy remuneration consist of a fixed mark up. For wholesalers, this mark up is statutorily fixed at 13.1% of the ex-factory price with a maximum of € 2.18. The mark up for pharmacies is statutorily fixed at 31% of the wholesale price with a maximum of €°7.44 for (non-hospital) pharmacies and of 22% for pharmaceuticals delivered in hospital pharmacies to non-hospitalised patients.

For all pharmaceuticals a value-added tax (VAT) of 6% is applied. There are no official discounts in Belgium. Due to the fact that the maximum mark up is limited for both wholesalers and pharmacies, margin cuts are not used as a tool for cost-containment.

In Belgium, regulated price cuts for “old pharmaceuticals” are applied (pharmaceuticals containing an active component that has been reimbursed for more than 12 years are reduced by 14% (ex-factory level); once the active component is reimbursed for more than 15 years, the applied pharmacy retail price (PRP) and the corresponding reimbursement basis are reduced by 2.3% (ex-factory level).

REIMBURSEMENT

In order to obtain reimbursement, the pharmaceutical company that is responsible for the commercialisation of the relevant pharmaceutical on the Belgian market must submit an application to the Reimbursement Committee (CTG).The Minister of Social Affairs makes a de-

cisions with regard to the reimbursement of pharmaceuticals on the basis of motivated proposals from the Reimbursement Committee (CTG).

Specific procedures (with specific application elements and time frames) are foreseen for applications for reimbursement of pharmaceuticals classified as class 1 (added therapeutic value), class 2 (line extensions, without added therapeutic value) or class 3 (generic) pharmaceuticals, along with orphan drugs and parallel traded pharmaceuticals.

According to EU Directives, the reimbursement procedure can take at the most 180 days for pharmaceuticals of classes 1, 2 or 3, or orphan drugs, and parallel traded pharmaceuticals can take at the most 90 days.

The actual procedures foresee that pharmaceutical companies must – in parallel – submit separate applications for price setting (Federal Public Service for Economy – procedure of 90 days) and for reimbursement (with the Reimbursement Committee (CTG). Although the maximum price of a pharmaceutical is set by the Minister of Economic Affairs, the Minister of Social Affairs determines the reimbursement basis and the resulting applied pharmacy retail price (PRP).

All reimbursed pharmaceuticals are placed on a positive reimbursement list, which consists of different chapters.

The Reimbursement Committee (CTG) studies files with regard to the following criteria:

- product-specific criteria (e.g. medical and therapeutic value, safety, lack of alternative therapies);
- economic criteria (e.g. price, cost-effectiveness, reference price, budget impact);
- patient-specific criteria (e.g. age, sex, chronic or terminal illness)
- disease-specific criteria (e.g. severity of illness, special medical needs).

The legal basis for the reimbursement categories is the Royal Decree of 21 December 2001. A reimbursement category is attributed to each reimbursed pharmaceutical and indicates to what extent the obligatory insurance is to reimburse the cost. This classification is not linked to price. The assignment of pharmaceuticals to these reimbursement categories (A, B, C, Cs or Cx) is carried out by the Minister of Social Affairs, based on a proposal by the Reimbursement Committee (CTG). Pharmaceuticals in the categories A, B and C are considered as “necessary” pharmaceuticals and they are classified according to their specific medical and therapeutic importance.

The reference price system was introduced by the Minister of Social Affairs on 1 June 2001 by means of the Royal Decree of 22 May 2001. The Reference price system is only applied for (off-patent) pharmaceuticals with generic alternatives (same active component). An original pharmaceutical enters the reference price system if a (cheaper) generic of the reimbursed pharmaceutical is available which contains the same active component(s) (same Anatomic Therapeutic Chemical (ATC) classification ATC 5). When an original pharmaceutical enters the reference price system, its reimbursement basis is diminished by 30% (of the ex-factory price), while its applied pharmacy retail price (PRP) remains the same. This means that a new

reimbursement basis is determined for each individual (new) reference pharmaceutical. The system has been extended on 1 July 2005 by only taking into account the active component (Anatomic Therapeutic Chemical (ATC) classification ATC 5) of the generic alternative.

Another extension of the reference price system was undertaken on 1 January 2007 to post-patent molecules without generic alternatives (e.g. esomeprazole – NEXIAM). Since January 2007 the reference price system can be applied to these molecules, at the request of the Reimbursement Committee (CTG).

In Belgium percentage co-payments are applied. Co-payment is limited to a percentage of the real cost, and limited to a "ceiling" fee.

The positive reimbursement list is valid for both the out-patient sector and the hospital sector. Thus there are no specific reimbursement conditions for pharmaceuticals when used in hospitals.

On 1 July 2006 a new financing system was introduced for pharmaceuticals dispensed in hospitals, according to which hospitals receive a fixed reimbursement sum for pharmaceuticals dispensed during a patient stay, independent of the real expenditure for that patient. Hospitalised patients are only charged a fixed daily amount of € 0.62 for dispensed reimbursed pharmaceuticals, while non-reimbursed pharmaceuticals are always charged in full.

The most important recent reimbursement-related cost-containment measures are the introduction of the extended reference price system (in 2005 and 2007) and the lowering of out-of-pocket payments for category B (ATC 4 level group) and C (ATC 4 level group) in 2007. In May 2008 they were again sustainably lowered.

RATIONAL USE OF PHARMACEUTICALS

A vast amount of prescription guidelines exist. Most of these are designed by non-profit-making organisations or are endorsed by the National Institute for Health and Disability Insurance (RIZIV/INAMI). Very important among these are those resulting from the consensus conferences that are organised twice a year by the National Institute for Health and Disability Insurance (RIZIV/INAMI). These conferences focus on the rational use of pharmaceuticals in a specific pathology with corresponding guidelines. Other guidelines are those of the Belgian Antibiotic Policy Coordination Committee (BAPCOC), with a specific focus on the use of antibiotics in ambulatory practice and in hospitals. The guidelines endorsed and drawn up by the National Institute for Health and Disability Insurance (RIZIV/INAMI) can be found on its web site and the results of the consensus conferences are sent to all doctors and pharmacists.

Information to patients and doctors concerning pharmaceuticals is regulated by Royal Decree. Direct advertising for over-the-counter (OTC) pharmaceuticals to patients is allowed, but must comply with these regulations and requires authorisation to be granted for the advertising campaign granted by the Supervisory Committee for Drug Advertising (Commissie van Toezicht op de reclame voor geneesmiddelen).

With regard to prescribing pharmaceuticals there are no budgetary constraints for doctors in Belgium, which means that there are no fixed monetary prescribing budgets. Since 1 April

2006, however, physicians are obliged to prescribe a minimum percentage of “cheap pharmaceuticals” (defined as generics or original pharmaceuticals included in the reference price system, with a price equal to the reimbursement basis, and pharmaceuticals prescribed by International Nonproprietary Name (INN)).

The experts of the National Institute for Health and Disability Insurance (RIZIV/INAMI) and the Belgian Health Care Knowledge Centre are in charge of the evaluation of the pharmacoeconomic guidelines. These methodological and reporting guidelines are developed as a tool to make pharmaceutical reimbursement requests submitted to the Reimbursement Committee (CTG) more consistent. These guidelines help the Reimbursement Committee (CTG) in the evaluation of the cost-effectiveness of the reimbursement requests and provide transparency for the companies regarding methodology and criteria. These health-economic analyses are performed by the company applying for reimbursement and by specialist consultants. No health-economic analysis is required in order to obtain market authorisation, and there is no obligation to produce such an analysis in order to receive a decision on the pharmaceutical price.

In Belgium all forms of substitution, including generic substitution, are not allowed.

Data about reimbursed pharmaceuticals delivered in pharmacies are collected by the Pharmanet system. This database is the property of the National Institute for Health and Disability Insurance (RIZIV/INAMI) and is updated every three months. Pharmacies send their data to an invoice office (Tariferingsdienst/Office de tarification) on a monthly basis, which in turn sends the data to the sickness fund. Once the data has been rendered anonymous by a trusted third party it is finally transmitted to the National Institute for Health and Disability Insurance (RIZIV/INAMI).

These data can be used by the Institute to create individual profiles of doctors, which are then used to give them feedback about their prescribing patterns. The data are however not used to monitor individual consumption of patients, as this is impossible because it has been rendered anonymous.

CURRENT CHALLENGES AND FUTURE DEVELOPMENTS

In 2008, the main current challenges are the implementation of the new chapter II control system, the need for administrative simplification, harmonisation and rationalisation regarding the pharmaceuticals, known as “chapter IV” pharmaceuticals(reimbursement is subject to specific restricting reimbursement conditions and a prior authorisation of the medical officer of the social insurance) and preventing patent disputes between the originator and the generic products companies to interfere with the implementation of reference pricing. Furthermore, a new remuneration system for pharmacists is to be implemented by 2010.

Table of content

List of tables and figures

List of abbreviations

APB	Belgian Pharmaceutical Association (Algemene Pharmaceutische Bond)
APR-DRG	All Patient Refined Diagnosis-Related Group(s)
ATC	Anatomic Therapeutic Chemical classification
BAPCOC	Belgian Antibiotic Policy Coordination Committee
BCFI	Belgian Centre for Pharmacotherapeutical Information
CHMP	Committee for Medicinal Products for Human Use
CRP	Price Committee for Non-reimbursable pharmaceuticals – Federal Public Service of Economic Affairs (Commissie tot Regeling der Prijzen)
CTG	Reimbursement Committee (Commissie Tegemoetkoming Geneesmiddelen) (RIZIV/INAMI)
DDD	Daily Defined Dose
FAGG	Federal Pharmaceuticals and Health Products Agency (Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten)
FeBelGen	Belgian Association of the Generics Industry
FOD VVVL	Federal Public Service of Health (Federale Overheidsdient Volksgezondheid, Veiligheid van de voedselketen en Leefmilieu)
FTP	File Transfer Protocol
GDP	Gross Domestic Product
GGE	General Government Expenditure
GP	General Practitioner
HE	Health Expenditure
HOM	Hospital-Only Medicine(s)
Mio.	Million
MPP	Medicinal Product Packing
MR	French-speaking liberal democrat party
n.a.	not available

n.app.	not applicable
NCU	National Currency Unit
OECD	Organisation for Economic Co-operation and Development
OPHACO	Organisation of Cooperative Pharmacies (Organisation des Pharmacies Cooperatives)
OTC	Over-The-Counter (pharmaceuticals)
PE	Pharmaceutical Expenditure
PFS	Price Committee for Reimbursable Pharmaceuticals – Federal Public Service of Economic Affairs (Prijzencommissie voor de Farmaceutische Specialiteiten)
POM	Prescription-Only Medicine(s)
PPI	Proton Pump Inhibitor(s)
PPPa	Purchasing Power Parity
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy Retail Price
PS	French-speaking socialist democratic party (“partie socialiste”)
QALY	Quality-Adjusted Life Year
R&D	Research and Development
RIZIV/INAMI	National Institute for Health and Disability Insurance (Rijksinstituut voor ziekte- en invaliditeitsverzekering / Institut national d’assurance maladie-invalidité)
SPA	Dutch-speaking socialist democratic party
SPC	Summary of Product Characteristics
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
VAT	Value-Added Tax
VLD	Dutch-speaking liberal democrat party
VZA	Belgian Society of Hospital Pharmacists (Belgische Vereniging van Ziekenhuisapothekers)

WHO	World Health Organization
WVVH	Scientific Society of Flemish General Practitioners (Wetenschappelijke Vereniging van Vlaamse Huisartsen)

PPRI Pharma Profile Update 2008

Rationale

In the beginning, the Pharmaceutical Pricing and Reimbursement Information (PPRI) project was a 31 month-project (2005-2007) commissioned by the Health and Consumer Protection Directorate-General (DG SANCO) of the European Commission and co-funded by the Austrian Federal Ministry of Health, Family and Youth (Bundesministerium für Gesundheit, Familie und Jugend, BMGFJ). The project was coordinated by the main partner Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG (GÖG/ÖBIG) and the associated partner World Health Organisation (WHO) Regional Office for Europe. The PPRI project has established a network of more than 50 participating institutions (competent authorities and other relevant organisations) in the field of pharmaceuticals (for the list of PPRI members see the PPRI website http://ppri.oebig.at → Network)

Within the course of the PPRI project, country reports on pharmaceutical pricing and reimbursement systems, the "so-called PPRI Pharma Profiles", were produced (see http://ppri.oebig.at → Publications → Country Information. These PPRI Pharma Profiles refer, in general, to the year 2006/2007. The works was mainly under the responsibility of the WHO Regional Office for Europe assisted by the team of the Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG / Austrian Health Institute (GÖG/ÖBIG).

Despite of the official end of the research project in 2007, the PPRI network participants have agreed to continue the network and up-date the PPRI Pharma Profiles.

Outline

The PPRI Pharma Profile consists of six chapters, referring to the situation in 2008:

- Chapter 1 (Background) gives a brief overview of the demographic, economic and political situation and a brief introduction to the health care system.
- Chapter 2 (Pharmaceutical system) provides a description of the pharmaceutical system; the regulatory framework, the pharmaceutical market, the market players and the funding of pharmaceuticals and the methods of evaluating the system.
- Chapter 3 (Pricing) covers a description of the organisation of the pricing system, the pricing policies, the pricing procedures, exceptions to these procedures, as well as a section on margins and taxes and pricing related cost-containing measures.
- Chapter 4 (Reimbursement) covers a description of the organisation of the reimbursement system, the reimbursement scheme including the eligibility criteria, the reimbursement categories and rates and the reimbursement lists. Also described in this chapter is the reference price system, the private pharmaceutical expenditure, the reimbursement in the hospital sector and the reimbursement related cost-containing measures.
- Chapter 5 (Rational Use of Pharmaceuticals) is a description of the methods used to improve rational use of pharmaceuticals including the impact of pharmaceutical budget, prescription guidelines, patient information, pharmaco-economics, generics and consumption.

- Chapter 6 (Current challenges and future developments) is a concluding chapter on the current challenges and future plans for developments in the pharmaceutical sector.

Further deliverables

Besides the PPRI Pharma Profiles and the PPRI network, the PPRI project produced further deliverables, among those:

- The **PPRI Glossary**, which is a unique glossary of pharmaceutical terms to establish a common "pharma" terminology within the EU. See http://ppri.oebig.at → Glossary
- The **PPRI Conference**, held in Vienna in June 2007. See http://ppri.oebig.at → Conferences → PPRI Conference
- The **Set of Core PPRI Indicators** to compare information of different pharmaceutical system. See http://ppri.oebig.at → Publications → Indicators
- A comparative analysis, based on the developed indicators, filled with real data from 27 PPRI countries. The PPRI comparative analysis is included in the **PPRI Report** and summed up in the concise report **"PPRI at a Glance"**. See http://ppri.oebig.at → Publications → PPRI Report and http://ppri.oebig.at → Publications → Concise Information

Contact

The PPRI Secretariat is located at Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (GÖG/ÖBIG) which featured as the main partner of the PPRI research project.

Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (GÖG/ÖBIG)
Stubenring 6, 1010 Vienna, Austria
E-Mail: ppri@goeg.at
Fax.: +43 1 5138472
URL: http://ppri.oebig.at

Dr. Sabine Vogler, PPRI Project Manager, E-Mail: vogler@goeg.at, Tel.: + 43-1-51561/147

Mag. Claudia Habl, Deputy Project Manager, E-mail: habl@goeg.at, Tel.:+ 43-1-51561/161

Mag. Christine Leopold, MSc., Communication Officer & Editor-in-Chief,
E-mail: Leopold@goeg.at, Tel. +43-1-51561/149

1 Background

1.1 Demography

Belgium has 10.6 Mio. inhabitants and a land surface area of 30,528 km² which results in a population density of 346 inhabitants per km². The population of the capital, Brussels, is by itself just 145,917, but the 19 communities that form the Brussels Capital Region have a population of approximately 1 Mio. people. The largest cities are Antwerp, where 466,203 people live, followed by Ghent with 235,143, Charleroi with 201,550 and Liège with 188,907 inhabitants.[1]

As is the case in various other European countries, the share of the population over the age of 64 has been increasing and that of the population under 64 has been decreasing since 2000 (cf. Table 1.1). The fact that this evolution will strain the long-term viability of the Belgian social security system has led to various government initiatives, e.g. the “Silver fund” (het Zilverfonds) and the “Generation pact” (het Generatiepact). These initiatives are focused, respectively, on keeping the existing pension system (a pay-as-you-go system) financially sound and on stimulating people to work longer than they do at present.

A Belgian born in 2006 can expect to live 79.83 years on average: 82.65 years if female and 77.01 years if male. Since 1995, Belgians have gained about two years in life expectancy, with men showing greater increase than women. In the year 1997, the three leading causes of mortality were cardiovascular diseases (37,954 deaths), malignant cancer (28,041 deaths) and diseases of respiratory organs (10,672 deaths).

[1] Data for 2007, Source: FOD Economie - Algemene Directie Statistiek en Economische Informatie, Dienst Demografie

Table 1.1: Belgium - Demographic indicators 2000-2007

Variable	2000	2001	2002	2003	2004	2005	2006	2007
Total population	10,239,085	10,263,414	10,309,725	10,355,844	10,396,421	10,445,852	10,511,382	10,584,534
Population density per km^2	338.17	338.97	340.50	342.03	343.37	345.00	345.00	346.00
Population aged 0-14 (in % of total)	17.63	17.59	17.51	17.41	17.29	17.18	17.09	16.98
Population aged 15-64 (in % of total)	65.62	65.56	65.55	65.57	65.59	65.59	65.70	64.91
Population aged > 64 (in % of total)	16.75	16.85	16.94	17.02	17.12	17.23	17.21	17.10
Life expectancy at birth, total	78.29	78.59	78.67	78.82	79.47	n.a.	79.83	n.a.
Life expectancy at birth, females	81.42	81,67	81.69	81.69	82.36	82.36	82.65	n.a.
Life expectancy at birth, males	75.08	75.42	75.58	75.85	76.47	76.64	77.01	n.a.

Source: FOD Economie - Algemene Directie Statistiek en Economische Informatie, Dienst Demografie

1.2 Economic background

In 2005, Belgium had a gross domestic product (GDP) of € 298,541 Mio. and a gross domestic product (GDP) per capita of € 28,580. As is apparent in Table 1.2, gross domestic product (GDP) has increased since 1995, although there are considerable changes in the growth rate. In 2005 the Belgian Government spent € 68,496 Mio. or just under 23% of gross domestic product (GDP). There is no general trend towards privatisation in health care, although the use of private health insurance is growing.

Table 1.2: Belgium - Macroeconomic indicators 2000-2007

Variable (in NCU = euro or percentage)	2000	2001	2002	2003	2004	2005	2006	2007
GDP in Mio. €	251,741	258,883	267,652	274,658	289,509	298,541	n.a.	n.a.
GDP / capita in €	24,586	25,224	25,961	26,522	27,847	28,580	n.a.	n.a.
GDP / capita in PPPa	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Annual economic growth rate in %[1]	3.7	0.8	1.5	1.0	3.0	1.1	n.a.	n.a.
General government expenditure (GGE) in Mio. €	53,678	56,378	60,303	63,163	66,177	68,496	n.a.	n.a.
GGE in % of GDP	21.32	21.78	22.53	23.00	22.86	22.94	n.a.	n.a.
Exchange rate (NCU per €), annual rate	n.a.	n.a.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.

GDP = gross domestic product, PPPa = purchasing power parity, n.a. = not available, GGE = general government expenditure, NCU = national currency unit

[1] variance to previous year in %

Source: Eurostat

1.3 Political context

Belgium is a parliamentary democracy with a federal monarchy. Legislative and executive powers are divided between the Federal Government, the regions (Gewest/Région) (Flanders, Wallonia and Brussels) and the Communities (Gemeenschap/Communauté/Gemeinschaft) (Flemish, French and German).

The federal legislation is exercised by the two Chambers of Parliament – the Chamber of Representatives (Kamer van Volksvertegenwoordigers/Chambre des Représentants) and the Senate (Senaat/Sénat). The Chamber of Representatives, which has 150 members, is the legislative authority. The Senate has 71 members and can only review legislation but has no power of veto.

The King is Belgium's Head of State. The Federal Cabinet consists of the Prime Minister and also a number of ministers appointed by the King.

The current Government (since March 2008) is a coalition government formed by christian, liberal and social democrats. Due to the federal nature of the country the Government is formed by five parties, two from the Dutch-speaking part, CD&V (Christian Democratic and Flemish party) and Open VLD (Liberal Democratic party); and three from the French-speaking part, MR (liberal democrats), PS (socialist party) and CDH (Christian Democratic party).

1.4 Health care system

1.4.1 Organisation

Health care in Belgium is a mixed private–public system; private, because most health care providers are not state owned; and public, because the reimbursement of health care costs is state regulated.

Health insurance is one of the seven pillars of the Belgian social security system, the other six being the old-age and survivors' pensions, unemployment insurance, insurance for accidents at work, insurance for professional diseases, family benefits (mostly child support) and yearly vacation. All pillars are based on the principles of intra- and intergeneration solidarity.

Health insurance is compulsory for all employees[2] and everybody has free choice of one of the seven sickness funds. Due to the compulsory nature of the system, almost everybody has health insurance. Certain groups (low-income, disability, etc.) receive extra benefits, e.g. lower co-payments.

The legal framework for the Belgian health care system, which originates from 1944, is the Law of 14 July 1994.

At the central level, the Belgian National Institute for Health and Disability Insurance (Rijksinstituut voor ziekte- en invaliditeitsverzekering / Institut national d'assurance maladie-invalidité, RIZIV/INAMI) is responsible for the organisation of reimbursement of health care expenses. At a more decentralised level, organisation is left to the sickness funds. Notwithstanding their private nature, the sickness funds are responsible for the correct application of the regulations and they can be held partially financially responsible in the event that the budget is exceeded.

All decisions concerning the scope of the health insurance are made at the central level in close collaboration with various actors, i.e. the sickness funds, professional bodies of health care providers, and the Government.

1.4.2 Funding

Since 1994 there is no longer any separate funding for the seven pillars of the social security system. It is therefore impossible to describe the funding of health care separately. Generally speaking, 67% of the total funding comes from social contributions, 19% from taxes and duties and approximately 10% from government funding (general taxes). The social contributions are paid both by the employee and the employer and are respectively 3.55% and 3.80% of a person's gross salary. There is no ceiling on the amount to be paid by each insured person.

[2] For reasons of brevity only the system for employees will be described although there exist three systems of social security in Belgium, one for employees, one for self-employed workers and one for federal civil servants.

In 2004 total health expenditure (THE) was € 27.9 billion or 9.6% of gross domestic product (GDP). Public health expenditure (HE) accounts for approximately two thirds of the total expenditure (71.1% in 2003) and private health expenditure (HE) (co-payments, co-insurance) for about one third (28.9% in 2003).

Table 1.3: Belgium - Health expenditure (HE) 2000-2007

Health expenditure (HE)	2000	2001	2002	2003	2004	2005	2006	2007
THE in NCU (Mio. €)	21,032	21,032	23,748	25,799	27,907	n.a.	n.a.	n.a.
THE in % of GDP	8.4	8.6	8.9	9.4	9.6	n.a.	n.a.	n.a.
THE per capita in €	2,054	2,049	2,303	2,491	2,684	n.a.	n.a.	n.a.
Public HE as a % of THE[1]	71.1	n.a.	n.a.	71.1	n.a.	n.a.	n.a.	n.a.
Private HE as a % of THE[1]	28.9	n.a.	n.a.	28.9	n.a.	n.a.	n.a.	n.a.

GDP = gross domestic product, HE= health expenditure, THE = total health expenditure, NCU = national currency unit, n.a. = not available

[1] Extrapolated from the OECD Factbook 2006

Source: Eurostat

1.4.3 Access to health care

A total of 42,176 medical doctors (cf. Table 1.4) provide in-patient and out-patient health care for the Belgian population. It is not possible to distinguish between in- and out-patient doctors[3] due to fact that only the mail address is known, and their workplace. In 2005, 4 doctors (not including dentists) were available per 1,000 inhabitants.

1.4.3.1 Out-patient care

Out-patient medical care is provided by 42,176 medical doctors. Of them, 18,216 are general practitioners (GP), 23,960 specialists and 8,655 dentists (these are not included in the total number of medical doctors). All of them work in private practice, though not necessary in a profit-making setting. Most physicians work in individual (single-doctor) practices, although there is a trend towards group practices, especially amongst younger doctors. Furthermore, there is a trend in Belgium towards limiting hospitalisations and if possible treating patients in the out-patient departments of hospitals, especially in specialist care cases (oncology, dialysis).

Patients are free to choose their doctor and can change as often as they want without any limitations. This choice is not limited to general practitioners (GP) or dentist but also extends to specialists. Since 2006, general practitioners (GP) have a limited role as gatekeeper, so patients mostly have direct access to specialist care (including in hospitals). Recently, measures to improve this gatekeeper role include reductions in out-of-pocket payments (OPP) for patients referred to a specialist by their general practitioner (GP).

[3] Note: all doctors can provide out-patient care (even those working in hospitals). Therefore, the number of out-patient doctors corresponds to the total number of doctors.

Physicians are paid on a fee-for-service basis and through out-of-pocket payments (OPP) by patients. These out-of-pocket payments (OPP) can be partially or fully reimbursed depending on the social status of the patient.

Table 1.4: Belgium - Out-patient care 2000-2007

Variable	2000	2001	2002	2003	2004	2005	2006	2007
Total number of doctors[1]	39,519	n.a.	40,763	n.a.	41,734	42,176	n.a.	n.a.
Number of doctors per 1,000 inhabitants[1]	3.9	n.a.	4.0	n.a.	4.0	4.0	n.a.	n.a.
Total number of out-patient doctors	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
thereof GPs	17,974	n.a.	18,244	n.a.	18,377	18,216	n.a.	n.a.
thereof dentists	8,465	n.a.	8,553	n.a.	8,660	8,655	n.a.	n.a.
Number of out-patient doctors per 1,000 inhabitants	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Number of out-patient clinics departments ("ambulatories")	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

[1] not including dentists

n.a. = not available, GP = general practitioner

Source: RIZIV/INAMI, Medical Direction

1.4.3.2 In-patient care

Hospital care in Belgium is offered both by private and public hospitals. Both are integrated into the Belgian social security system, but they have different owners. A patient will have his or her hospital costs reimbursed regardless of the hospital, apart from some exceptions. In total there were 147 hospitals providing in-patient care in 2005, a number that is down from 224 in 1995, mainly due to mergers. This results in a ratio of 7.41 acute care beds per 1,000 patients, 60% of which are provided by the private sector. Most doctors are associated with a hospital as independent workers and are paid on a fee-for-service basis as out-patient doctors.

Officially, there is neither specialisation nor a hierarchy of hospitals, although in practice there often is. Some hospitals have a good reputation for treating certain diseases and thus attract more people, which in turn enhances its reputation. University hospitals are often the only ones to treat rare diseases and are often where innovative techniques are first introduced.

Generally speaking, hospitals have five main sources of funding: a fixed annual budget based on historical all patient refined diagnosis-related group (APR-DRG) data; fee-for-service funding for certain activities, e.g. 1-day clinics and dialysis; part of the fees of doctors working in hospitals; profits made on pharmaceuticals and medical devices; and patients' out-of-pocket payments (OPP). Funding is gathered from various levels, the most important being the health care budget. Other sources of funding include the federal and regional governments.

Patients' out-of-pocket payments (OPP) (€ 40.59 for the first day and € 13.32 per day thereafter) for the hospital stay itself are only a very small part of a patient's total bill. The most significant costs for hospitalised patients are pharmaceuticals and doctors' fees.

Table 1.5: Belgium - In-patient care 2000-2007

Variable	2000	2001	2002	2003	2004	2005	2006	2007
Number of inpatient doctors	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Number of inpatient doctors per 1,000 inhabitants	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Number of hospitals	160	n.a.	152	n.a.	146	147	n.a.	n.a.
Number of acute care beds	79,509	n.a.	78,048	n.a.	77,716	77,440	n.a.	n.a.
thereof in private sector	45,992	n.a.	45,640	n.a.	46,164	45,548	n.a.	n.a.
Acute care beds per 1,000 inhabitants[1]	7.77	n.a.	7.57	n.a.	7.48	7.41	n.a.	n.a.
Average length of stay in hospital	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

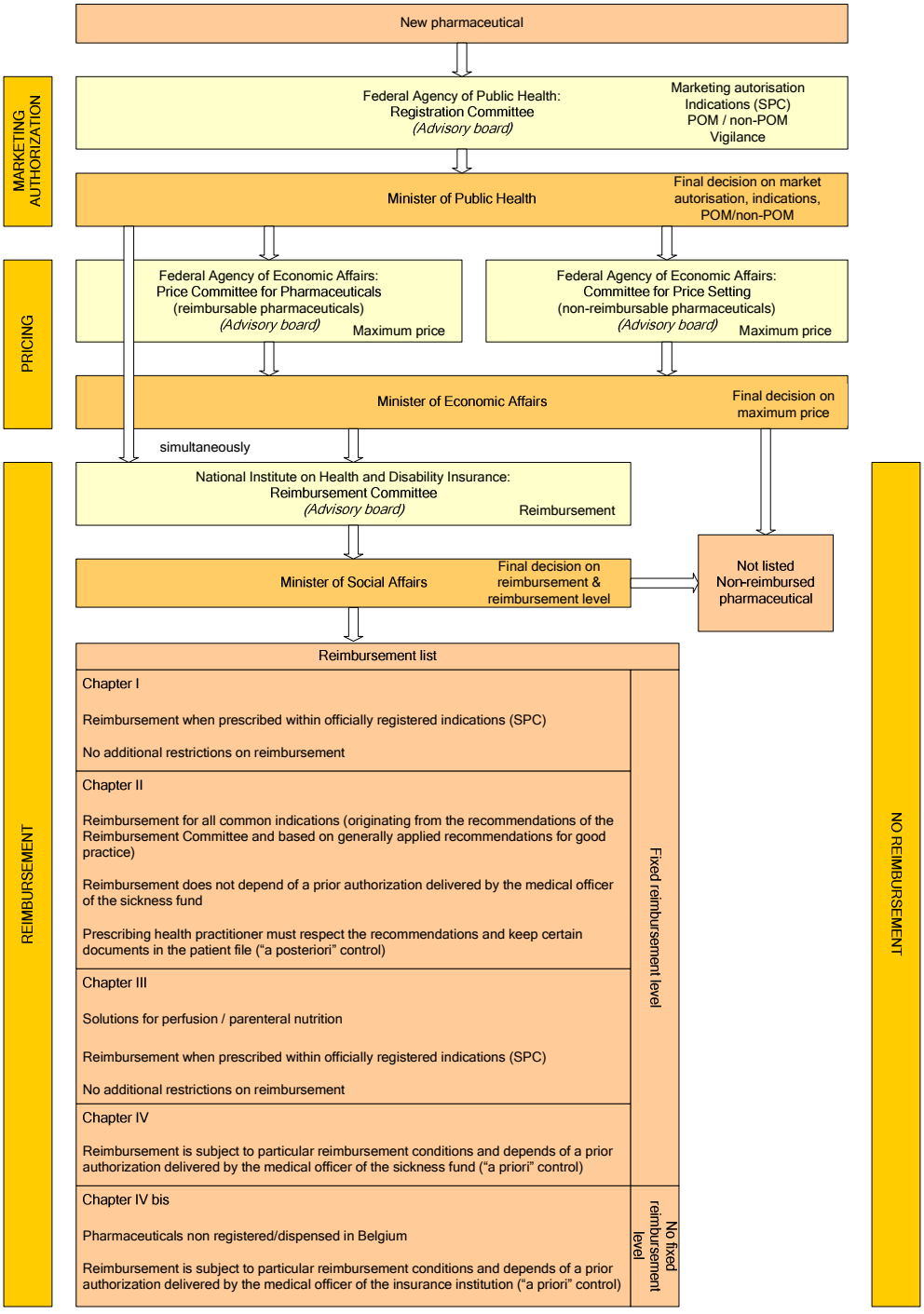
n.a. = not available

Source: Ministry of Public Health

2 Pharmaceutical system

2.1 Organisation

Figure 2.1: Belgium - Flowchart of the pharmaceutical system 2008



Source: RIZIV/INAMI

2.1.1 Regulatory framework

The pharmaceutical sector is regulated by two main actors: the Federal Pharmaceuticals and Health Products Agency (Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten, FAGG), which is responsible for all public health aspects of pharmaceuticals, registration, vigilance, etc., and the National Institute for Health and Disability Insurance (RIZIV/INAMI), which is responsible for the reimbursement of pharmaceuticals. Both are independent organisations with their own boards, but they work under the political responsibility of the Minister of Public Health and the Minister of Social Affairs, respectively. Besides these two main players, the Ministry of Economic Affairs is responsible for the pricing of pharmaceuticals (cf. section 3.). The Budget Minister, however, has an advisory role.

2.1.1.1 Policy and legislation

Various legislative acts regulate the pharmaceutical sector. The Medicines Act of 25 March 1964 (Wet op de geneesmiddelen) and the Royal Decree of 14 December 2006 form the legislative framework for the production, registration and distribution of pharmaceuticals.[4] The Royal Decrees of 10 November 1967 and of 25 September 1974 regulate the opening and transferring of public pharmacies. Rules regarding competition among pharmacists are not fixed by decree but through auto-regulation by the Order of Pharmacists (Orde der Apothekers). Statutory pricing is obligatory for all pharmaceuticals marketed in Belgium and is regulated by two Ministerial Decrees, both of 29 December 1989, one for reimbursable and one for non-reimbursable pharmaceuticals. The reimbursement of pharmaceuticals is regulated by the Law of 14 July 1994 (legal framework) and the Royal Decree of 21 December 2001 (practical aspects of reimbursement).

2.1.1.2 Authorities

Until 31 December 2006 the Belgian Ministry of Public Health (Federale Overheidsdient Volksgezondheid, Veiligheid van de voedselketen en Leefmilieu, FOD VVVL) was responsible for granting market authorisations, classification of pharmaceuticals according to prescription status, regulating distribution and vigilance of human and veterinary pharmaceuticals, along with medical devices. From 1 January 2007 this role has been taken over by the Federal Pharmaceuticals and Health Products Agency (FAGG).

The Medicines Act distinguishes a standard procedure for gaining a full market authorisation and a simplified procedure for gaining full market organisation, the latter of which is only applicable for certain types of products, e.g. generics. Data concerning the delays in granting market authorisation are not available.

Pricing of pharmaceuticals is the competence of the Minister of Economic Affairs, assisted by two pricing committees: one for reimbursable pharmaceuticals, the Pricing Committee for Pharmaceutical Specialties (Prijzencommissie voor de Farmaceutische Specialiteiten, PFS); and one for non-reimbursable pharmaceuticals, the Pricing Committee for Non-reimbursable Pharma-

[4] For a complete review of all acts and decrees governing the public health aspect of pharmaceutical, please consult following website: https://portal.health.fgov.be/portal/page?_pageid=56,4346389&_dad=portal&_schema=PORTAL

ceuticals (Commissie tot Regeling der Prijzen, CRP). The Pricing Committee for Pharmaceutical Specialties (PFS) is composed of representatives of the workers' unions, pharmacists, sickness funds, pharmaceutical industry and the Government.

Decisions regarding reimbursement of pharmaceuticals are made by the Minister of Social Affairs, on the basis of the advice of the Reimbursement Committee (Commissie Tegemoetkoming Geneesmiddelen, CTG), a body consisting of 56 experts nominated by various concerned groups, i.e. the Medical departments of the Belgian universities, the sickness funds and professional bodies of doctors and pharmacists. Their advice regarding reimbursement (conditions) is based on multiple parameters, e.g. the therapeutic value, safety, efficacy and price of the pharmaceutical in question.

Table 2.1: Belgium - Authorities in the regulatory framework of the pharmaceutical system 2008

Name in local language (Abbreviation)	Name in English	Description	Responsibility
Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten (FAGG)	Federal Pharmaceuticals and Health Products Agency	Regulatory body for pharmaceuticals regarding registration, distribution, vigilance	Granting marketing authorisations Regulating distribution Vigilance
Minister van Volksgezondheid	Minister of Public Health	Minister of Public Health	Final decisions regarding registration, distribution, vigilance
Prijzencommissie voor de Farmaceutische Specialiteiten (PFS)	Pricing Committee for Pharmaceutical Specialties	Advisory Board composed of experts nominated by various institutions	Advising the Minister of Economic Affairs with regards to the maximum price of reimbursable pharmaceuticals
Commissie tot Regeling der Prijzen (CRP)	Pricing Committee for Non-reimbursable Pharmaceuticals	Advisory Board composed of experts nominated by various institutions	Advising the Minister of Economic Affairs with regards to the maximum price of non-reimbursable pharmaceuticals
Minister van Economie	Minister of Economic Affairs	Minister of Economic Affairs	Final decision on maximum prices for both reimbursable and non reimbursable pharmaceuticals
Commissie Tegemoetkoming Geneesmiddelen (CTG)	Committee for the Reimbursement of Pharmaceuticals	Advisory Board composed of experts nominated by various institutions	Advising the Minister of Social Affairs with regards to reimbursement decisions
Minister van Sociale Zaken	Minister of Social Affairs	Minister of Social Affairs	Final decision regarding reimbursement of pharmaceuticals

Source: RIZIV/INAMI

2.1.2 Pharmaceutical market

2.1.2.1 Availability of pharmaceuticals

Table 2.2 gives an overview of the pharmaceuticals that are authorised respectively on the market.

Table 2.2: Belgium - Number of pharmaceuticals 2000-2008[1]

Pharmaceuticals	2000	2001	2002	2003	2004	2005	2006	2007	2008
Authorised (*)	6,362	7,289	8,000	9,031	9,785	10,817	11,480	12,391	14,326
On the market	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
POM (*)	4,214	5,023	5,659	6,596	7,294	8,277	8,874	9,727	11,622
Reimbursable (**)	n.a.	3.929	4.046	4.030	4.259	4.363	4.888	6.063	6.530
Generics	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Parallel traded (***)	16	24	49	73	99	137	176	198	257
Hospital-only	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

POM = prescription-only medicine(s), n.a. = not available

[1] as of 1 January

(*) method of counting:
– incl. different pharmaceutical forms
– excl. different pack sizes
– incl. different dosages
– incl. parallel traded

(**) method of counting:
– incl. different pharmaceutical forms
– incl. different pack sizes
– incl. different dosages
– incl. parallel traded

(***) method of counting:
– incl. different pharmaceutical forms
– excl. different pack sizes
– incl. different dosages

Source: RIZIV/INAMI

2.1.2.2 Consumption

Table 2.3: Belgium – Annual prescriptions and consumption, 2000-2007

Consumption	2000	2001	2002	2003	2004	2005	2006	2007
No. of prescriptions per year (in volume)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of annual prescriptions in value (in NCU = euro)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of annual consumption in packs[1] (in Mio.)	n.a.	n.a.	n.a.	n.a.	n.a.	230.8	n.a.	n.a.
No. of annual consumption in DDD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

[1] packages sold by wholesalers to community pharmacies

n.a. = not available

Source: RIZIV/INAMI

2.1.2.3 Market data

Table 2.4 presents pharmaceutical market data for Belgium for 1995 and 2000-2005. In 2005 the total pharmaceutical sales at consumer price level amounted to € 3,989 Mio. Between 2000 and 2003 the annual growth rate continued to rise year on year from 4.05% in 2001 to 7.49% in 2003. From 2004 onwards a diminishing trend is observed and in 2005 the annual growth rate was only 2.62%. For sales at ex-factory price levels, which amounted to € 2,681 Mio. in 2005, the same trend is observed.

Levels of generics sales remain relatively low compared to other European countries, but show a clear upward trend, from 0.56% of total pharmaceutical sales in 1995 to 9.09% in 2005.

Due to the presence of both research-oriented companies and European distribution centres of pharmaceutical companies, Belgium is a net exporter of pharmaceuticals.

Table 2.4: Belgium - Market 2000-2007

In Mio. €	2000	2001	2002	2003	2004	2005	2006	2007
Pharmaceutical sale[3, 5]								
Sales at ex-factory price level	2,016	2,115	2,258	2,457	2,600	2,681	n.a.	n.a.
Sales at wholesale price level	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales at pharmacy retail price level	3,157	3,285	3,471	3,731	3,887	3,989	n.a.	n.a.
Sales at hospitals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales of generics	53.4	114.1	150.6	219.9	284.6	362.5	n.a.	n.a.
Sales of parallel traded pharmaceuticals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Exports and imports[4]								
Total pharmaceutical exports[1]	3,148[2]	5,222[2]	14,279[2]	12,524[2]	12,827[2]	14,464[2]	n.a.	n.a.
Total pharmaceutical imports[1]	2,209[2]	2,688[2]	4,369[2]	5,046[2]	5,638[2]	5,218[2]	n.a.	n.a.

n.a. = not available

[1] Data concern only trade with EU25, United States and Japan

[2] Belgium and Luxembourg

[3] Sales in pharmacies only

[4] Source: Eurostat

[5] Source: IMS Health

In 2005, Belgian wholesalers sold a total of 230.8 Mio. packages to community pharmacies, which corresponds to an average of 22.1 packs per inhabitant. Data concerning the total number of prescriptions filled, as well as on the average costs per prescription, are not available.

Table 2.5 lists the top 10 reimbursable pharmaceuticals based on their costs for the health insurance system in 2005.

Table 2.5: Belgium - Top 10 reimbursable pharmaceuticals by value, by active ingredient, 2007

Position	Pharmaceutical, by active ingredient
1	Atorvastatin
2	Clopidogrel
3	Salmeterol + corticosteroid
4	Simvastatin
5	Omeprazole
6	Pantoprazole
7	Coagulation factor VIII
8	Etanercept
9	Venlafaxine
10	Molsidomin

Source: RIZIV/INAMI, Pharmanet-team

2.1.2.4 Patents and data protection

The Federal Public Service of Economic Affairs is in charge of granting patents. Within the national legislation, there are no explicit provisions for compulsory licensing, parallel import and "government use" of patented products.

The most recent example of a court case in relation to pharmaceuticals patent protection is the "alendronate case". The first generic alternatives of FOSAMAX (MSD) were added to the reimbursement list on 1 January 2007. After a short period of commercialisation (two months), generics manufacturers were forbidden to commercialise their "alendronates" due to patent disputes between the originator and the generic companies. Consequently, FOSAMAX could not enter the reference price system (cf. section 4.3) on 1 July 2007. From 15 April 2008 onwards, generic manufacturers were once again allowed to release their products and therefore, FOSAMAX entered the reference price system on 1 July 2008.

2.1.3 Market players

2.1.3.1 Industry

According to Eurostat, there are 97 companies in Belgium that manufacture pharmaceutical preparations (2004). It is worth noting that this number does not include those companies that only distribute pharmaceuticals. Pharma.be represents the interests of the Belgian pharmaceutical industry. In addition, 11 generics firms form a separate organisation, the Belgian Association of the Generics Industry (FeBelGen). Both Pharma.be and FeBelGen are represented in the Reimbursement Committee (CTG).

All major pharmaceutical companies are represented in Belgium, with Glaxo Smith Kline having the largest turnover in 2001. The 10 largest firms together have a market share of 50%. The generics market in dominated by Eurogenerics, which accounted for almost 45% of total sales in pharmacies in the same year, but generics have a market share of only 9% in terms of turnover at pharmacy level.

Pharmaceutical production in Belgium amounted to € 4,811.3 Mio.[5] in 2005. The total pharmaceutical sales at ex-factory level have continued to rise over the years and amounted to € 2,681 Mio. in 2005. As can be seen in Table 2.3, Belgium is a net exporter of pharmaceuticals, with exports almost three times higher than imports. Pharmaceutical research and development (R&D) expenditure in 2005 amounted to € 1,551 Mio.[6] In the same year, the Belgian pharmaceutical industry employed 28,603 people.

Pharmacies are mostly provisioned by wholesalers. Direct supply is allowed, but it is used mainly for over-the-counter (OTC) pharmaceuticals. In general, hospitals are directly supplied with pharmaceuticals.

[5] Source: Pharma.be

[6] Source: Pharma.be

Table 2.6: Belgium - Key data on the pharmaceutical industry 2000-2007

Pharmaceutical industry	2000	2001	2002	2003	2004	2005	2006	2007
Total no. of companies[1,2]	84	88	n.a.	99	97	n.a.	n.a.	n.a.
- research-oriented	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- generics producers	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- biotech	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of people employed[3]	22,732	24,201	25,408	26,390	27,338	28,603	n.a.	n.a.

n.a. = not available

[1] NACE dg2442 Manufacture of pharmaceutical preparations

[2] Source: Eurostat

[3] Source: Pharma.be

2.1.3.2 Wholesalers

Official data concerning wholesalers are not available.

Table 2.7: Belgium - Key data on pharmaceutical wholesale 2000-2007[1]

Wholesalers	2000	2001	2002	2003	2004	2005	2006	2007
Total number of whole-sale companies	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total number of importers	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total number of outlets	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

[1] as of 1 January

n.a. = not available

2.1.3.3 Pharmaceutical outlets / retailers

Pharmaceuticals can be distributed by pharmacies and hospital pharmacies (cf. section 2.1.3.3.4).

From the health insurers' perspective, in 2005, 69% of pharmaceutical expenditure (PE) was generated in pharmacies and 31% in hospitals.

Only pharmacies are allowed to dispense pharmaceuticals directly to patients, therefore no other types of dispensaries of pharmaceuticals exist. Normally, hospitals can only distribute pharmaceuticals to hospitalised patients, and to patients from their own out-patient wards; however, some hospitals are authorised to dispense pharmaceuticals to patients who live in retirement and care homes.

2.1.3.3.1 Pharmacies

The establishment of a new pharmacy in Belgium requires the authorisation of the Minister of Public Health. This authorisation is only granted if the requirements of the Royal Decree of 25 September 1974 are fulfilled. According to this Royal Decree:

- The establishment of a new pharmacy requires that the number of pharmacies in a city (more than 30,000 inhabitants), town (between 7,500 and 30,000 inhabitants) or village (less than 7,500 inhabitants) can never exceed the number of inhabitants divided by 3,000, 2,500 or 2,000 respectively. The minimal number of pharmacies is three in case of more than 9,000 inhabitants, and two if there are less than 7,500 inhabitants.

- A derogation to the above rules is possible if the minimal distance between an existing pharmacy and the new pharmacy is at least 1 km and the new pharmacy covers the needs of at least 2,500 inhabitants; this minimal distance changes to 3 km or 5 km if 2,000 or 1,500 inhabitants are covered.

Anybody is allowed to own a pharmacy, with the only obligation being that in each pharmacy at least one pharmacist must be present at all times. Most pharmacies are privately owned by a pharmacist. Chains of pharmacies are by definition allowed, due to the fact that there is no limit on the number of pharmacies that can be owned by one party. Pharmacy chains are mostly owned by cooperatives, wholesalers, sickness funds or private enterprises.

On 1 January 2007 there were 5,158 pharmacies in Belgium, all of which are privately owned. This corresponds to one pharmacy per 2,000 inhabitants or 0.5 pharmacies per 1,000 inhabitants, which makes Belgium one of the countries with the densest network of pharmacies. From the year 2000 the number of pharmacies has decreased slowly, probably due to the closure of small pharmacies.

There are two important professional organisations of pharmacists, the Belgian Pharmaceutical Association (Algemene Pharmaceutische Bond, APB) and the Organisation of Cooperative Pharmacies (Organisation des Pharmacies Cooperatives, OPHACO). The Belgian Pharmaceutical Association (APB) represents the privately owned pharmacies and the Organisation of Cooperative Pharmacies (OPHACO) represents the pharmacies owned by cooperatives. Hospital pharmacists are represented by the Belgian Society of Hospital Pharmacists (Belgische Vereniging van Ziekenhuisapothekers, VZA). These associations are the sole representatives of pharmacists at government level. They participate in all negotiations regarding the remuneration of pharmacists. They are represented in the Reimbursement Committee (CTG), in the Pricing Committee for Pharmaceutical Specialties (PFS), and in various other committees within the Belgian social security system.

According to Belgian law, pharmacists are remunerated through a mark-up scheme. This mark up is fixed at 31% of the wholesale retail price, with a maximum of € 7.44 per package. For more information about the remuneration of pharmacies, cf. section 3.5.2. No data about discounts and/or rebates can be given, due to the fact that these procedures are not open to public scrutiny and are not regulated by statutory laws other than those that are generally applied to commercial activities.

Within the limitations of the Belgian law (cf. section 2.1.3.3.3), pharmacies are allowed to sell pharmaceuticals via the Internet and they can deliver them by mail order.

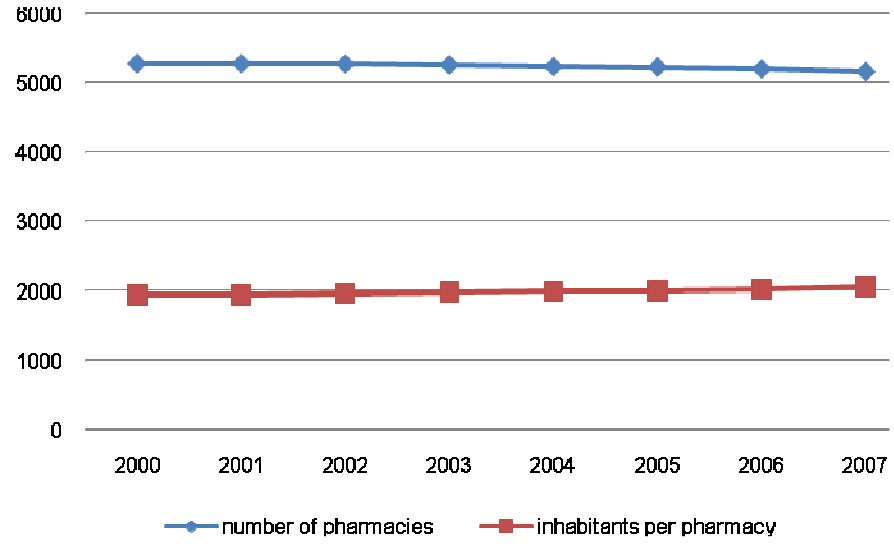
Table 2.8: Belgium - Retailers of pharmaceuticals 2000-2007[1]

Retailers	2000	2001	2002	2003	2004	2005	2006	2007
Number of community pharmacies	5,273	5,272	5,268	5,254	5,230	5,224	5,196	5,158
Number of private pharmacies	5,273	5,272	5,268	5,254	5,230	5,224	5,196	5,158
Number of public pharmacies	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
Number of hospital pharmacies for outpatients	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
Number of other POM dispensaries	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
Total number of POM dispensaries	5,273	5,272	5,268	5,254	5,230	5,224	5,196	5,158
Number of internet pharmacies	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Number of OTC dispensaries, like drugstores	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.

OTC = over-the-counter, POM = prescription-only medicine(s); n.app. = not applicable; n.a. = not available

Source: APB

Figure 2.2: Belgium - Number of pharmacies and number of inhabitants per pharmacy 1995 and 2000-2007



Source: APB

2.1.3.3.2 Other pharmacy outlets

There are no other pharmacy outlets in Belgium.

2.1.3.3.3 Internet pharmacies

Internet pharmacies as such are not allowed under Belgian law, which states that all deliveries of pharmaceuticals must take place to a pharmacy. However, pharmacies can offer the possibility of ordering pharmaceuticals (prescription-only medicine(s) (POM) (if they have a prescription) and over-the-counter (OTC) via the Internet and are allowed to send them by mail order to a patient.

2.1.3.3.4 Dispensing doctors

Since 1 June 2007 dispensing of pharmaceuticals by doctors (other than medical samples) is no longer allowed.

2.1.3.4 Hospitals

Most Belgian hospitals have their own pharmacy, but due to a recent wave of consolidation some hospitals make use of different sites with a central pharmacy and dispensing point. Hospital pharmacies are normally not allowed to deliver pharmaceuticals to out-patients, although some hospital pharmacies may deliver pharmaceuticals to patients who live in retirement and care homes.

The positive reimbursement list (also cf. section 4.2.3) is valid for both the out-patient sector and the hospital sector. There are therefore no specific reimbursement conditions for pharmaceuticals when used in hospitals.

Each hospital draws up a so-called “hospital repertory”, a list of pharmaceuticals (reimbursed/non-reimbursed) continuously available in the central hospital pharmacy. In each hospital, the Repertory Commission (composed of, among others, the principal pharmacist and the principal physician) decides which pharmaceuticals will be listed in that hospital repertory (also cf. section 4.5).

Hospitals negotiate directly with manufacturers to obtain rebates/discounts. These negotiations are private and are not monitored.

There are no data available on the influence of pharmaceutical companies over the decision to include new pharmaceuticals in the hospital lists. However, the introduction of the new financing system for pharmaceuticals dispensed in hospitals on 1 July 2006 (cf. section 4.5) may have influenced their behaviour.

Part of the hospital global budget is designated to the functioning of the hospital pharmacy. The hospital pharmacist is only allowed to charge a mark up for pharmaceuticals dispensed to ambulatory (non-hospitalised) patients (cf. section 3.5.2). As mentioned earlier, on 1 July 2006 a new financing system for pharmaceuticals dispensed in hospitals was introduced (cf. section 4.5).

2.1.3.5 Doctors

Doctors are represented by their professional organisations in the Reimbursement Committee (CTG) and in various other committees of the Belgian social security system. Although there are

no official contracts between doctors, this representation guarantees them an impact on decisions that directly concern doctors. For more information about policies regarding changing prescribing patterns, cf. section 5.

Generally speaking, reimbursed pharmaceuticals are divided into three main groups (pharmaceuticals of chapters I, II and IV of the reimbursement list – cf. section 4.2.3). Pharmaceuticals of the first chapter are reimbursed when prescribed within the officially registered indications mentioned in the summary of product characteristics (SPC). Others are subject to ex-ante approval by a sickness fund physician (adviserend-geneesheer) or to an ex-post evaluation to see if the doctor has followed the recommendations.

2.1.3.6 Patients

In theory, the influence of the patient over the choice of prescription-only medicine(s) (POM) is quite limited. It is the prerogative of the physician to choose the pharmaceutical s/he deems necessary for the patient. Once prescribed, the patient's influence is limited to deciding whether or not s/he will pick up the pharmaceutical at the pharmacy. In practice, due to the fact that sickness funds have an obligation to convey certain information to the public, patients are well informed of price differences between similar pharmaceuticals and doctors can be asked by the patient to prescribe a pharmaceutical that costs less. This trend is augmented by the fact that patients' co-payments are a percentage of the price of a pharmaceutical.

One of the sources of information about prices is the sickness funds. There are also publicly accessible databases maintained by the National Institute for Health and Disability Insurance,[7] for all reimbursable pharmaceuticals, and by the Belgian Centre for Pharmacotherapeutical Information[8] (BCFI) for all pharmaceuticals. Finally, it is a legal obligation to cite the absolute value of the co-payment on the package; on the other hand, an official price list must be available in pharmacies.

Patients' influence on policy-making is at the same time both limited and extensive. Formally, patients are not directly involved in policy-making; they are represented indirectly by the sickness funds. Informally, however, the influence of patients' organisations on the Minister of Social Affairs can be quite substantial and as such they can have a real influence on policy.

2.2 Funding

2.2.1 Pharmaceutical expenditure

Due to the small amount of data available, figures in this section are limited to pharmaceutical expenditure (PE) in pharmacies; no hospital expenditure is included.

[7] http://www.riziv.fgov.be/riziv_prd/ssp/cns2/pages/SpecialityCns.asp Contains both prices, co-payments, conditions for reimbursement and hospital prices and reimbursement

[8] http://www.bcfi.be/GGR/Index.cfm?ggrWelk=MAIN

The total sales of pharmaceuticals (prescription-only medicine(s) (POM) and over-the-counter (OTC) in pharmacies amounted to € 3,989 Mio. (€°382 per inhabitant) in 2005. These sales have been increasing year on year, although the yearly increase is declining. Since 1995 the pharmaceutical expenditure (PE) has risen by 80%. This increase is probably due to demographic factors, e.g. the ageing population, and scientific progress, e.g. the introduction of new biological pharmaceuticals, such as blood products and vaccines.

Table 2.9: Belgium - Total pharmaceutical expenditure (TPE) 2000-2007

Pharmaceutical expenditure[1]	2000	2001	2002	2003	2004	2005	2006	2007
TPE in Mio. €[2] (NCU = euro)	3,157	3,285	3,471	3,731	3,887	3,989	n.a.	n.a.
TPE as a % of Total Health Expenditure	15.01	15,62	14.62	14.46	13.93	n.a.	n.a.	n.a.
TPE per capita in NCU	308	320	337	360	374	382	n.a.	n.a.
Public PE in % of THE[3]	7.99	8.52	8.09	8.00	7.91	n.a.	n.a.	n.a.
Private PE in % of THE	7.02	7.10	6.52	6.47	6.02	n.a.	n.a.	n.a.

GDP = gross domestic product, n.a. = not available, NCU = national currency unit, PE = Pharmaceutical Expenditure, THE = Total Health Expenditure, TPE = Total Pharmaceutical Expenditure

[1] Only outpatient sector, hospital expenditure is excluded

Source: [2] IMS Health, [3] RIZIV/INAMI Pharmanet team

2.2.2 Sources of funds

Due to the integrated nature of health care funding in Belgium, it is impossible to give specific data about pharmaceutical funding. Cf. section 2.2 for general information about health care funding in Belgium.

Private pharmaceutical expenditure (PE) consists of expenses for non-reimbursed pharmaceuticals (both prescription-only medicine(s) (POM) and over-the-counter (OTC) and out-of-pocket payments (OPP) for reimbursable pharmaceuticals. In 2005, patients paid € 511 Mio. in out-of-pocket payments (OPP).

2.3 Evaluation

Within the National Institute for Health and Disability Insurance (RIZIV/INAMI) two data sources exist concerning pharmaceutical expenditure (PE). One is the Pharmanet database,[9] which contains data about reimbursable pharmaceuticals delivered in public pharmacies. The other comprises the accounts which contain details of expenditure for reimbursable pharmaceuticals delivered by both public and hospital pharmacies.

[9] A detailed description of the data collected via the Pharmanet system can be found at the following web site: Farmanet Report in English

The accounts are continuously used to monitor pharmaceutical expenditure (PE), the results of which can be used to implement general measures to limit expenditure if there is a risk of exceeding the budget. Each quarter, a report containing the latest data is submitted to the various committees of the National Institute for Health and Disability Insurance (RIZIV/INAMI) responsible for controlling the budget, in order to enable them to evaluate the expenditure.

The data from the Pharmanet system are used to monitor expenditure, but also to analyse pharmaceuticals consumption, to aid reimbursement decisions and for general research on pharmaceuticals use in Belgium. Several indicators have been used to provide feedback to doctors concerning specific subjects, e.g. antibiotics, along with other more general areas, in a yearly report that evaluates the prescribing of various types of pharmaceuticals. These general reports and the feedback can both be found on the web site of the National Institute for Health and Disability Insurance (RIZIV/INAMI). This Institute is responsible for revising and using the data, but Pharmanet data can also be used by third parties for non-commercial research, after approval.

To the extent of the authors' knowledge, there have not been any problems with the Transparency directive regarding the use of these data, nor any legal action taken.

3 Pricing

3.1 Organisation

In Belgium, all pharmaceuticals, reimbursed prescription-only medicine(s) (POM) (non-reimbursed prescription-only medicine(s) (POM) and over-the-counter (OTC) pharmaceuticals) fall by law under state pricing regulation; the reimbursement system and the pricing system are very closely linked.

Figure 3.1: Belgium - Pricing - general principles

General principles

1. Public Price = Level of reimbursement, except for original pharmaceuticals in reference reimbursement system

The Belgian reference reimbursement system was introduced on 1 June 2001 and aimed to stimulate the prescription of cheaper pharmaceuticals. If a (cheaper) generic reimbursed pharmaceutical is available which contains the same active component (or components), the original pharmaceutical enters the reference reimbursement system.
This means that the level of reimbursement of the original pharmaceutical is diminished by 30% (ex-factory level), while it's applied price remains the same.
Although the level of reimbursement of the original pharmaceutical is diminished, the personal contribution increases, as the difference between the applied price and the new level of reimbursement (the so-called "supplement") will be charged to the patient.
However, pharmaceutical companies have the possibility to lower their applied price, in order to reduce the patient's "supplement", or even let it expire.

2. Maximum Public Price is first set by the Minister of Economic Affairs

3. Level of reimbursement is then set by Minister of Social Affairs (this will consequently be the applied Public Price). It is the value used to calculate the personal contribution of the patient and the contribution of the health insurance system

4. For generics:

1. **Level of reimbursement = Maximum Public Price**
   = Level of reimbursement of the original (if a reference pricing system is in place)
   or = Level of reimbursement of the original minus 30% if this reference pricing system is not yet set up
2. **Margins = Margins for the original pharmaceutical (in absolute value !)**

Source: RIZIV/INAMI

Two Ministerial Decrees of 29 December 1989 form the legal framework for setting the prices of both reimbursable and non-reimbursable pharmaceuticals (including over-the-counter (OTC) pharmaceuticals). The Ministry of Economic Affairs is the competent authority setting the maximum prices of all pharmaceuticals. There are two pricing committees, one for reimbursed and one for non-reimbursed pharmaceuticals. Both committees have an advisory role, but their advice is not binding and the Minister of Economic Affairs makes the final decision.

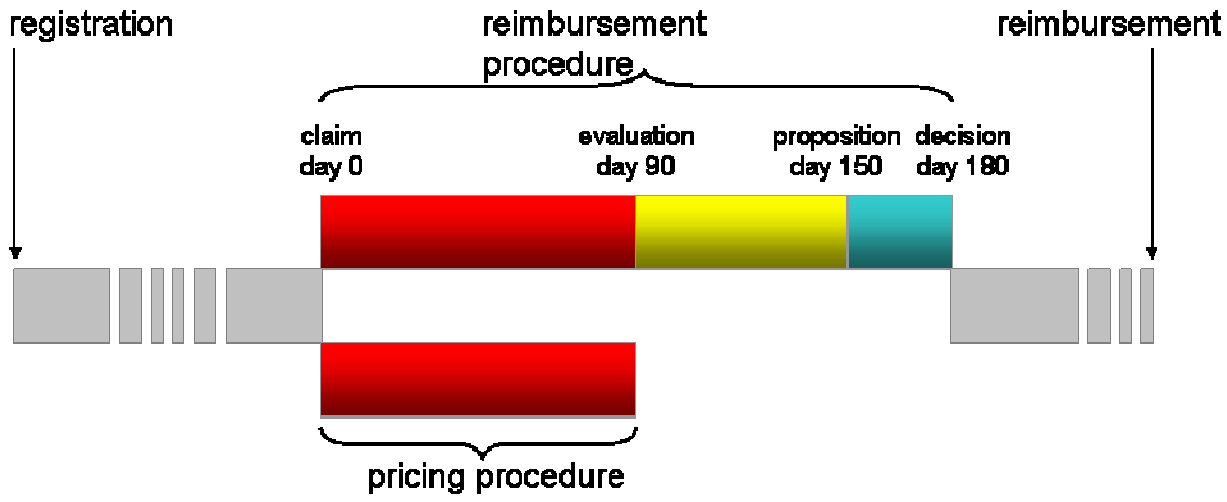
As mentioned earlier, the pricing system and the reimbursement system are closely linked. The pricing process runs simultaneously with the reimbursement process and both the request for a price and for reimbursement must be submitted on the same day. The close relation between the pricing and the reimbursement process is outlined in Figure 3.3. However, this does not mean that the same institution is responsible for both processes.

The decisions concerning reimbursement are the prerogative of the Minister of Social Affairs. After the maximum price has been set by the Minister of Economic Affairs, the Reimbursement Committee (CTG) can negotiate with the responsible pharmaceutical company to determine the reimbursement level that will be proposed to the Minister of Social Affairs. This reimbursement level can be equal to or lower than the maximum price set by the Minister of Economic Affairs and will be the applied pharmacy retail price (PRP) (cf. Figure 3.2).

Price setting for generics is based on the following principles: if a reference price system is in place, the price of a generic may not be higher than the maximum price of the original pharmaceutical; if a reference price system is not yet in place, the price of a generic must be at least 30% lower (at retail price level) than the original pharmaceutical.

The whole pricing process takes a maximum of 90 calendar days. For parallel traded pharmaceuticals, the process takes a maximum of 45 calendar days.

Figure 3.2 Belgium - Pricing - reimbursement procedure



Source: RIZIV/INAMI

Only one major change has been made to the aforementioned system. From June 2006 onwards it is no longer the Minister of Economic Affairs who makes a unilateral decision after the pricing process. Instead, for certain pharmaceuticals (e.g. generics) a price notification is issued by the company introducing the pharmaceutical.

3.2 Pricing policies

Table 3.1: Belgium - Ways of pricing pharmaceuticals

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free pricing	Not applied		
Statutory pricing	Maximum prices are set for all pharmaceuticals	Via a percentage mark up	Via a percentage mark up. Prices of reimbursable POM are influenced through the reimbursement system (i.e. set at the reimbursement level)
Price negotiations	Between the responsible pharmaceutical company and the Minister of Economic Affairs and/or the Minister of Social Affairs (both the maximum price and the reimbursement level)	Not applied	Not applied
Discounts / rebates	Not applied		
Public procurement	Not applied		
Institution in charge of pricing	Ministry of Economic Affairs for the maximum price Minister of Social Affairs for the reimbursement levels		
Legal basis	ministerieel besluit van 29 december 1989 betreffende de prijzen van de terugbetaalbare geneesmiddelen ministerieel besluit van 5 mei 2006 tot vaststelling van de maximum-verkoopprijzen en de maximummarges voor de verdeling in het groot en de terhandstelling van de geneesmiddelenvoor menselijk gebruik geregistreerd als generieken of op basis van de gepubliceerde wetenschappelijke literatuur ministerieel besluit van 29 december 1989 betreffende de prijzen van de niet-terugbetaalbare geneesmiddelen ministerieel besluit van 5 mei 2006 tot vaststelling van de maximum-verkoopprijzen en de maximummarges voor de verdeling in het groot en de terhandstelling van de geneesmiddelenvoor menselijk gebruik geregistreerd als generieken of op basis van de gepubliceerde wetenschappelijke literatuur ministerieel besluit van 20 april 1993 houdende bijzondere bepalingen inzake prijzen ministerieel besluit van 5 mei 2006 tot vaststelling van de maximum-verkoopprijzen en de maximummarges voor de verdeling in het groot en de terhandstelling van de geneesmiddelenvoor menselijk gebruik geregistreerd als generieken of op basis van de gepubliceerde wetenschappelijke literatuur ministerieel besluit van 2 april 1996 tot vaststelling van de maximumverkoopprijzen en de maximummarges voor de verdeling in het groot en de terhandstelling van de niet-terugbetaalbare geneesmiddelen voor menselijk gebruik waarvan geen enkele vorm aan een medisch voorschrift is onderworpen ministerieel besluit van 12 december 2000 tot vaststelling van de prijs van grote verpakkingen van terugbetaalbare geneesmiddelen vanaf 15 december 2000		

POM = prescription-only medicine(s)

Source: RIZIV/INAMI, Ministry of Economic Affairs

The current system has been in place since 1989 and is applicable for all types of pharmaceuticals, with differences for the various types, as described earlier. Price decisions are always made at manufacturer level. The pharmacy retail price (PRP) is obtained by adding the various

wholesale and pharmacy mark ups and value-added tax (VAT) to the ex-factory price (cf. section 3.5 and Figure 3.2).

Price changes are possible and can be demanded at any time by the firm responsible for the initial pricing application. In practice, there is a price freeze in place so that, once the Minister of Economic Affairs has set the maximum applicable price, it is highly unlikely, though not impossible, that this maximum price will be raised. In the event of price rises the Minister of Economic Affairs makes the final decision. In the event of a price drop the new, lower price only has to be announced and no formal decision by the Minister is needed.

3.2.1 Statutory pricing

All pharmaceuticals are subject to statutory pricing by the Ministry of Economic Affairs. As stated earlier, the final pricing decision is made by the Minister of Economic Affairs after receiving advice from the competent Pricing Committee. In its advice, the Committee takes into account economic criteria, European average prices and the relative value of the pharmaceutical with regards to a set price level. The whole pricing process takes a maximum of 90 calendar days and is started at the same time as the reimbursement claim. If the maximum price is not notified to the responsible pharmaceutical company within this period of 90 days, the firm can apply the price it has asked for. The price set by the Minister of Economic Affairs is a maximum price, thus a pharmaceutical can never be marketed at a higher price.

3.2.2 Negotiations

Although the pricing process leaves no room for negotiation, the actual applied price is subject to negotiations during the reimbursement process.

3.2.3 Free pricing

There is no system of free pricing in Belgium. All pharmaceuticals are subject to statutory pricing.

3.2.4 Public procurement / tendering

Officially, public procurement / tendering are not applied. However, for vaccines, manufacturers negotiate a price directly with the competent authorities (regions).

At the end of 2006 the legal basis was established for a new procedure (designed for the modification of reimbursement conditions for pharmaceuticals for budgetary reasons) based on the principles of “public tendering”. In general terms, an indirect competitive benefit is offered to the pharmaceutical company, by means of a lower co-payment for the patients for its pharmaceutical(s), offering the lowest cost for the treatment (from the health insurance and patient perspective). The Minster of Social Affairs launched two of these procedures (for simvastatin and amlodipin) in mid-2007. For amlodipin, the procedure has been stopped.

3.3 Pricing procedures

Both internal and external price referencing are applied in Belgium. External price referencing is applied for all pharmaceuticals, whereas internal price referencing is only used for those pharmaceuticals where a comparable product is marketed in Belgium.

Table 3.2: Belgium - Pricing procedures

Pricing procedure	In use: Yes / No	Price type	Scope
Internal price referencing	Yes	Ex-factory price	Me-too pharmaceuticals, generics, copies, parallel import
External price referencing	Yes	Ex-factory price	All pharmaceuticals
Cost-plus pricing	n.app.	n.app.	n.app.
Other, e.g. indirect profit control	n.app.	n.app.	n.app.

n.app. = not applicable

Source: RIZIV/INAMI

3.3.1 External price referencing

External price referencing is applied to all pharmaceuticals at the manufacturer level. External price referencing is just one of the criteria used in pricing decisions, another being e.g. economic criteria. Although they are technically not a part of the actual pricing process, evaluations of a pharmaceutical by the Reimbursement Committee (CTG) provide data about its relative value and are used in negotiations during the reimbursement process.

External pricing in Belgium consists of a head-to-head comparison of the proposed ex-factory price with all the ex-factory prices applied in those European countries where the pharmaceutical is marketed. It is the responsibility of the company introducing the pharmaceutical to include these data in their application.

There are no provisions to automatically change the price in Belgium in the event of a price change in one or more of the reference countries. In essence, it is a one-off comparison.

3.3.2 Internal price referencing

Internal price referencing is applied to generics, copies, me-too pharmaceuticals and parallel traded pharmaceuticals. The system of internal price referencing is based on the aforementioned Ministerial Decree of 29 December 1989, as well as the Ministerial Decree of 5 May 3006, which empowers the Pricing Committees to undertake this comparison. For generics the Royal Decree of 21 December 2001 stipulates that the price of a generic must be at least 30% lower (at retail price level) than the original pharmaceutical.

Comparators are defined as having the same active molecule (World Health Organization (WHO)) Anatomic Therapeutic Chemical (ATC) classification and registered indications.

3.3.3 Cost-plus pricing

There is no cost-plus pricing system in Belgium.

3.3.4 (Indirect) Profit control

A system of either direct or indirect profit control is not used in Belgium.

3.4 Exceptions

Some exceptions exist and are described below.

3.4.1 Hospitals-only

Although the price of hospital-only medicine(s) (HOM) is set as described earlier, hospitals negotiate directly with the manufacturers to obtain rebates/discounts. These negotiations are private and are not monitored.

3.4.2 Parallel traded pharmaceuticals

The pricing decision for parallel traded pharmaceuticals is made within 45 calendar days instead of the statutory 90 days for other pharmaceuticals.

3.5 Margins and taxes

In Belgium the prices of all pharmaceuticals are regulated by means of delimited percentage mark ups for both wholesalers and pharmacies.

Table 3.3: Belgium - Regulation of wholesale and pharmacy mark ups 2008

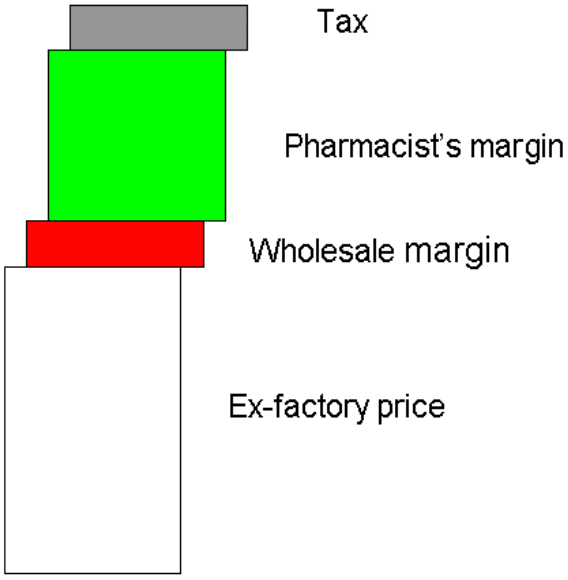
	Wholesale mark up			Pharmacy mark up		
	Regulation (yes / no)	**Content**	**Scope**	**Regulation (yes / no)**	**Content**	**Scope**
Belgium	Yes	Percentage mark ups	All pharma-ceuticals	Yes	Percentage mark ups	All pharma-ceuticals

Source: Ministry of Economic Affairs

Figure 3.3: Belgium - Price structure

Price structure: general

Public Price = Ex-factory price + Wholesale margin (Fee) + Pharmacist's margin (Fee) + Tax



Source: RIZIV/INAMI

3.5.1 Wholesale remuneration

Wholesale remuneration in Belgium consists of a fixed mark up, which is statutorily fixed at 13.1% of the ex-factory price, with a maximum of € 2.18 per package.

Table 3.4: Belgium - Wholesale mark-up scheme 2008

Pharmacy retail price (PRP) in €	Mark up as a % of wholesale price	Maximum mark up
0.00-38.97	13.1%	€ 2.18
38.98-62.98	13.1% of the first € 24 + 0.68% of (PRP - € 24)	n.app.
> 62.98	13.1% of the first € 24 + 0.77% of (PRP - € 24)	n.app.

PRP = pharmacy retail price

Source: RIZIV/INAMI

3.5.2 Pharmacy remuneration

Pharmacy remuneration in Belgium consists of a fixed mark up, which is statutorily fixed at 31% of the wholesale price, with a maximum of € 7.44 per package for (non-hospital) pharmacies and 22% for pharmaceuticals delivered to non-hospitalised patients in hospital pharmacies.

Table 3.5: Belgium - Pharmacy mark-up scheme 2008

Pharmacy retail price (PRP) in €	Mark up as a % of PRP	Maximum mark up
0.00-38.97	31%	€ 7.44
38.98-62.98	31% of the first € 24 + 2.32% of (PRP - € 24)	n.app.
> 62.98	31% of the first € 24 + 2.61% of (PRP - € 24)	n.app.

n.app. = not applicable, PRP = pharmacy retail price

Source: RIZIV/INAMI

3.5.3 Remuneration of other dispensaries

The remuneration of self-dispensing doctors no longer applies (cf. section 2.1.3.3.4).

3.5.4 Value-added tax

For all pharmaceuticals a value-added tax (VAT) of 6% is applied.

3.5.5 Other taxes

No other taxes are foreseen.

3.6 Pricing-related cost-containment measures

3.6.1 Discounts / Rebates

There are no official discounts/rebates in Belgium.

3.6.2 Margin cuts

Due to the fact that the maximum mark up is limited for both wholesalers and pharmacies, margin cuts are not used as a tool for cost-containment.

3.6.3 Price freezes / Price cuts

In Belgium, price freezing is no longer applied by the Minister of Economic Affairs. Regulated price cuts for “old pharmaceuticals”, however, are applied.

The applied pharmacy retail price (PRP) and the corresponding reimbursement basis of original pharmaceuticals containing an active component that has been reimbursed for more than 12 years, are reduced by 14% (ex-factory level). Once the active component is reimbursed for more than 15 years, the applied pharmacy retail price (PRP) and the corresponding reimbursement basis are reduced by 2.3% (ex-factory level). If a pharmaceutical contains more than one active component, each active component must be reimbursed for more than 12 years.

This measure is applied every six months (on 1 January and on 1 July) to the original pharmaceuticals listed in chapters I, II or IV of the list of reimbursed pharmaceuticals, with the exception of the following therapeutic classes: blood substitutes and derivatives, insulin, anti-haemophilia factors, contraceptive medicines, vaccines, immunoglobulins, and glycosides. Generic pharmaceuticals are not submitted to this course of action. Nevertheless, their applied pharmacy retail price (PRP) must be reduced in the event that it is above the new reimbursement basis for the corresponding original pharmaceutical.

3.6.4 Price reviews

At the time of writing, no price reviews are foreseen.

4 Reimbursement

4.1 Organisation

In order to obtain reimbursement, the pharmaceutical company that is responsible for the commercialisation of the relevant pharmaceutical on the Belgian market must submit an application to the Reimbursement Committee (CTG).The Minister of Social Affairs makes decisions with regard to the reimbursement of pharmaceuticals on the basis of motivated proposals from the Reimbursement Committee (CTG).

The Reimbursement Committee (CTG) is composed of representatives of the insurance institutions, professional associations of pharmacists and doctors, academic institutions, professional organisations of the pharmaceutical industry and the Minister of Social Affairs, the Minister of Public Health and the Minister of Economic Affairs.

Specific procedures (with specific application elements and time frames) are foreseen for applications for reimbursement of pharmaceuticals classified as class 1 (added therapeutic value), class 2 (line extensions, without added therapeutic value) or class 3 (generic) pharmaceuticals, along with orphan drugs and parallel traded pharmaceuticals.

According to the EU Directives, the reimbursement procedure can take at the most 180 days for pharmaceuticals of classes 1, 2 or 3 or orphan drugs, and at the most 90 days for parallel traded pharmaceuticals.
Since December 2007, pharmaceutical companies are allowed to already submit class 1 reimbursement applications to the Reimbursement Committee, from the moment that they dispose of a positive advice of the CHMP (Committee for Medicinal Products for Human Use). In this case, the evaluation by the expert can start earlier, whilst the actual reimbursement procedure on Reimbursement Committee level can still only be launched after reception of the market authorisation.

Since 1 April 2007, a shortened, strictly administrative procedure, is foreseen for generic products that have an identical packing (pharmaceutical form, pack size and dose) as the relevant original product (reference pharmaceutical) and for which reimbursement conditions identical to the reference pharmaceutical and a price not exceeding the latter’s price is applied for. This administrative procedure does not include an evaluation by an expert nor by the Reimbursement Committee and takes at the most 60 days.

The actual procedures foresee that pharmaceutical companies must – in parallel – submit separate applications for price setting (Federal Public Service for Economy – procedure of 90 days) and for reimbursement (Reimbursement Committee (CTG). Although the maximum price of a pharmaceutical is set by the Minister of Economic Affairs, the Minister of Social Affairs determines the reimbursement basis and the resulting applied pharmacy retail price (PRP).

All reimbursed pharmaceuticals are placed on a positive reimbursement list, which consists of different chapters.

Pharmaceuticals listed in chapter I of the list of reimbursed pharmaceuticals are not subject to any additional restrictions on reimbursement. All officially registered indications, mentioned in the summary of product characteristics (SPC) of the pharmaceutical, are taken into account for reimbursement.

For the classes of pharmaceuticals that are listed in chapter II, reimbursement is foreseen for all common indications, originating from the recommendations of the Reimbursement Committee (CTG) and based on generally applied recommendations for good practice. The principle of an "a posteriori" control applies for these classes of pharmaceuticals.

Reimbursement of pharmaceuticals listed in chapter IV of the reimbursement list is subject to specific restricting reimbursement conditions, which are imposed for medical and/or budgetary reasons. These conditions are set out in the corresponding paragraph. Moreover, reimbursement requires a prior authorisation by the insurance institution's medical officer, in case the patient meets these conditions: the so-called "a priori" control.

Table 4.1: Belgium - Chapters of the reimbursement list

Chapter	Characteristics
I	Reimbursement when prescribed within officially registered indications mentioned in the SPC No additional restrictions on reimbursement
II	Reimbursement for all common indications, originating from the recommendations of the CTG and based on generally applied recommendations for good practice Reimbursement does not depend on a prior authorisation by the medical officer of the insurance institution, but the prescribing health practitioner must respect the recommendations and keep certain documents in the patient file ("a posteriori" control)
III	Perfusion solutions Reimbursement when prescribed within officially registered indications (SPC) No additional restrictions on reimbursement
IV	Reimbursement is subject to specific restricting reimbursement conditions and depends on a prior authorisation by the medical officer of the insurance institution ("a priori" control)
IVbis	Pharmaceuticals not registered/dispensed in Belgium Reimbursement is subject to specific restricting reimbursement conditions and depends on a prior authorisation by the medical officer of the insurance institution ("a priori" control)
V (*)	
VI	Radio-isotopes Reimbursement is subject to specific restricting reimbursement conditions
VII	Therapeutically important pharmaceuticals for which the responsible company has refused to apply for reimbursement, added to the list as instructed by the CTG

(*) abolished on 1 April 2007 (human fibrinogen),
CTG = Reimbursement Committee, SPC = summary of product characteristics

Source: RIZIV/INAMI

This general policy covers the whole country. The decision on reimbursement also states whether the pharmaceutical is reimbursed when it is dispensed in a pharmacy and/or hospital.

The reimbursement status (reimbursed/non-reimbursed) of a pharmaceutical can change at the request of the pharmaceutical company or at the request of the Reimbursement Committee (CTG) (as a result of reimbursement reviews – cf. section 4.6.5).

4.2 Reimbursement schemes

There is a difference in the system of social security for salaried people and self-employed individuals. The system for salaried people is the most extensive. Salaried people are insured for risks of high costs (e.g. hospitalisation) and of lower costs (e.g. treatment with pharmaceuticals in out-patient care). Self-employed people are only insured for high-cost risks. This does not include reimbursement of pharmaceuticals, except for oncological therapy and the treatment of AIDS.

Retired people, widowers, orphans and those individuals that receive disability benefits (and meet certain income criteria), as well as the people being supported by these so-called “preferentially insured persons”, are entitled to a raised indemnification by the health insurance system. As of 1 April 2007, this arrangement has been extended to people with low income.

According to the EU Directives, the reimbursement procedure can take a maximum of 180 days for pharmaceuticals of classes 1, 2 or 3 or orphan drugs, and a maximum of 90 days for parallel traded pharmaceuticals (suspensions of the procedure at the request of the pharmaceutical company not included).

4.2.1 Eligibility criteria

The Minister of Social Affairs decides on the reimbursement of a pharmaceutical on the basis of the proposal formulated by the Reimbursement Committee (CTG).

The Reimbursement Committee (CTG) studies files with regard to the following criteria:

- product-specific criteria (e.g. medical and therapeutic value, safety, lack of alternative therapies);
- economic criteria (e.g. price, cost-effectiveness, reference price, budget impact);
- patient-specific criteria (e.g. age, sex, chronic or terminal illness);
- disease-specific criteria (e.g. severity of illness, special medical needs).

On the basis of these criteria, pharmaceuticals are classified according to the nature of reimbursement (listing in chapter I, II or IV of the reimbursement list – cf. section 4.1) and according to the reimbursement category (cf. section 4.2.2).

Appeal procedure

Once the Minister of Social Affairs has announced his/her decision on reimbursement of a pharmaceutical, the responsible pharmaceutical company can appeal against this decision. Competing companies can also appeal against decisions regarding pharmaceuticals brought onto the market by other companies in the event that they feel they have been put at a disadvantage by the decision.

4.2.2 Reimbursement categories and reimbursement rates

The legal basis of the reimbursement categories is the Royal Decree of 21 December 2001. A reimbursement category is attributed to each reimbursed pharmaceutical and it is indicated to what extend the obligatory insurance is to reimburse the cost. This classification is not linked to price. The assignment of pharmaceuticals to these categories (A, B, C, Cs or Cx) is carried out by the Minister of Social Affairs, based on the proposal of the Reimbursement Committee (CTG).

Pharmaceuticals of the categories A, B and C are considered as “necessary” pharmaceuticals and they are classified according to their specific medical and therapeutic importance. Category A is attributed to vital pharmaceuticals, e.g. pharmaceuticals to treat diabetes or cancer, while therapeutically important pharmaceuticals, e.g. antibiotics, are categorised in category B. Pharmaceuticals intended for symptomatic treatment, e.g. mucolytic agents to treat chronic bronchitis, are classified in category C. The categories Cs and Cx are attributed to influenza vaccines and antihistamines (Cs), and contraceptives (Cx). The reimbursement rates for each category are listed in Table 4.1.

No exceptions to this general system, for individual patients, are foreseen.

Table 4.2: Belgium - Reimbursement of pharmaceuticals (reimbursement categories) 2008

Reimbursement category	Reimbursement rate (%)	Characteristic of category
Category A	100	Vital pharmaceuticals (Example: for treatment of diabetes or cancer)
Category B	75 or 85 (*)	Therapeutically important pharmaceuticals (Example: antibiotics, cardiovascular pharmaceuticals)
Category C	50	Pharmaceuticals for symptomatic treatment (Example: mucolytic agents to treat chronic bronchitis, PPI)
Category Cs	40	Influenza vaccines and antihistamines
Category Cx	20	Contraceptive medicines

(*) a reimbursement rate of 85% is applied for “preferentially insured persons” (cf. section 4.2) – a reimbursement rate of 75% is applied to all other insured people,
PPI = proton pump inhibitor

Source: RIZIV/INAMI

4.2.3 Reimbursement lists

In Belgium, a positive list of reimbursable pharmaceuticals is used. This list is updated on a monthly basis, by means of Ministerial Decrees in which decisions on reimbursement (admission/modification/exclusion) of the preceding period are grouped. These decrees are drawn up by the administration of the National Institute for Health and Disability Insurance (RIZIV/INAMI) and are necessary to formalise the decisions of the Minister of Social Affairs.

Each month, a reference database is updated and made available (both on a specific file transfer protocol (FTP) server and on the internet (www.inami.be) for the social insurance companies, hospitals and associations of pharmacists. An updated version of the reimbursement list is available on the Internet (www.inami.be) (PDF version and database with search engine). Major changes in reimbursement conditions (e.g. reimbursement reviews of a specific class of pharmaceutical) are also communicated via this web site.

No procedures are foreseen to add pharmaceuticals that do not completely fulfil the inclusion criteria to the list. Although a specific reimbursement system is in place (cf. section 4.5), no specific reimbursement conditions exist for pharmaceuticals used in hospitals or nursing homes.

4.3 Reference price system

The reference price system was introduced by the Minister of Social Affairs on 1 June 2001 by means of the Royal Decree of 22 May 2001.

Reference pricing is only applied on (off-patent) pharmaceuticals with generic alternatives (with the same active component). Parallel trade pharmaceuticals are included in reference groups.

On 1 July 2005 the extended reference price system was introduced. While initially (1 June 2001) an original pharmaceutical only entered the system when a reimbursed generic alternative existed with an identical (qualitative and quantitative) composition and a comparable pharmaceutical form, the extended reference price system only takes into account the active component (Anatomic Therapeutic Chemical (ATC) classification ATC 5) of the generic alternative. In addition, a procedure to apply for exception status is now foreseen.

Since 1 November 2005, pharmaceuticals that belong to a therapeutic group of pharmaceuticals (ATC level 4) containing at least one (reimbursed) generic pharmaceutical are subject to a higher maximum personal contribution. This governmental measure aims to encourage patients to switch – where possible – to generic alternatives.

On 1 January 2007 the system was extended to post-patent molecules without generic alternatives (e.g. esomeprazole – NEXIAM). Since January 2007 the reference price system can be applied to these molecules, at the request of the Reimbursement Committee (CTG).

Neither the pharmaceutical form or the mode of delivery, nor the strength of the active component(s) are taken into account to determine whether or not an original pharmaceutical enters the reference price system. However, some exceptions are foreseen:

- an injectable, original pharmaceutical does not enter the reference price system if the reimbursed generic alternative is a non-injectable pharmaceutical;
- original pharmaceuticals can temporarily obtain an exception status if they have an Anatomic Therapeutic Chemical (ATC) code different to the generic alternative; however, this temporary status must be confirmed, by means of an application submitted to the Reimbursement Committee (CTG) by the pharmaceutical company (if not, the original pharmaceutical enters the reference reimbursement system after all); the original pharmaceutical loses its exception status (on the occasion of the first review) when a generic alternative with an identical Anatomic Chemical Classification (ATC) code is added to list;
- some original pharmaceuticals can also obtain an exception status by means of a justified application submitted to the Reimbursement Committee (CTG) by the pharmaceutical company.

The reference price system is reviewed every six months (on 1 January and on 1 July) by the administration of the National Institute for Health and Disability Insurance (RIZIV/INAMI). Three months ahead of the review (before the 1 October or 1 April), the new “reference price pharmaceuticals” (original pharmaceuticals that will enter the system) are determined, or the maintenance of the exception status of pharmaceuticals already in the system is checked. The pharmaceutical company then has the opportunity to submit applications to obtain exception status or applications for (applied pharmacy retail) price reduction (in order to avoid a “supplementary” co-payment for the patient).

Clusters are only formed if generic alternatives with the same Anatomic Chemical Classification (ATC) code are available. This implies that in the event that the only reimbursed generic alternative is not available for more than three months (e.g. in case of production problems) or is no longer on the market and a “supplementary” co-payment is charged to the patient (cf. section 4.4.2), the generic will be deleted from the list of reimbursed pharmaceuticals and the corresponding original pharmaceutical will lose its status of “reference price pharmaceutical” (and its reimbursement basis will be increased to the level of the applied pharmacy retail price (PRP).

On 1 July 2008, 2.679 pharmaceuticals (medical product packing, MPP) are grouped in 147 reference groups.

When an original pharmaceutical enters the reference price system, its reimbursement basis is diminished by 30% (of the ex-factory price), while its applied pharmacy retail price (PRP) remains the same. This means that a new reimbursement basis is determined for each individual (new) reference pharmaceutical. This implies that if a patient (doctor) opts for a reference pharmaceutical for which the pharmaceutical company has not lowered the applied price, the patient

will have to pay the difference between the applied price and the reimbursement basis (the so-called “supplementary” co-payment).

Doctors can prescribe the pharmaceutical they consider as being the most appropriate in a certain situation. However, prescription percentages for “cheap pharmaceuticals” are set (“premium system”). Generic pharmaceuticals and original pharmaceuticals included in the reference reimbursement system with an applied pharmacy retail price (PRP) equal to the reimbursement basis are considered as “cheap pharmaceuticals” (cf. section 5.2).

Legally, generic substitution is not allowed, but doctors have the option to prescribe by International Nonproprietary Name (INN) (in this case pharmacists must deliver a “cheap pharmaceutical”).

Legal framework:

- Coordinated Law of 14 July 1994
- Royal Decree of 21 December 2001

4.4 Private pharmaceutical expenses

Co-payment is equal for everyone, except for patients with a preferential reimbursement status (e.g. widows, orphans, retired people and people receiving disability benefits (and meeting certain income criteria), as well as the people being supported by these so-called “preferentially insured persons”) (cf. section 4.2), who benefit from preferential reimbursement and for whom the social security system contributes a higher percentage of the costs for the delivered medical aid. As of 1 April 2007, this arrangement has been extended to people with low incomes.

In order to increase the financial accessibility of medical care, the “maximum invoice” was introduced: when the medical aid costs of a family reach a certain limit (variable, depending on the type of “maximum invoice”), all expenses exceeding this amount are to be fully reimbursed, i.e. personal contributions for “indispensable” pharmaceuticals (reimbursed according to category A, B and C – cf. section 4.2.2) as well as fixed personal contributions for pharmaceuticals during hospital stays are taken into account.

Promotion of rational consumption of pharmaceuticals aimed at patients is carried out by sickness funds on a voluntary basis.

Cost-sharing policies (e.g. Anatomic Chemical Classification (ATC) “ATC level 4” – cf. section 4.6.3) aim to encourage both consumers and prescribing health practitioners to take on the responsibility of opting for cheaper alternatives, which consequently will, in time, facilitate better health care cost-containment.

4.4.1 Direct payments

Patients are faced with direct payments in cases where self-medication and non-reimbursed pharmaceuticals are involved, e.g. obesity treatment pharmaceuticals, nicotine replacement pharmaceuticals, nootropics, and pharmaceuticals used to stimulate or increase the sexual drive.

4.4.2 Out-of-pocket payments

The system of third-party payment (co-payment or out-of-pocket payment (OPP)) applies for reimbursed pharmaceuticals. When a patient presents her/himself in pharmacy with a prescription for a reimbursed pharmaceutical, this system provides that s/he only pays part of its total cost. The pharmacist sends the prescription to the patient's insurance fund, who pays the remaining part of the cost of the pharmaceutical directly to the pharmacist.

Co-payment is equal for everyone, except for patients with a preferential reimbursement status (e.g. widows, orphans, retired people and people receiving disability benefits (and meeting certain income criteria), as well as the people being supported by these so-called "preferentially insured persons") (cf. section 4.2), who benefit from preferential reimbursement and for whom the social security system contributes a higher percentage of the costs for the delivered medical aid. As of 1 April 2007, this arrangement has been extended to people with low incomes.

Co-payment is furthermore limited to a percentage of the real cost, with a "ceiling" fee. The percentage and the maximum of the cost that is reimbursed depend on the reimbursement category that is attributed to the pharmaceutical (cf. Table 4.2). Characteristics of the reimbursement categories are provided in Table 4.1.

Table 4.3: Belgium - Reimbursement rates and patient co-payment rates on 1st May 2008

Reimbursement categories	Preferentially insured patients (non-hospitalised)	Patients with "standard" insurance (non-hospitalised)
Category A	100% reimbursed No personal contribution	100% reimbursed No personal contribution
Category B	85% reimbursed 15% personal contribution: maximum € 7.20	75% reimbursed 25% personal contribution: maximum € 10.80
Category B big packages[1]	85% reimbursed 15% personal contribution: maximum € 8.90	75% reimbursed 25% personal contribution: maximum € 13.50
Category B ATC level 4 group[2]	85% reimbursed 15% personal contribution: maximum € 8.20	75% reimbursed 25% personal contribution: maximum € 12.20
Category B big packages[1] and ATC level 4 group[2]	85% reimbursed 15% personal contribution: maximum € 12.20	75% reimbursed 25% personal contribution: maximum € 18.50
Category C	50% reimbursed 50% personal contribution: maximum € 8.90	50% reimbursed 50% personal contribution: maximum € 13.50
Category C ATC level 4 group[2]	50% reimbursed 50% personal contribution: maximum € 12.20	50% reimbursed 50% personal contribution: maximum € 18.50
Category Cs	40% reimbursed 60% personal contribution: no maximum	40% reimbursed 60% personal contribution: no maximum
Category Cx	20% reimbursed 80% personal contribution: no maximum	20% reimbursed 80% personal contribution: no maximum

[1] A big package is defined as a package that contains more than 60 units

[2] At least one reimbursable generic or therapeutic equivalent is available within the ATC class (level 4)

ATC = Anatomic Therapeutic Chemical (classification)

Source: RIZIV/INAMI

Pharmaceuticals that belong to a therapeutic group (Anatomic Therapeutic Chemical (ATC) classification ATC level 4) containing at least one (reimbursed) generic pharmaceutical are subject to a higher maximal personal contribution. This governmental measure was introduced in November 2005 and aims to encourage patients to switch – where possible – to generic alternatives.

On top of these maximum co-payments, a "supplementary" co-payment can be charged to the patient if s/he (in consolidation with her/his doctor) opts for a reference pharmaceutical for which the pharmaceutical company has not lowered the applied price (cf. section 4.3).

4.4.2.1 Fixed co-payments

Fixed co-payments do not exist in Belgium.

4.4.2.2 Percentage co-payments

In Belgium, percentage co-payments are applied (cf. Table 4.2). Co-payment is limited to a percentage of the real cost, and limited to a “ceiling” fee.

4.4.2.3 Deductibles

Deductibles are not used in Belgium.

4.5 Reimbursement in the hospital sector

The positive reimbursement list is valid for both the out-patient sector and the hospital sector, and thus there are no specific reimbursement conditions for pharmaceuticals when used in hospitals. However, specific financing systems and reimbursement (out-of-packet payment) systems are in place.

On 1 July 2006 a new financing system was introduced for pharmaceuticals dispensed in hospitals, according to which hospitals receive fixed reimbursement for dispensed pharmaceuticals per stay for pharmaceuticals included in this fixed system, independent of the real expenditure of the patient.

Hospitalised patients are only charged a fixed daily amount of € 0.62 for dispensed reimbursed pharmaceuticals, while non-reimbursed pharmaceuticals are always charged in full.

For pharmaceuticals that are delivered to out-patient patients (patients that are not hospitalised), the same principle applies as in public pharmacies: the personal contribution is calculated according to the number of units of the pharmaceutical(s) the patient receives.

Each hospital draws up a so-called “hospital repertory”, a list of pharmaceuticals (reimbursed/non-reimbursed) continuously available in the central hospital pharmacy. In each hospital, the Repertory Commission (composed of, among others, the principal pharmacist and the principal physician) decides which pharmaceuticals will be listed in that hospital repertory (also cf. section 2.1.3.4).

4.6 Reimbursement-related cost-containment measures

4.6.1 Major changes in reimbursement lists

No major changes in the reimbursement list have been made since the late 1990s.

4.6.2 Introduction / review of reference price system

On 1 July 2005 the extended reference price system was introduced. While initially (1 June 2001) an original pharmaceutical only entered the system when a reimbursed generic alternative existed with an identical (qualitative and quantitative) composition and a comparable pharmaceutical form, the extended reference price system only takes into account the active component (Anatomic Therapeutic Chemical (ATC) classification ATC 5) of the generic alternative. In addition, a procedure to apply for exception status is now foreseen.

On 1 January 2007 the system was extended to post-patent molecules without generic alternatives (e.g. esomeprazole – NEXIAM). Since January 2007 the reference price system can be applied to these molecules, at the request of the Reimbursement Committee (CTG).

4.6.3 Introduction of new / other out-of-pocket payments

"ATC level 4":

Since 1 November 2005, pharmaceuticals that belong to a therapeutic group of pharmaceuticals (ATC level 4) containing at least one (reimbursed) generic pharmaceutical are subject to a higher maximum personal contribution. This governmental measure aims to encourage patients to switch – where possible – to generic alternatives. Furthermore, the maximum rates for category B (ATC level 4 group) and category C (ATC level 4 group) were substantially lowered on 1 May 2008.

On a yearly basis (1 January):

Indexing of the maximum out-of-pocket payment (OPP) rates. On 1 April 2007 the maximum rates of out-of-pocket payment (OPP) for category B (big packages) and category C were lowered, while the maximum rates for category B (ATC level 4 group) and category C (ATC level 4 group) were substantially lowered on 1 May 2008.

4.6.4 Claw-backs

In Belgium, a payback procedure has existed since 2002. This procedure was introduced for budgetary reasons and was based on the total pharmaceutical expenditure (TPE) (only) for reimbursable products.

Each year the target budget of the year in question was estimated, while the real expenditure of that year was calculated the following year. During the year in question, each firm paid an advance (a fixed percentage of the sales of the previous year) on an eventual payback. During the following year, the real expenditure was calculated and the difference between the prior estimated budget and the real expenditure was determined. In the event that the real expenditure exceeded the estimated budget, firms (and sickness funds) had to make up for part (65%) of this excess.

In 2006 this payback system was replaced by the so-called “Provision fund” system; a fund of €°100 Mio. created through the advances paid by the firms. This “Provision fund” will be used when the calculated real expenditure for the year X appears to be higher than the estimated budget (estimated the year before). In this case, firms must pay the required taxes during the year X in order to fill up the fund again.

The budgetary impact of the claw-back is evaluated once a year.

4.6.5 Reimbursement reviews

The Royal Decree of 21 December 2001 imposes an individual review of pharmaceuticals of class 1 (innovative pharmaceuticals) within a period of 18 months to 3 years after admission.

Individual reviews of other classes of pharmaceuticals (line extensions, non-innovative pharmaceuticals and generics) are possible at the justified request of the Minister of Social Affairs or the Reimbursement Committee (CTG).

The reimbursement decisions are reviewed on the basis of, e.g., expenditure data, reimbursement conditions in other European Union (EU) countries, and clinical data.

In general, the decisions on reimbursement (admission/modification/exclusion) are published on the Internet. Recently, the evaluation reports, drawn up by the Reimbursement Committee, are also published on the internet (www.inami.be).

5 Rational use of pharmaceuticals

5.1 Impact of pharmaceutical budgets

With regard to prescribing pharmaceuticals there are no budgetary constraints for doctors in Belgium, which means that there are no fixed monetary prescribing budgets.

Monitoring of prescribing habits is carried out by the National Institute for Health and Disability Insurance (RIZIV/INAMI). In most cases this is not a tool to monitor pharmaceutical expenditure (PE) but rather to stimulate good prescribing practices (cf. section 5.2).

It is recommended that doctors use the feedback from the National Institute for Health and Disability Insurance (RIZIV/INAMI) both for self-reflection and as a basis for discussion with their peers in local groups. So far there has been feedback on prescribing of antibiotics and antihypertensive pharmaceuticals. For an overview of all pharmaceutical feedback topics to physicians please consult the web site of the National Institute for Health and Disability Insurance (RIZIV/INAMI).[10]

Since 1 April 2006, physicians are obliged to prescribe a minimum percentage of “cheap pharmaceuticals”, which are being defined as generics or original pharmaceuticals included in the reference price system, with a price equal to the reimbursement basis, and International Non-proprietary Name (INN) prescribed pharmaceuticals. For more information about the reference price system, cf. section 4.3.

A first evaluation of the “cheap pharmaceuticals” rule has revealed that most doctors reach their target, but a formal evaluation of its impact on both patients and social security expenses has not yet been carried out.

Each doctor, including dentists, has to prescribe a minimum amount of these “cheap pharmaceuticals” – the exact percentage differs depending on the medical specialisation. If doctors do not comply with these percentage levels, they are asked to explain their actions. If the explanation is deemed unsatisfactory, the physician can be further monitored. If during the monitoring the physician’s prescribing pattern does not improve, doctors can either loose their accreditation and the accompanying higher fee-for-service payment(s) or receive a fine.

5.2 Prescription guidelines

As in most countries, there is a vast amount of prescription guidelines, mostly designed by non-profit-making organisations. In Belgium the Scientific Society of Flemish General Practitioners (Wetenschappelijke Vereniging van Vlaamse Huisartsen, WVVH) draws up guidelines about

[10] http://www.riziv.fgov.be/care/nl/doctors/promotion-quality/feedbacks/index.htm

various subjects. There are also other guidelines endorsed by the National Institute for Health and Disability Insurance (RIZIV/INAMI) and used both for monitoring and for giving feedback to doctors. Very important among these are those resulting from the consensus conferences that are organised twice a year by the National Institute for Health and Disability Insurance (RIZIV/INAMI). These conferences focus on the rational use of pharmaceuticals within a specific pathology, with corresponding guidelines. Other guidelines are those of the Belgian Antibiotic Policy Coordination Committee (BAPCOC), with a specific focus on the use of antibiotics in out-patient practice and in hospitals.

The guidelines of the consensus conferences have been used to change the legislation concerning the reimbursement of pharmaceuticals, e.g. statins and proton pump inhibitors (PPI). Based on other guidelines, indicators of rational drug use can be developed. Doctors who differ substantially from their peers in their use of pharmaceuticals which are dealt with in these guidelines can be committed to monitoring. Cf. section 5.1 for a description of the possible consequences of this monitoring.

The guidelines endorsed and drawn up by the National Institute for Health and Disability Insurance (RIZIV/INAMI) can be found on its web site and the results of the consensus conferences are sent to all doctors and pharmacists through the “Folia Phamacotherapeutica” which is a monthly bulletin about the rational use of pharmaceuticals published by the Belgian Centre for Pharmacotherapeutical Information (BCFI).

5.3 Information to patients / doctors

Information to patients and doctors concerning pharmaceuticals is regulated by Royal Decree. The Decree of 7 April 1995,[11] which is in line with the Directive 2001/83/EC, regulates both advertising of and distributing information about pharmaceuticals. Until 31 December 2006 the Ministry of Public Health (FOD VVVL) was responsible for implementing this regulation. On 1 January 2007 this role was taken over by the Federal Pharmaceuticals and Health Products Agency (FAGG).

Direct advertising for over-the-counter (OTC) pharmaceuticals to patients is allowed, but must comply with the regulations of the aforementioned Royal Decree and requires authorisation for the advertising campaign to be granted by the Supervisory Committee for Drug Advertising. Since it is forbidden to advertise pharmaceuticals using e-mails and IT tools, it can be deduced that advertising on the Internet is not allowed, although the Royal Decree does not forbid it explicitly.

Legally, there are no limitations on the amount that can be spent on advertising. Spending on advertising in general is regulated by the Belgian Tax Code and there are no exceptions for

11 https://portal.health.fgov.be/pls/portal/docs/PAGE/INTERNET_PG/HOMEPAGE_MENU/GENEESMIDDELEN1_MENU/LISTEDESLOISETARRETES1_HIDE/LISTEDESLOISETARRETES1_DOCS/AR-KB-1995-04-07-COORD_0.PDF

pharmaceutical advertising. This also means that there are no limitations on the quantity of advertising activities. The Decree only regulates the qualitative aspects of advertising. Articles 8 and 9 of the aforementioned Royal Decree set out the rules for advertising to doctors, but there is no formal audit of the material used. However, the Federal Pharmaceuticals and Health Products Agency (FAGG) has the authority to review all advertising campaigns at will. Article 11 of the same Royal Decree regulates the activities of pharmaceutical representatives, with no limitations on their activities other than those which are valid for all other forms of pharmaceutical advertising mentioned in the Decree.

Distribution of pharmaceutical samples is regulated by the Royal Decree of 11 January 1993.[12] This Decree stipulates that no prescriber can receive more than 600 samples per year and that no pharmaceutical firm can send more than eight packages of a pharmaceutical to the same doctor during any one year. Furthermore, it is forbidden to distribute samples of tranquilizers or psychotropic pharmaceuticals.

For general information on information to patients cf. section 2.1.3.6. More specifically, with regard to informing patients on the rational use of pharmaceuticals, there has been a large campaign concerning the use of antibiotics. It was a general campaign (television, Internet, billboards)[13] to inform patients about the danger of antibiotics resistance. Doctors and pharmacists were also included in the campaign to give additional information to patients.

There are no specific regulations on information to patients in the in-patient sector.

5.4 Pharmacoeconomics

The experts of the National Institute for Health and Disability Insurance (RIZIV/INAMI) and the Belgian Health Care Knowledge Centre are in charge of the evaluation of pharmacoeconomic guidelines. These methodological and reporting guidelines are developed as a tool to make pharmaceutical reimbursement requests submitted to the Reimbursement Committee (CTG) more consistent. These guidelines help the Reimbursement Committee (CTG) in the evaluation of the cost-effectiveness of the reimbursement requests and provide transparency for the companies regarding methodology and criteria. These health-economic analyses are performed by the company applying for the reimbursement and by specialist consultants.

Since 1 January 2002 the Reimbursement Committee (CTG) has issued a written notice including the formal requirements for a reimbursement request. The notice specified the criteria for submission stipulated in the Royal Decree concerning the procedures, terms and conditions for the reimbursement. A request for reimbursement by a pharmaceutical company of a pharma-

12 https://portal.health.fgov.be/pls/portal/docs/PAGE/INTERNET_PG/HOMEPAGE_MENU/GENEESMIDDELEN1_MENU/LISTEDESLOISETARRETES1_HIDE/LISTEDESLOISETARRETES1_DOCS/AR-KB-1993-01-11_0.PDF

13 http://www.antibiotics-info.be/

ceutical product of reimbursement Class 1 must include a compulsory pharmacoeconomic evaluation. Class 1 pharmaceuticals are those with a claimed therapeutic added value compared to existing therapeutic alternatives. Any deviations need a clear and detailed justification.

No provision of health-economic analyses is required in order to obtain market authorisation, or for pharmaceutical pricing decisions.

Officially, Belgium does not adopt a maximum sum that can be paid for one quality-adjusted life year (QALY). However, the usual of US$ 40,000 per quality-adjusted life year (QALY) is often considered as the maximum.

An overview of the content of the pharmacoeconomic guidelines:

- GUIDELINE 1: LITERATURE REVIEW
- GUIDELINE 2: PERSPECTIVE OF THE EVALUATION
- GUIDELINE 3: TARGET POPULATION
- GUIDELINE 4: COMPARATORS
- GUIDELINE 5: ANALYTIC TECHNIQUE
  - 1 Cost-utility analysis
  - 2 Cost-effectiveness analysis
  - 3 Cost-minimisation analysis
  - 4 Cost-benefit analysis
- GUIDELINE 6: STUDY DESIGN
  - 1 Trial-based pharmacoeconomic evaluations
  - 2 Modelling
- GUIDELINE 7: CALCULATION OF COSTS
  - 1 Cost categories
  - 2 Measurement of resource use
  - 3 Valuation of resource use
- GUIDELINE 8: ESTIMATION AND VALUATION OF OUTCOMES
  - 1 Effectiveness evaluation in cost-effectiveness analysis
  - 2 Utility assessment in cost-utility analysis
- GUIDELINE 9: TIME HORIZON
- GUIDELINE 10: MODELLING
  - 1 Need for modelling
  - 2 Precision of model structure and hypotheses
- GUIDELINE 11: HANDLING UNCERTAINTY AND TESTING ROBUSTNESS OF RESULTS
- GUIDELINE 12: DISCOUNT RATE
- GUIDELINE 13: USE OF DATA FROM OTHER COUNTRIES

These pharmacoeconomic guidelines are currently being revised.

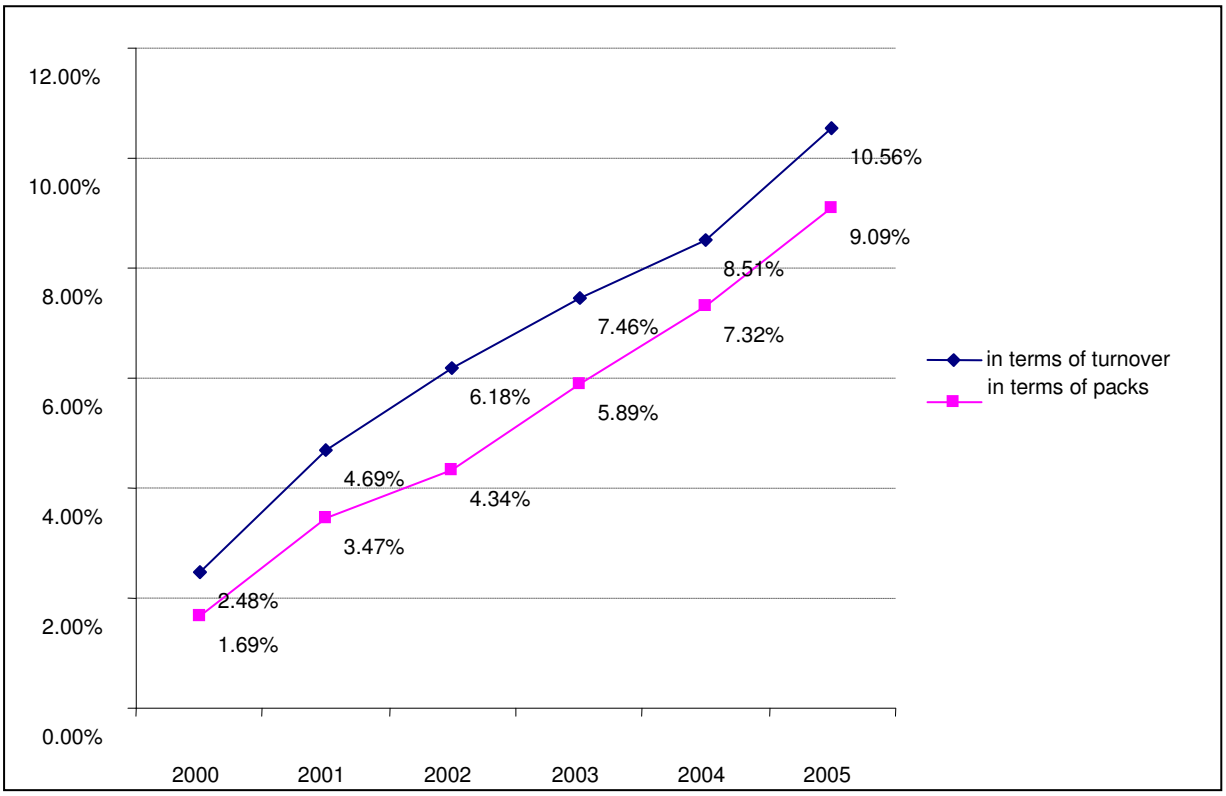
5.5 Generics

Although still low, the market share of generics both in volume and value is on the rise in Belgium. In 2000, generics accounted for 2.48% in volume and 1.69% in value of the total pharma-

ceutical sales in pharmacies. In 2005 these figures are 10.56% and 9.09% respectively, a 5-fold increase in both cases.

If looking only at the reimbursement market, the share of this kind of pharmaceutical is higher and has seen a greater increase. Data from the Pharmanet team of the National Institute for Health and Disability Insurance (RIZIV/INAMI) show that the generics market share in terms of volume (expressed as defined daily dose (DDD)) grew from 1.05% in 2000 to 16.7% in 2005.

Figure 5.1: Belgium - Market shares of generics at pharmacy market levels by value and volume, 2000-2005



Source: IMS

Table 5.1: Belgium - Development of the generics market in the out-patient sector 2000-2007

Generics market share	2000	2001	2002	2003	2004	2005	2006	2007
Volume (no. of packages per year) (%)	2.48	4.69	6.18	7.46	8.51	10.56	n.a.	n.a.
Value (%)	1.69	3.47	4.34	5.89	7.32	9.09	n.a.	n.a.

n.a. = not availble

Source: IMS

5.5.1 Generic substitution

In Belgium no form of substitution, including generic substitution, is allowed. However, doctors can prescribe by International Nonproprietary Name (INN), in which case the pharmacist is obliged to deliver a “cheap” pharmaceutical if one exists. A “cheap” pharmaceutical can be a generic pharmaceutical or an original pharmaceutical with a price equal to the reimbursement price.

There are, however, incentives for patients to ask their doctor to prescribe “cheap” pharmaceuticals, since these will cost them less. Furthermore, as explained in 5.1, doctors have to prescribe a minimum amount of “cheap” pharmaceuticals, and they can face sanctions if they do not comply to this rule.

5.5.2 Generic prescription

As stated earlier, doctors have to prescribe a minimum percentage of “cheap” pharmaceuticals and if they do not, they can face sanctions. Avoiding these sanctions, which have financial implications, could be seen as a “profit” for the doctor.

Belgian doctors have the possibility, but are not obliged, to prescribe by International Nonproprietary Name (INN). If they do, the pharmacist has to deliver a “cheap” pharmaceutical if one exists, and even if a cheap alternative does not exist, as is the case with patented pharmaceuticals, an International Nonproprietary Name (INN) prescription still counts as a “cheap” prescription.

Although no official scientific data exist, it appears from the medical press that a substantial number of doctors are opposed to the use of generics and to prescribing by International Nonproprietary Name (INN).

5.5.3 Generic promotion

The Belgian Government has a recurrent campaign to promote the use of generics. This campaign is geared both to health care professionals (doctors and pharmacists) and patients. The campaign consists of specialised information being disseminated to doctors and pharmacists to convince them of the value of generics, along with some more general information.

Patients are also informed about generics by their sickness funds. This information focuses mostly on the price and the resulting reduced costs of generic prescribing.

Generally speaking, promotion of generics is a cost-containment measure. Due to the fact that generics have to be at least 30% cheaper than the original pharmaceutical, promoting the use of generics at the expense of original pharmaceuticals is intended to lead to lower pharmaceutical expenditure (PE).

5.6 Consumption

Data about reimbursed pharmaceuticals delivered in pharmacies are collected by the Pharmanet system. This database is the property of the National Institute for Health and Disability Insurance (RIZIV/INAMI) and is updated every three months, due to the way in which the data are collected. Pharmacies send their data to an invoice office (tariferingsdienst/office de tarification) on a monthly basis, which in turn sends the data to the sickness fund. Once the data has been rendered anonymous by a trusted third party it is finally transmitted to the National Institute for Health and Disability Insurance (RIZIV/INAMI).

These data can be used by the National Institute for Health and Disability Insurance (RIZIV/INAMI) to create individual doctor profiles, which are then used to give them feedback about their prescribing patterns. However, it is not possible to use the data to monitor individual patient consumption, because of the process of rendering the data anonymous. Theoretically, sickness funds could use the data to monitor individual patients' consumption, but this is rarely, if ever, implemented.

Compliance data are not used in decisions regarding individual reimbursement. If a pharmaceutical is not subject to conditional reimbursement, a doctor may freely prescribe it and it will be reimbursed. The possibility exists, however, to include compliance in conditional reimbursement, i.e. a pharmaceutical can be reimbursed if the doctor proves that a patient does not respond to a certain (other) therapy or the event of intolerance to a particular (course of) pharmaceutical(s).

6 Current challenges and future developments

6.1 Latest changes

Table 6.1: Belgium - Changes in the pharmaceutical System, 2005 – 2008

Year	Pricing	Reimbursement	Not attributable to Pricing or Reimbursement
2005	-	1 July 2005: Introduction of the "extended" reference price system (only the active component ATC 5 is taken into account)	1 October 2005: Doctors have the possibility, but are not obliged, to prescribe by International Nonproprietary Name (INN)
2006	June 2006: Price notification by the company for certain pharmaceuticals (e.g. generics)	1 July 2006: New financing system for pharmaceuticals in hospitals	1 April 2006: Physicians are obliged to prescribe a minimum percentage of "cheap pharmaceuticals"
2007	-	1 January 2007: Extension of the reference price system to post-patent molecules without generic alternatives (at the request of the Reimbursement Committee)	1. June 2007: SD-doctors not are no longer allowed
	-	1 April 2007: Review of certain practical aspects; introduction of the shorter, administrative procedure for generics The maximum rates of out-of-pocket payment (OPP) for category B (big packages) and category C were lowered	-
	-	15 December 2007: Introduction of the "CHMP+" procedure, in which pharmaceutical companies may submit class 1 reimbursement applications earlier	-
2008	-	1. May 2008 The maximum rates for category B (ATC level 4 group) and category C (ATC level 4 group) were substantially lowered	-

Source: RIZIV-INAMI

6.2 Current challenges

6.2.1 Implementation of the new chapter II control system ("a posteriori" control):

In summer 2008 the new chapter II control system was introduced. It is based on the following principles:

- no need for a prior reimbursement authorisation granted by the insurance institution;
- the prescribing physician must respect the recommendations;
- the prescribing physician must keep certain documents in the patient's file.

6.2.2 Administrative simplification:

New and expensive pharmaceuticals are mostly submitted to a prior reimbursement authorisation for budgetary reasons. The increase of these "chapter IV" pharmaceuticals with specific reimbursement conditions and imposed application forms lead to a need and a clear request from the physicians for simplification, harmonisation and rationalisation.

6.2.3 Legal concerns - Reference price system versus patent disputes

As mentioned before, reference pricing is only applied on off-patent pharmaceuticals when a reimbursed generic alternative (ATC 5) is available (the strength is not taken into account).

More frequent additional patent disputes between the originator and the generic products companies arise, preventing the commercialization of the generic product and consequently interfering with the implementation of reference pricing (ex. FOSAMAX versus generic alendronates).

6.3 Future developments

New remuneration system for pharmacists: (status: under implementation)

The present pharmacy remuneration system is based on a strictly economical margin.

Due to the increase of big pack size pharmaceuticals and the rise of high priced pharmaceuticals (implying a margin erosion), pharmacists insisted on a reform of the remuneration system.

In the new system the margin will only partially depend of the pharmaceutical's price and will mainly depend of the quality of the pharmaceutical care.

This reform aims to revalorize the pharmacist's input and to motivate pharmacists to take up responsibility. The main restriction consists of the fact that the whole operation must be a neutral one (for health insurance, patients and pharmacists).

The reform will lead to a new retail price structure (note: for reimbursed pharmaceuticals only) and the introduction of specific honoraria (e.g. for executing INN prescriptions).

7 Appendixes

7.1 Web links

http://riziv.fgov.be, http://inami.fgov.be

7.2 Authors

The following authors contributed to this Pharma Profile:

Mrs Yoeriska ANTONISSEN, pharmacist

Mr Francis ARICKX, pharmacist

Mr Johan DE HAES, pharmacist

Mr André DE SWAEF, pharmacist

Mr Philippe VAN WILDER, pharmacist

7.3 Editors

The editors of the PPRI Pharma Profile 2008 were Dr. Sabine Vogler and Mag.(FH) Christine Leopold, MSc. from the Gesundheit Österreich GmbH / Austrian Health Institute.

The previous version of the PPRI Pharma Profile was edited by Dr. Danielle Arts; copy-editing was done by Ms. Nicole Satterly and the editor-in-chief was Ms. Trine Lyager Thomson.