



Pharmaceutical Health Information System

PHIS Hospital Pharma Report 2009

Draft report

BELGIUM

Commissioned by the European Commission, Executive Agency for Health and Consumers (EAHC) and the Austrian Federal Ministry of Health (BMG)

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PHIS Hospital Pharma Report

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Executive Summary

Hospitals are establishments for health care where, at any moment, appropriate medical-specialised examinations and/or treatments in the field of medicine, surgery and eventual obstetrics can be provided in a multidisciplinary relation, within the necessary and adapted medical, medical-technical, nursing, paramedical and logistic framework, to patients who are admitted to and can stay in the establishment because their state of health requires this entirety of care in order to challenge or relieve in the shortest possible time their illness, to recover or improve their state of health or to improve or stabilise their injuries.

In Belgium, health care 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.

The responsibilities are divided among several players in the health system (Federal Public Service of Health, the regional Ministries, the National Institute for Health and Disability Insurance (RIZIV-INAMI) and the sickness funds). Due to the complex split of responsibilities, the variety of payers and the mixture of means of financing (social insurance contributions and tax revenues), a significant amount of coordination and arrangements among the various decision-making bodies and financing institutions is required.

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.

The Ministry of Economic Affairs is the competent authority for setting the maximum prices of all medicines. All medicines are subject to statutory pricing. Although the pricing process leaves no room for negotiation, the actual applied price for reimbursed medicines is thus subject to negotiations during the reimbursement process.

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 medicines, whereas internal price referencing is only used for those medicines where a comparable product is marketed in Belgium.

The official prices differ from the actual prices (ex factory level) due to individual negotiations. There's no obligation for hospitals on the transparency of hospital prices.

In order to obtain reimbursement for a medicine, the pharmaceutical company that supplies the Belgian market must submit an application to the Reimbursement Committee (CTG). The Minister of Social Affairs decides on the reimbursement of medicines on the basis of a motivated proposal from the CTG.

All reimbursed medicines are placed on a positive reimbursement list, which is valid for both the out-patient sector and the hospital sector on a national level. Thus there are no specific reimbursement conditions for medicines when used in hospitals except for some medicines that are only reimbursed for in-patients.

On 1 July 2006, a new financing system was introduced for medicines dispensed in hospitals, according to which hospitals receive a fixed reimbursement sum for medicines dispensed during an in-patient stay, independent of the real expenditure for that patient.

In Belgian hospitals the organisation of a pharmaceutical therapeutic committee (PTC), that meets at least once a year and the use of a hospital pharmaceutical formulary (HPF) are a legal obligation. In general, each hospital draws up its own HPF which includes (in general) 750-1,000 medicines.

The consumption of pharmaceuticals for in-patients is decreasing year after year because there is a shift to patients treated in one-day-clinics.

The Belgian health care knowledge centre (KCE) has formulated different studies and rapid assessments of medicines, while the National Institute for Health and Disability Insurance (NIHDI) publishes the evaluation reports by the Reimbursement Committee of new reimbursed medicines, as well as the semi-annual M.O.R.S.E. reports (Monitoring of Reimbursement Significant Expenses), on its website.

Every six months an internal audit report is submitted to the NIHDI. This report is also submitted to a committee with representatives of the pharmacists and the sickness funds, which comments on the evolution of the expenditures and the use of medicines for in- and out-patient care.

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List of abbreviations

AIFA	Agenzia Italiana del Farmaco / Italian Medicines Agency
APB	Belgian Pharmaceutical Association (Algemene Pharmaceutische Bond)
BMG	Austrian Ministry of Health
CIVAS	Centralized Intravenous Admixtures Service
CTG	Commissie Tegemoetkoming Geneesmiddelen
DDD	Defined Daily Doses
DG SANCO	Health and Consumer protection Directorate General
DRG	Diagnosis-related group
EAHC	Executive Agency for Health and Consumers
EU	European Union
GÖG/ÖBIG	Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG / Austrian Health Institute
HOSHE	Health expenditure in hospitals
HOSPE	Pharmaceutical expenditure in hospitals
IHHII	International Healthcare and Health Insurance Institute
INAMI	Institut national d'assurance maladie-invalidité
KCE	Belgian health care knowledge centre
M.O.R.S.E.	Monitoring Of Reimbursement Significant Expenses
NCU	National Currency Unit
NIHDI	National Institute for Health and Disability Insurance
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
OECD	Organization for Economic Co-operation and Development
OPP	Out-of pocket payments
PE	Pharmaceutical Expenditure
P _{ex fact}	Ex factory price
PHIS	Pharmaceutical Health Information System
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PTC	Pharmaceutical Therapeutic Committee

RIZIV	Rijksinstituut voor ziekte- en invaliditeitsverzekering
SUKL	Statny Ustav pre Kontrlu Lieciv / State Institute for Drug Control (Slovakia)
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
VAT	Value Added Tax
WP	Work Package

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Introduction

PHIS research project

PHIS (Pharmaceutical Health Information System) is a research project commissioned under the call for proposals 2007 in the priority area “health information” of the European Commission, DG SANCO. It has been commissioned by the Executive Agency for Health and Consumers (EAHC) and co-funded by the Austrian Ministry of Health (BMG).

The PHIS project aims at increasing knowledge and exchange of information on pharmaceutical policies, in particular on pricing and reimbursement, in the European Union (EU) Member States, covering both the out-patient and the in-patient sector.

This will be done via different work packages (WP) resulting in the following deliverables:

- the PHIS Glossary with key terms related to pharmaceuticals,
- the PHIS Library offering country specific information on out-patient and in-patient pharmaceutical pricing and reimbursement for the EU Member States,
- the PHIS Indicators and the PHIS Database, containing major data for the developed indicators in the Member States,
- the PHIS Hospital Pharma Report with information on pharmaceutical policies in the in-patient sector in the EU Member States, including a price survey.

The PHIS project management is a consortium of the project leader Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (GÖG/ÖBIG), which is a research institute situated in Vienna, Austria, and four associated partners:

- the Italian Medicines Agency (AIFA),
- the International Healthcare and Health Insurance Institute (IHHII), Bulgaria,
- SOGETI Luxembourg SA., which is a services provider, and
- the State Institute for Drug Control (SUKL), Slovakia
- SUKL is the WP leader of Hospital Pharma.

Further key stakeholders are the PHIS Advisory Board covering EU Commission services and agencies and other international organisations, and the PHIS network, which comprises national representatives from competent authorities and further relevant institutions from the EU Member States and associated countries.

The PHIS project runs from September 2008 to April 2011 (32 months). Further information and all deliverables are made available at the PHIS project website <http://phis.goeg.at>.

PHIS Hospital Pharma

The aim of the work package “Hospital Pharma” is an in-depth investigation of the in-patient sector, as systematic knowledge of pharmaceutical policies in this sector has been rather poor.

The survey is divided in two phases:

- Phase 1: General survey

Country reports on pharmaceuticals in hospitals (“PHIS Hospital Pharma Reports”), designed to describe specific pharmaceutical policies in the in-patient sector in the EU Member States (spring 2009)

- Phase 2: Case studies

A specific survey, including a price survey, provided by means of case studies, in a limited number of hospitals in a few countries (autumn 2009).

The final PHIS Hospital Report, covering information from the general survey (phase 1) and the case studies (phase 2), is scheduled for February 2010.

Methodology of the general survey

The production of the country-specific PHIS Hospital Pharma Reports is based on three steps:

1. Development of a uniform PHIS Hospital Pharma Report Template

The PHIS Hospital Pharma Report Template offers a homogenous, very detailed structure for describing the pharmaceutical pricing and reimbursement system in the in-patient sector of a country. The Template was developed by SUKL, Slovakia (Work Package leader of Hospital Pharma) in coordination with GÖG/ÖBIG (PHIS project leader) and further members of the PHIS project management. It is based on literature and internet reviews as well as interviews with experts in the hospital sector in the EU Member States. Members of the PHIS network received the draft Template for feed-back, and had an opportunity to discuss and provide personal feed-back during a meeting.

2. Collecting information and data and drafting the PHIS Hospital Pharma Report

The country-specific PHIS Hospital Pharma Reports were written by members of the PHIS network. In order to get the needed information and data, hospital experts were contacted and involved in several countries. They provided information and data in written form and during telephone conversations and personal talks. In some countries the reports (or parts of it) were written by hospital experts. In several countries, the preparatory work for drafting the PHIS Hospital Pharma Reports also included study visits of the authors to hospitals and hospital pharmacies. Information on persons and institutions involved can be found in the

“Acknowledgements” at the beginning of this PHIS Hospital Pharma Report and in section 8 “References and data sources”, listing “Literature and documents” (section 8.1) and “Contacts” (section 8.2).

3. Editorial process

The draft PHIS Hospital Pharma Reports were submitted to the project management for review, which was undertaken by SUKL, Slovakia (Work Package leader of Hospital Pharma) in coordination with GÖG/ÖBIG (PHIS project leader). The review focused on checking clarity and consistency in general and with regard to the outline of the Template and terminology (PHIS Glossary). In the course of the editorial process, the reviewers contacted the authors for providing feed-back on language and content, offering suggestions for re-phrasing and change and clarified open and/or misunderstanding points.

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1 Background

1.1 Definition and scope

The definition of a hospital is constitutionalised in articles 1, 2 and 3 of the Belgian law on hospitals, coordinated on 7 August 1987:

“Hospitals are establishments for health care where, at any moment, appropriate medical-specialised examinations and/or treatments in the field of medicine, surgery and possibly obstetrics can be provided in a multidisciplinary relation, within the necessary and adapted medical, medical-technical, nursing, paramedical and logistic framework, to patients who are admitted to and can stay in the establishment because their state of health requires this entirety of care in order to challenge or relieve in the shortest possible time their illness, to recover or improve their state of health or to improve or stabilize their injuries.”

Hospitals are engaged in the execution of a task of public interest.

Three types of hospitals are explicitly defined in law:

- Psychiatric hospitals: hospitals which are exclusively intended for patients who need psychiatric treatment.
- University hospitals: (university) hospital units or university care programs that, considering their specific function in the field of patient care, clinical education, applied scientific research, development of new technologies and evaluation of medical activities, meet the required legal conditions and are officially designed as such on the proposal of the academic authorities of a Belgian university with a faculty for medicine with a complete statement of intention, principles and organisation.
- Small hospitals: hospitals with a limited number of departments and/or beds or a limited number of active hospital physicians.

Besides these three defined types of hospitals other hospitals exist as shown in table 1.1.

All hospitals are licensed by the Minister of Public Health.

The descriptions in the different chapters of this profile apply to all hospitals. If necessary, a clear distinction is made in the relevant subsection.

Table 1.1 gives an overview of a complementary classification of hospitals.

Table 1.1: Belgium – classification of hospitals

Dimension : type of hospital
General hospitals for all patients without distinction as to gender, age or type of medical care provided. These hospitals execute a task of public interest.
Psychiatric hospitals for all patients who need psychiatric treatment.
Special hospitals for the examination and treatment of patients with particular diseases or for other special purposes.
Hospitals for convalescent patients in need of medical care and special nursing care.
Independent out-patient health clinics: (more than 60) independent establishments that fall outside the scope of the official definition. They mainly work in the field of aesthetic surgery and alternative therapies.
Dimension: type of care
Acute care hospitals are publicly funded hospitals with an average length of stay of 8 days or less.
Non-acute care is provided by all other hospitals.
Dimension: legal status
Public law status: a hospital may be granted public law status if it is non-profit making and if it meets certain requirements.
Public benefit: a hospital is classified as being for public benefit if it is operated for non-profit. Furthermore the hospital admits any patient requiring admission if it is equipped to provide the appropriate treatment.
Profit organisations: Independent out-patient health clinics that make profits in the treatment of patients.
Dimension: ownership
Political administrative units: regional - municipal
Sickness funds
Private owners: religious orders and congregations - private societies - associations/foundations

Source: RIZIV / INAMI / NIHDI

1.2 Organisation

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

The federal legislation is exercised by the two Chambers of Parliament – the Chamber of Representatives and the Senate. 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, Vice-prime ministers and also a number of ministers and state secretaries appointed by the King.

In Belgium, health care 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.

The responsibilities are divided among several players in the health system: Federal Public Service of Health, the regional ministries, the National Institute for Health and Disability Insurance (NIHDI) and the sickness funds.

The basis for this split of responsibilities is laid down in articles 127 to 140 of the Federal Constitution Law. The Federal Constitution Law only enacts the basic principles and laws, whereas the regions are responsible for the legislation on the implementation, the execution and the enforcement.

Due to the complex split of responsibilities, the variety of payers and the mixture of means of financing (social insurance contributions and tax revenues), a significant amount of coordination and arrangements among the various decision-making bodies and financing institutions is required.

Within the in-patient sector, the Federal Public Service of Health mainly uses health care planning as an instrument of controlling health care provisions and services.

The regional ministries define the quality criteria for hospitals, do the homologation of the hospital services for a restricted period (for example five years for the hospital pharmacy) and they also control these criteria.

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Belgium

Table 1.2: Belgium – Key data on in-patient care, 2000 and 2004–2008

In-patient care	2000	2004	2005	2006	2007	2008
No. of hospitals¹	n.a.	214	216	215	210	n.a.
<i>Classified according to ownership</i>						
- thereof public hospitals	n.a.	62	64	64	60	n.a.
- thereof private hospitals	n.a.	152	152	151	150	n.a.
- thereof other hospitals (please specify)	n.appl.	n.appl.	n.appl.	n.appl.	n.appl.	n.appl.
<i>Classified according to subtypes¹</i>						
- thereof general hospitals	n.a.	146	147	146	142	n.a.
- thereof mental health and substance abuses hospitals	n.a.	68	69	69	68	n.a.
- thereof speciality (other than mental health and substance abuse) hospitals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of acute care beds	n.a.	70,936	70,724	70,660	70,444	n.a.
- thereof in the public sector	n.a.	24,760	24,335	24,611	23,800	n.a.
- thereof in the private sector	n.a.	46,176	46,389	46,049	46,644	n.a.
Average length of stay in hospitals	8.4	8.1	8	7.9	n.a.	n.a.
No. of hospital pharmacies	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
thereof no. of hospital pharmacies that serve out-patients	n.a.	146	147	146	142	n.a.

n.a. = not available, n.appl. = not applicable

Note: Data are indicated as of 31 December

¹ according to OECD definition and its subtypes

Source: FOD Volksgezondheid / FPS Public Health

The figures in table 1.2 indicates that

- the number of hospital pharmacies is slightly decreasing due to fusion of hospitals;
- the number of acute beds is slightly decreasing;
- 70% of the hospitals are private hospitals.

Table 1.3: Belgium – Pharmaceuticals, 2000 and 2005–2009

Number of pharmaceuticals	2000	2005	2006	2007	2008	2009
Authorised pharmaceuticals in total (*)	9,151	12,999	13,694	14,372	15,397	16,130
- thereof hospital-only pharmaceuticals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

n.a. = not available

Note: Data are indicated as of 1 January

(*) method of counting: incl. different pharmaceutical form, different pack sizes, incl. different dosages

Source: APB

On the average, 15,000 marketing authorisations are registered in Belgium. The exact number of medicines that are really available on the market is unknown.

Hospital-only medicines are not explicitly indicated as such in the list of authorised medicines; if reimbursement is limited to hospital use only, this is clearly indicated in the positive reimbursement list.

All (acute) general hospitals have their own pharmacy that dispenses to in- and out-patients (one day clinic). Due to a recent wave of consolidation, some hospitals make use of different sites with a central pharmacy and dispensing point.

The purchase and supply of medicine and diagnostic products and medical devices, the custom made production of specific medicines and the medicine support of the medical treatment (clinical pharmacy) and nursing aid, are the main services offered by hospital pharmacists.

Hospital pharmacies mostly obtain medicines and medical devices directly from pharmaceutical companies. Wholesalers only play a minor role in the in-patient sector. Private pharmacies do not operate in hospitals.

1.3 Funding

1.3.1 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 142 hospitals providing in-patient care in 2007, 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.

Generally speaking, hospitals have five main sources of funding: a (1) fixed annual budget based on historical all patient refined diagnosis-related group (APR-DRG) data; (2) fee-for-service funding for certain activities, e.g. 1-day clinics and dialysis; (3) part of the fees of doctors working in hospitals; (4) profits made on medicines and medical devices; and (5) 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 medicines and doctors' fees.

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Belgium

Table 1.4: Belgium – Health and pharmaceutical expenditure, 2000 and 2004–2008

Expenditure (in million EUR)	2000	2004	2005	2006	2007	2008
Total health expenditure (THE)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- thereof THE public	12,820	16,772	17,250	17,735	18,873	20,704
thereof THE private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
THE in hospitals (HOSHE)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
thereof HOSHE public	5,452	6,602	6,613	6,693	6,983	7,434
thereof HOSHE private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total pharmaceutical expenditure (TPE)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- thereof TPE public	2,440	3,248	3,331	3,304	3,548	3,956
- thereof TPE private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Pharmaceutical expenditure in hospitals (HOSPE)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- thereof HOSPE public	480	581	588	580	580	590
- thereof HOSPE private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

HOSHE = health expenditure in hospitals, HOSPE = pharmaceutical expenditure in hospitals, n.a. = not available, NCU = national currency unit, PE = pharmaceutical expenditure, THE = total health expenditure, TPE = total pharmaceutical expenditure

Note: Data are indicated as of 31 December (as from January 2008, more expenses are reimbursed to self-employed persons)

Source: RIZIV / INAMI / NIHDI

2 Pricing

2.1 Organisation

2.1.1 Framework

The Ministry of Economic Affairs is the competent authority for setting the maximum prices of all medicines.

All medicines are subject to statutory pricing, which is regulated by two Ministerial Decrees, both of 29 December 1989, one for reimbursable and one for non-reimbursable medicines. European average prices and the relative value of the medicine with regards to a set price level are taken into account.

There are two pricing committees, one for reimbursed and one for non-reimbursed medicines. Both committees have an advisory role. The price set by the Minister of Economic Affairs is a maximum price, thus a medicine can never be marketed at a higher price than this.

After the maximum price has been set by the Minister of Economic Affairs, the Reimbursement Committee (Commissie Tegemoetkoming Geneesmiddelen, CTG) can negotiate with the medicine company to determine the reimbursement level that will be proposed to the Minister of Social Affairs, who makes the final decision concerning reimbursement. Although the pricing process leaves no room for negotiation, the actual applied price for reimbursed medicines is thus 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).

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 medicines, whereas internal price referencing is only used for those medicines where a comparable product is marketed in Belgium.

As medicines used in hospitals are purchased directly at the manufacturer, negotiations are private and are not monitored.

The pricing regulation for the out-patient sector is partly relevant for hospitals as well.

2.1.2 Hospital prices

Table 2.1: Belgium - Structure of hospitals prices

Ex factory price ($P_{\text{ex fact}}$)	Price per unit (€)	
	In-patient	Out-patient
< 30,86 €	$[P_{\text{ex fact}} * 1,06] / \text{unit}^1$	$[P_{\text{ex fact}} * 1,2905] / \text{unit}^1$
$\geq 30,86$ €	$[P_{\text{ex fact}} * 1,06] / \text{unit}^1$	$[(P_{\text{ex fact}} * 1,06) + 7,11] / \text{unit}^1$

unit¹: the number of units in the packing that serves as the basis for the calculation of the hospital prices (i.e. the biggest reimbursed pack size destined for sale in public pharmacy or, in the absence of the latter, the smallest hospital packing)

Source: RIZIV / INAMI / NIHDI

Medicines sold to hospitals are subject to 6% VAT which is the VAT valid for all medicines.

For medicines delivered to non-hospitalised patients the hospital pharmacy remuneration consists of a fixed mark-up, which is statutorily fixed at 21.746% of the ex factory price, with a maximum of € 7.11. There is no remuneration for hospital pharmacies when providing services for in-patients.

The official prices differ from the actual prices (ex factory level) due to individual negotiations. There is no obligation for hospitals on the transparency of hospital prices.

Prices between hospitals are different and are lower in the in-patient sector than in the out-patient sector.

2.2 Pricing policies

2.2.1 Procurement

Procurement is the major pricing policies in Belgium hospitals.

Hospitals are free to practice their own procurement procedures. There are no legal obligations.

The price is the decisive factor but also qualitative factors (storage, supply conditions etc.) are taken into account.

2.2.2 Negotiation

There are no other pricing policies besides procurement.

3 Reimbursement

3.1 National reimbursement procedure

In order to obtain reimbursement for a medicine, the pharmaceutical company that supplies the Belgian market must submit an application to the Reimbursement Committee (CTG). The Minister of Social Affairs decides on the reimbursement of medicines on the basis of a motivated proposal from the CTG.

The 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, gender, chronic or terminal illness)
- disease-specific criteria (e.g. severity of illness, special medical needs).

All reimbursed medicines are placed on a positive reimbursement list.

The positive reimbursement list is valid for both the out-patient sector and the hospital sector on a national level. Thus there are no specific reimbursement conditions for medicines when used in hospitals except for some medicines that are only reimbursed for in-patients.

The list can be consulted on the website of the National Institute for Health and Disability Insurance (www.inami.be) (update on a monthly basis). 5,914 packages of medicines (November 2009) are listed on the positive reimbursement list. 699 packages are only reimbursed for in-patients.

On 1 July 2006, a new financing system was introduced for medicines dispensed in hospitals, according to which hospitals receive a fixed reimbursement sum for medicines dispensed during a patient stay, independent of the real expenditure for that patient.

A list with exceptions on the rule of the lump sum system contains expensive medicines like medicines for cancer and AIDS-treatment. This list was formulated to avoid that in some hospitals patients would not be treated because of the expensive cost of the treatment and would be sent on to another hospital.

Specific budgets for orphan medicines are fixed within the global budget for medicines.

Hospitalised patients are charged a fixed daily amount of € 0.62 for dispensed reimbursed medicines, while non-reimbursed medicines are always charged in full. For medicines that are delivered to ambulatory 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 medicine(s) the patient receives.

3.2 Hospital pharmaceutical formularies

The organisation of a pharmaceutical therapeutic committee (PTC) and the use of a hospital pharmaceutical formulary are a legal obligation.

Belgian hospitals are obliged to establish this committee, which meets at least once a year.

The members of the PTC are the head of the hospital pharmacy, the chief doctor, the chief nurse and some physicians representing the medical team.

The PTC has the following defined tasks:

- organisation and decision-making on the articles of association
- compilation of a list of medicines (reimbursed or not) that are purchased by the hospital (hospital pharmaceutical formulary, HPF)
- update of the HPF

When doing this the committee has to consider the following guidelines:

- the selection of the medicines has to be done on the basis of evidence based medicine;
- in the process of the setting up of the HPF the purpose and the services of the hospital have to be considered to guarantee the provision of the required medicines to the patients.

In general, each hospital draws up its own HPF, which includes (in general) 750-1,000 medicines.

4 Consumption of pharmaceuticals

Table 4.1 shows the consumption of pharmaceuticals for in-patients which has been decreasing year after year because there is a shift of patients treated in one day clinics.

Table 4.1: Belgium – Pharmaceutical consumption, 2000 and 2004–2008

Pharmaceutical consumption	2000	2004	2005	2006	2007	2008
Annual pharmaceutical consumption in total						
in packs	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
in DDD (data from public pharmacies)	n.a.	3,037,551	2,988,737	3,195,269	3,421,801	3,814,699
In other measures units (e.g. unit doses)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Annual pharmaceutical consumption in hospitals						
in packs	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
in DDD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
In numbers of units of administration	459,785,403	323,145,358	309,173,437	299,814,479	288,449,562	n.a.

DDD = Defined Daily Doses, n.a. = not available

Source: RIZIV / INAMI / NIHDI

Table 4.2: Belgium – Top 10 pharmaceuticals by pharmaceutical expenditure and consumption 2007 or latest available year in hospitals

Position	Top pharmaceuticals used in hospitals, indicated by active ingredient, ranked with regard to consumption	Position	Top pharmaceuticals used in hospitals, indicated by active ingredient ranked with regard to expenditure
1	SEVOFLURAN	1	INFLIXIMAB
2	ALBUMINE	2	EPOETIN
3	ELECTROLYTS	3	DARBEPOETIN ALFA
4	DIATRIZOIC ACID	4	TRASTUZUMAB
5	HEPARIN	5	IMMUNOGLOBULIN
6	COAGULATION FACTORS IX, II, VII AND X IN COMBINATION	6	RISPERIDON
7	PARACETAMOL	7	ELECTROLYTS
8	DESFLURAN	8	DOCETAXEL
9	RANITIDIN	9	PERFUSION SOLUTIONS
10	AMOXICILLIN AND ENZYME INHIBITOR	10	COAGULATION FACTOR VIII

Source: RIZIV / INAMI / NIHDI

5 Evaluation

5.1 Monitoring

Every six months an internal audit report is submitted to the Insurance Committee of the NIHDI. The Insurance Committee is a decision making board existing of representatives of the doctors, hospitals, pharmacists, paramedics and the sickness funds.

This report is also submitted to a committee with representatives of the pharmacists and the sickness funds, which comments on the evolution of the expenditures and the use of medicines for in- and out-patient care.

These reports are not publicly available on the website of the NIHDI.

The majority of the hospitals uses electronic prescription systems linked to the purchase order, inventory control and stock-taking. The administration of medicines is recorded and serves as the basis for the units of care supplies and the invoices that are electronically sent to the sickness funds. Every hospital uses an electronic message system for the exchange of information with the sickness funds. These data are also transferred to the NIHDI by means of an anonymous patient record.

Hospital pharmacists are responsible for the following services:

- product services, which include the preparation of non-sterile and/or sterile products and Centralised Intravenous Admixtures Service (CIVAS);
- support services, which include the purchasing, the supply of medicines towards and/or to patients, the education and training of personnel and patients, computer services, research and development;
- clinical services, which include medicine information, formulary services and the formulation of recommendations of optimal medicine therapy for the individual patient (in 2010, these activities will be reinforced as additional budgets will be liberated for the development of clinical pharmacy);
- communication and interaction with other professionals (e.g. interactions of clinical pharmacologists with physicians).

Two hospital pharmacists are member of the Reimbursement Committee (CTG) (see 3.1).

5.2 Assessment

The Belgian health care knowledge centre (KCE) has formulated different studies and rapid assessments of medicines. "The use of Alzheimer drugs", "The use of tiotropium" and "The need of blood plasma" are some examples. These reports are available on the website of the KCE (www.kce.fgov.be).

The NIHDI on the other hand, publishes the evaluation reports of the Reimbursement Committee of new reimbursed medicines, as well as the semi-annual M.O.R.S.E. reports (Monitoring Of Reimbursement Significant Expenses), on its website (<http://www.inami.fgov.be/drug/fr/statistics-scientific-information/report/index.htm>).

There have been no recent specific cost-containment measures regarding medicines taken in hospitals. In 2009, hospitals were pointed out the importance of an adequate use of expensive medicines (such as orphan medicines).

6 Interface management

To be completed.

7 Developments and outlook

To be completed.

8 References and data sources

8.1 Literature and documents

To be completed.

8.2 Contacts

This first draft version was written without consulting hospitals in order to collect data.

draft - not to be cited