Pharmaceutical Health Information System

PHIS Hospital Pharma Report

The Netherlands

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

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Executive Summary

For this profile the OECD definition of hospitals is used. In the Netherlands, all hospitals are non-profit hospitals in the public sector.

For all “curative care” hospitals (including curative mental health hospitals) remuneration is on the basis of Diagnosis and Treatment Combination system (Diagnose Behandeling Combinaties, DBCs). This is rather similar to the diagnosis-related group system. A DBC entails all activities of the hospital from the initial diagnosis to the last treatment and check-up. The costs covered by a DBC also include the use of resources of the hospital, costs of medical specialists, and most of the pharmaceutical care.

For reimbursement purposes, no specific procedure exists for medicines which are used inside hospitals. However, the Dutch Healthcare Authority (Nederlandse Zorgautoriteit, NZa) is responsible for maintaining a list of high-cost medicines and a list of orphan medicines, for which a procedure for their inclusion is needed. The medicines on the orphan medicines list and on the list of high-cost medicines of NZa are not covered by DBCs. These medicines are remunerated separately. For medicines on the NZa list of high-cost medicines, the hospital receives 80% reimbursement from the health insurer. The remaining 20% is paid by the hospital out of its own budget, which serves to stimulate hospitals to use these medicines in an efficient way. For medicines on the orphan medicines list the hospital receives 100% reimbursement from the health insurance.

No special pricing mechanisms exist for medicines used in the in-patient sector. Prices are controlled by setting maximum prices for those medicines which are reimbursable when dispensed in the out-patient sector. These maximum prices also apply to the same medicines when dispensed in the in-patient sector.

For the purpose of purchasing medicines, hospitals join together in regional purchasing groups. The regional purchasing groups purchase medicines by means of tendering. For medicines which are not obtained by means of the purchasing groups, a hospital generally makes arrangements with the manufacturer. The results of the tenders by the regional purchasing groups are not published. Information on the outcome is not shared.

Expenditure, prices and consumption of medicines on the list of high-cost medicines of NZa are monitored at national level by the Foundation for Pharmaceutical Statistics (Stichting Farmaceutische Kengetallen, SFK). For all other medicines used in the in-patient sector, no monitoring takes place at national level. Therefore, the information on consumption and expenditure in the in-patient sector is limited.

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List of abbreviations

ATC	Anatomic therapeutic chemical classification
AWBZ	Algemene Wet Bijzondere Ziektekosten / Exceptional Medical Expenses Act
CVZ	College voor Zorgverzekeringen / Dutch Health Care Insurance Board
CBS	Centraal Bureau voor de Statistiek / Statistics Netherlands
DBC	Diagnose Behandeling Combinaties / Diagnosis and Treatment Combination system
DDD	Defined daily doses
DG SANCO	Health and Consumer Protection Directorate General
DRG	Diagnosis-related group
EU	European Union
GDP	Gross domestic product
HE	Health expenditure
HOSHE	Health expenditure in hospitals
HOSPE	Pharmaceutical expenditure in hospitals
HPF	Hospital pharmaceutical formulary
HTA	Health Technology Assessment
IHHII	International Healthcare and Health Insurance Institute
NCU	National currency unit
NHS	National health service
NZa	Nederlandse Zorgautoriteit / Dutch Health Care Authority
NVZ	Nederlandse Vereniging van Ziekenhuizen / Dutch Hospitals Association
Mio.	Million
OECD	Organisation for Economic Co-operation and Development
OPD	Out-patient department(s)
OPP	Out-of pocket payments
OTC	Over-the-counter medicine
PE	Pharmaceutical expenditure
PHIS	Pharmaceutical Health Information System

POM	Prescription-only medicines
PPP	Pharmacy purchasing price
PPPa	Purchasing power parities
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy retail price
SHI	Social health insurance
SFK	Stichting Farmaceutische Kengetallen / Foundation for Pharmaceutical Statistics
THE	Total health expenditure
TPE	Total pharmaceutical expenditure
VAT	Value added tax
WP	Work package
WTZi	Wet Toelating Zorginstellingen / Act on Licensing of Care Provider Institutions
ZBC	Zelfstandige Behandel Centrum / Independent Health Centres

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 outline 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 conservations 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

1 Background

1.1 Definition and scope

In the Netherlands, no legal definition exists of the term hospital. The Act on Licensing of Care Provider Institutions *(*Wet Toelating Zorginstellingen, WTZi*)* regulates the authorisation of hospitals and other institutions providing health care.

For the purpose of this profile, the OECD definition is used which is (in general) applicable for hospitals in the Netherlands. The three subtypes defined by the OECD can also be distinguished in the Netherlands: general hospitals, speciality hospitals ("categorale ziekenhuizen") and mental health and substance abuse hospitals.

Apart from these, Independent Health Centres (Zelfstandige Behandel Centra*,* ZBCs) and private health clinics may provide health care in the Netherlands. Both ZBCs and private health clinics focus on relatively simple surgeries and operations. ZBCs are very small institutions (sometimes consisting of just two physicians) that mostly provide health care covered by the health care insurance. Private clinics mostly provide health care which is not covered by insurance. Since only very limited data are available on both private clinics and ZBCs, these are not covered in the profile. The market share of these institutions is still very limited, though it is increasing.

1.2 Organisation

The Act on Licensing of Care Provider Institutions (Wet Toelating Zorginstellingen, WTZi*)* regulates the establishment and governance of hospitals. All hospitals are non-profit hospitals in the public sector.

Hospitals are not allowed to pay dividends. When a hospital makes profit, this is reinvested in the hospitals itself. This also applies for Independent Health Centres (ZBCs, cf. section 1.1). However, private clinics, which mostly provide health care which is not insured, are allowed to pay dividends. The types of health care private clinics may provide is restricted by the WTZi.

Concerning the governance, a framework is also laid out in the WTZi. Hospitals are run by a board of directors. The board of directors is responsible for making budgetary decisions in hospitals (of course in consultation with the medical staff). As stipulated in the WTZi, all hospitals also have an independent board of supervision.

To provide highly specialised care (for which advanced equipment, facilities and specifically trained personal is needed), hospitals need special authorisation from the Ministry of Health,

Welfare and Sport. Some highly specialised care is only provided by university hospitals, which function as a “last resort” for patients with complex or very rare disease patterns.

The Dutch Healthcare Authority (Nederlandse Zorgautoriteit, NZa) is the governmental supervisory body for both health care providers and insurers, in the curative markets as well as the long-term care markets. NZa sets conditions (including tariffs) for market forces to operate and enforces these conditions. Its main task is to monitor the public interests in health care: health care must remain accessible, of good quality and affordable for consumers.

The Dutch Hospitals Association (Nederlandse Vereniging van Ziekenhuizen, NVZ) functions as the major stakeholder organisation of the Dutch hospital sector, both for the general hospitals and the speciality hospitals. The Dutch Federation of University Hospitals (Nederlandse Federatie van Universitaire Medische Centra) represents the university hospitals. Mental health and substance abuse hospitals are represented by Mental Healthcare Nederland (Geestelijke Gezondheidszorg Nederland, GGZ Nederland).

Table 1.1: The Netherlands – Key data on in-patient care, 2000 and 2004–2008

In-patient care	2000	2004	2005	2006	2007	2008
No. of hospitals[1]	261	208	208	206		
Classified according to ownership						
- Thereof in the public sector (non-profit hospitals)	261	208	208	206	n.a.	n.a.
- thereof in the private sector	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
- thereof other hospitals (please specify)	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
Classified according to subtypes[1]						
- thereof general hospitals*	104	97	96	96	n.a.	n.a.
- thereof mental health and substance abuses hospitals**	124	106	103	100	n.a.	n.a.
- thereof speciality (other than mental health and substance abuse) hospitals*	27	9	9	8	n.a.	n.a.
No. of acute care beds[2]	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- thereof in the public sector***	n.a.	47,887	47,017	46,515	n.a.	n.a.
- thereof in the private sector	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
Average length of stay in hospitals (in days)[2] *	8.4	7.0	6.8	n.a.	n.a.	n.a.
No. of hospital pharmacies[2]	131	106	105	104	n.a.	n.a.
thereof no. of hospital pharmacies that serve outpatients	n.a.	n.a.	n.a.	~ 55%		

n.a. = not available, n.app. = not applicable
Note: Data are indicated as of 31 December
[1] according to OECD definition and its subtypes, without independent health centres and private clinics
[2] only applies to general &speciality hospitals

Source:* Nederlansde vereniging van Ziekenhuizen (NVZ)
** GGZ Nederland
*** Centraal Bureau voor de Statistiek (CBS)

Table 1.2: The Netherlands – Pharmaceuticals, 2000 and 2005–2009

Number of pharmaceuticals	2000	2005	2006	2007	2008	2009
Authorised pharmaceuticals in total	10,344	11,440	11,911	12,256	12,387	n.a.
- thereof hospital-only medicines	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.

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

Data as of 1 January

Source: College ter Beoordeling van Geneesmiddelen (CBG), Medicines Evaluation Board

No special marketing authorisation procedure exists for medicines which are used in hospitals. There is no specific classification of hospital-only medicines (medicines that may only be administered within a hospital). However, some medicines are only used within a hospital as they are not reimbursed in the out-patient sector. Hospital medicines which are not reimbursed outside the hospital mainly include intravenous antibiotics, chemotherapeutic agents, agents for plasma replacement therapy and products derived from blood. No quantitative information is available on the market share of medicines which is not reimbursed in the out-patient sector and on the medicines only used in hospitals.

To facilitate financing of high-cost- and orphan medicines in hospitals, a special government regulation exists. Medicines taking up more than 0.5% of the total pharmaceutical expenditure inside hospitals might be taken up on the list of high-cost medicines, while high-cost orphan medicines might be taken up on the orphan medicines list. The Dutch Health Care Authority (NZa) is responsible for updating both of these lists (cf. section 3.1).

Though most of the medicines on these lists are only used in the hospital, some of the medicines on the NZa-list of high-cost medicines are also used and reimbursed in the out-patient sector. Medicines on the NZa-list of orphan medicines may only be used in university hospitals.

All hospitals are obliged to provide proper pharmaceutical care. Most hospitals have a hospital pharmacy which is part of the hospital, but some have a pharmacy which is in private ownership. Currently, approximately 55% of the hospitals also contain a pharmacy which dispense to out-patients.

Industry, wholesalers and parallel traders are all allowed to supply medicines to hospitals. In practice, most deliveries are provided by wholesalers (cf. section 2.2.1), but the number of deliveries provided directly by manufacturers is increasing, especially for expensive medicines.

Hospitals produce annual reports, but generally, these provide no detailed data on the consumption of medicines.

1.3 Funding

Costs of in-patient curative care is completely covered by the health care insurance, as regulated in the Health Insurance Act (Zorgverzekeringswet). Mental health care is partly covered by the health care insurance, and partly covered by the Exceptional Medical Expenses Act (Algemene Wet Bijzondere Ziektekosten, AWBZ).

Basic health care insurance is offered by private insurance funds. These insurance funds are obliged to provide a legally defined set of insured health care services, as regulated in the Health Insurance Act. People may purchase supplementary packages from the insurance companies to cover additional treatments. Because health care insurance is obligatory for all Dutch citizens, the premiums are considered to be public costs. For table 1.3, health expenditure financed by private health insurers is considered to be public health expenditure.

Basic health care insurance covers all medical expenses, except for long-term treatments (e.g. disability costs such as wheelchairs, (semi-)permanent hospitalisation). These are covered by AWBZ, a public mandatory insurance system.

For all “curative care” hospitals (including curative mental health hospitals) remuneration is on the basis of Diagnosis and Treatment Combination system (Diagnose Behandeling Combinaties, DBCs). This is rather similar to the diagnosis-related group system. A DBC entails all activities of the hospital from the initial diagnosis to the last treatment and check-up. The costs covered by a DBC also include the use of resources of the hospital, costs of medical specialists, and most of the pharmaceutical care.

DBCs allow for transparency in expenditure for all interventions in the hospital. This system also facilitates competition between hospitals, if differentiation in DBC prices between hospitals is allowed. Currently, this is only partly allowed: for some DBCs, hospitals may negotiate on the tariffs.

A distinction is made between DBCs with fixed tariffs (list A) and DBCs with negotiable tariffs (list B). Tariffs for list B DBCs are a result of negotiations between the health insurer and the hospital. The hospital is fully responsible for the financing of the so called B segment (the health care services covered by list B DBCs), so expenditures in this segment should completely be covered by list B DBCs. Currently the market share of list B DBCs is 34% of the total number of DBCs. These DBCs mostly cover elective care (care which is easily prearranged and scheduled such as knee and hip replacements), for which the costs are predictable.

List A DBCs have fixed prices which are set by the Dutch Healthcare Authority (Nederlandse Zorgautoriteit, NZa). Therefore, prices for these DBCs are identical for all hospitals. Furthermore, for the so called A segment of the hospital (the health care services covered by list A DBCs), an allowable budget is set by the NZa. The budget is based on a limited number of parameters, such as the number of patients and number of interventions. If at the end of the year remuneration from DBCs exceed or remain below the budget which was set, differences are compensated between the health insurers and hospitals.

Typically, no out-of-pocket payments occur within the in-patient sector, with the possible exception of treatments in private health clinics, since these may provide care which is not insured. Costs of food and accommodation in hospitals are also covered by health insurance.

Table 1.3: The Netherlands – Health and pharmaceutical expenditure, 2000 and 2004–2008

Expenditure (in million €)	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	34,642	44,876	46,501	48,522	51,174	54,350
thereof THE private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
THE in hospitals (HOSHE) [1]*	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
thereof HOSHE public	8,746	12,046	12,414	13,251	13,137	13,777
thereof HOSHE private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total pharmaceutical expenditure (TPE) out-patient sector **	3,347	4,207	4,424	4,679	5,089	5,153
- thereof TPE public	3,327	4,192	4,408	4,656	5,055	5,106
- thereof TPE private	20	15	16	23	34	47
Pharmaceutical expenditure in hospitals (HOSPE) [1]***	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- thereof HOSPE public	n.a.	418	484	573	n.a.	n.a.
- 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, PE = pharmaceutical expenditure, THE = total health expenditure, TPE = total pharmaceutical expenditure

Note: Data are indicated as of 31 December.

[1] without independent health centres and private clinics

In this table public health expenditure is health expenditure financed by private health insurers.

Source:* Financial department of the Ministry of Health, Welfare and Sport.

** Stichting Farmaceutische Kengetallen, based on data registered at pharmacy level

*** Stichting Farmaceutische Kengetallen, based on surveys at hospitals

2 Pricing

2.1 Organisation

2.1.1 Framework

In principle, prices are set by the manufacturer. However, as stipulated in the Medicines Pricing Act (Wet op de Genneesmiddelenprijzen, WGP) prices are controlled by setting maximum prices for reimbursable out-patient medicines. These maximum prices also apply to the same medicines when dispensed inside the hospital.

The hospital pharmacist is responsible for the procurement of medicines, raw materials, packaging materials, and infusion and rinsing fluids for the pharmacy. Therefore, the hospital pharmacist is responsible for the price which is paid.

Within the hospital, a part of the budget is allocated by hospital management to pharmaceutical care. This pharmaceutical budget is either allotted to the hospital pharmacist, or divided and allotted to the budget holders of the different divisions within the hospital. As a result of this, it is either the responsibility of the hospital pharmacist or of the individual divisions to keep within the pharmaceutical budget. Budgetary limitations should serve to stimulate hospitals to use pharmaceuticals in an efficient way and purchase them as cheaply as possible.

Mostly, medicines are purchased by tendering. For this purpose, hospitals join together in regional purchasing groups (cf. section 2.2).

2.1.2 Hospital prices

For out-patient medicines, an official price list is available which is updated every month, the *taxe*. Hospital pharmacists also use this price list as a reference (upper limit). Prices in the *taxe* are pharmacy purchasing prices excluding VAT. Medicines are subject to VAT (6%).

When purchased through a wholesaler, medicines are sold to hospitals including a wholesale mark-up. There is no regulation on these wholesale mark-ups.

When compared to the prices listed in the *taxe,* hospitals generally pay a lower price (they receive discounts), which is a result of a tendering procedure or negotiation between manufacturer and hospital (cf. section 2.2.1). There is no public information available on the actual prices which are paid when discounts are taken into account. Hospitals do not share this information, and there is no legal obligation to do so.

However, the Dutch Health Care Authority (NZa) has conducted a study (Onderzoek inkoopvoordelen en praktijkkosten farmacie, October 2008) to assess the volume of discounts both for community pharmacies and for hospital pharmacies. As is expected, since hospitals have more bargaining power, prices paid by hospitals are lower than those paid by public pharmacies. On average, NZa found that hospital pharmacists received 31% discount while public pharmacist received 20% discount in 2008. The difference was even more striking when only considering specialty medicines (27% vs. 8% respectively).

2.2 Pricing policies

2.2.1 Procurement

The hospital pharmacist is responsible for the procurement of medicines, raw materials, packaging materials, and infusion and rinsing fluids for the pharmacy. For the purpose of purchasing medicines (and other materials), hospitals join together in regional purchasing groups. In general, an individual hospital will purchase most medicines by means of these regional purchasing groups, but will also purchase part of the medicines on individual basis (while prices are set by negotiation) directly through the wholesaler or manufacturer (see 2.2.2).

The regional purchasing groups purchase medicines by means of tendering. Manufacturers should state at which price they can deliver a particular medicine, and the regional purchasing groups can select the lowest bidder. Manufacturers are usually contracted for 1 to 3 years. Most of the times, the price includes delivery by a wholesaler, as arranged by the manufacturer, and the wholesaler negotiates with the manufacturer about a mark-up.

In principle, budgetary restrictions apply for the hospital pharmacist. A hospital pharmacist may, in consultation with the responsible physicians, restrict the choice of medicines to one of a certain class, excluding other classes, when therapeutic substitution is possible. However, the therapeutic need may overrule these restrictions in individual cases.

The results of the tenders by the regional purchasing groups are not published. Information on the outcome is not shared.

2.2.2 Others

For medicines which are not obtained by means of the purchasing groups, negotiation arrangements are made by an individual hospital with a wholesaler or with a manufacturer. Generally, this is the case when no large discounts can be obtained by means of the purchasing groups (e.g. because of their smaller volumes or non-negotiable price), or when hospitals have diverging views with respect to the preferred pharmaceutical.

In this case, the hospital may negotiate with the manufacturer on the price, which may apply for direct delivery but may also include delivery by a wholesaler. Alternatively, hospitals may

purchase a pharmaceutical from a contracted wholesaler. Generally, a hospitals and contracted wholesaler have agreed on a discount received from the wholesaler for all medicines purchased through the wholesaler.

For unique medicines for which a manufacturer maintains a monopoly (substitution is not possible), the hospital may find that price negotiations are not possible. This is in particular the case for most of the expensive medicines on the list of high-cost medicines and on the list of orphan medicines of NZa (cf. section 3.1). These medicines are bought on individual basis while hospitals have to take the price as it is.

3 Reimbursement

3.1 National hospital reimbursement procedure

Pharmaceutical in-patient care is paid for out of the hospital budget. A hospital will fill its budget in the course of the year using the Diagnosis and Treatment Combination (DBC) system; DBC tariffs are paid for by the health insurer. The DBC tariffs cover the costs of most medicines, though these medicines are not earmarked within DBCs.

The situation is different for orphan medicines on the orphan medicine list and expensive medicines on the list of high-cost medicines of Dutch Health Care Authority (NZa): these are not covered by DBCs.

Costs of expensive new medicines have been growing rapidly and are an increasing burden to budgets of hospitals. Because of this financial burden, it was feared that the policy in the use of high-cost medicines might vary between hospitals. Therefore, since 2006 separate funding is available for medicines indicated by the NZa.

For medicines on the NZa list of high-cost medicines, the hospital receives 80% reimbursement from the health insurer. The remaining 20% is paid by the hospital out of its own budget, which serves to stimulate hospitals to use these medicines in an efficient way.

For medicines on the NZa list of orphan medicines, university hospitals receive 100% reimbursement from the health insurer. These orphan medicines may only be used in university hospitals.

To be taken up on the list of high-cost medicines of NZa the following criteria are relevant:

- the medicine should be registered and be used for the registered indication
- the expenditure should take up more than 0.5% of the hospital medication budget
- the medicine should have added therapeutic value
- a plan is available to study the cost-effectiveness

The list of orphan medicines is only relevant for university hospitals. Use of medicines on the NZa list of orphan medicines is restricted to university hospitals. To be taken up on this list, the following criteria are relevant

- the medicine should be registered at EU level as an orphan medicine and be used for the registered indication
- the expenditure should take up more than 5% of the average medication budget of the university hospitals.

- the medicine should have added therapeutic value
- a plan is available to study the cost-effectiveness

The NZa is responsible for updating both of these lists. Initially, admission on the list is temporary, i.e. for four years only (preliminary assessment). In these four years the parties involved (hospitals and manufacturers) should ensure the proof of value of the medicine. Additional data regarding therapeutic value and cost-effectiveness in clinical practice should be generated.

For new candidates, NZa is advised by the Dutch Health Care Insurance Board (College voor Zorgverzekeringen, CVZ). CVZ evaluates the therapeutic value, and expenditure prognosis of new candidates for the list. Criteria used to assess therapeutic value are efficacy/effectiveness, side effects, applicability, convenience, experience and quality of life. Apart from the therapeutic value and cost prognosis, CVZ evaluates research questions which are formulated for cost-effectiveness studies to be performed during the three years of temporary approval. These cost-effectiveness studies are the responsibility of the parties involved (manufacturer and hospitals) and should ensure that additional data regarding therapeutic value and cost-effectiveness in clinical practice are generated.

Four years after being taken up on the list, a re-appraisal procedure begins. The actual expenditure, the added therapeutic value (as proven in clinical practice) and cost-effectiveness are evaluated by CVZ to decide whether the medicine should remain on the list. All medicines currently on the list only have had a preliminary assessment.

Currently, 32 medicines are taken up (by generic names) on the list of high-cost medicines and 7 medicines are taken up on the list of orphan medicines. In table 4.2 ten most costly medicines are shown ranked with regard of their expenditure.

For in-patient care, no co-payments exist for medicines. However, when pharmacies within a hospital dispense to out-patients, co-payments do occur according to the regulations concerning reimbursement of out-patient medicines.

3.2 Hospital pharmaceutical formularies

No legislation exists on pharmaceutical formularies in the in-patient sector. The hospital pharmaceutical formularies (HPFs) contain an overview of medicines which are available in a hospital. Physicians are restricted in their choice to the medicines taken up in the HPF, though in exceptional cases it may be decided to use a different medicine for an individual patient.

Most hospitals have their own HPF. Of course, they may overlap since they are partly a result of the choices made by the regional purchasing groups. HPFs may also contain medicines which are not preferably prescribed inside the hospital, but which patients have been

using in the out-patient sector. These will generally not be described as extensively as the other medicines.

Most hospitals have a pharmaceutical and therapeutic committee (PTC), consisting of hospital pharmacists and physicians. The PTC generally decides whether a newly available medicine should be made available for the use inside the hospital and put on the formulary. Criteria may include both medical/therapeutic benefit, and economic criteria, such as cost-effectiveness and budget impact. The PTC may restrict the choice of medicines to one of a certain class, excluding other classes, when therapeutic substitution is possible. When this is the case, a physician may still use an excluded medicine for an individual patient, when treatment with the preferred medicines is not possible.

The development of hospital pharmaceutical formularies (HPF) is generally the responsibility of the PTC. Most hospitals have their own HPF. The frequency of updating and manner of publication may differ among the hospitals. In some hospitals, the HPF is completely integrated in the electronic system used for medication administration.

4 Consumption of pharmaceuticals

No information is available on consumption of pharmaceuticals in general within hospitals. However, monitoring of pharmaceutical expenditure takes place for medicines on the list of high-cost medicines of NZa (cf. section 5.1). These data are used for table 4.2.

The expenditure on the medicines on the list of high-cost medicines is currently approximately half of the total pharmaceutical expenditure in hospitals. Its share in expenditure is still increasing.

Table 4.1 The Netherlands – 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 (Defined Daily Doses)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
In other measures units (e.g. unit doses, please specify	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 other measures units (e.g. unit doses, please specify	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

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

Source:

Table 4.2 The Netherlands – Top 10 pharmaceuticals by pharmaceutical expenditure and consumption 2007 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	n.a	1	Infliximab
2	n.a	2	Trastuzumab
3	n.a	3	Rituximab
4	n.a	4	Oxaliplatin
5	n.a	5	Docetaxel
6	n.a	6	Immunoglobuline i.v.
7	n.a	7	Gemcitabine
8	n.a	8	Bevacizumab
9	n.a	9	Irinotecan
10	n.a	10	Pacliltaxel

Source: Foundation for Pharmaceutical Statistics (Stichting Farmaceutische Kengetallen, SFK)

5 Evaluation

5.1 Monitoring

Concerning the use of hospital medicines in general, no monitoring takes place at national level. Also inside a hospital, this is not done on a routine basis, though the hospital pharmacist monitors the pharmaceutical expenditure.

Expenditure, prices and consumption of medicines on the list of high-cost medicines of NZa (cf. section 3.1) are monitored at national level by the Foundation for Pharmaceutical Statistics (Stichting Farmaceutische Kengetallen, SFK). SFK collects these data by means of surveys at hospitals, and reports annually on this issue.

The role of the pharmacist with regard to rational use might differ between the hospitals. A hospital pharmacist may, in consultation with the responsible physicians, restrict the choice of medicines to one of a certain class, excluding other classes, when therapeutic substitution is possible (cf. sections 2.2.1 and 3.2). Recommendations in hospital formularies might be based on therapeutic value, safety, and cost-effectiveness (cf. section 3.2). Generally, a hospital pharmacist will be involved in training of physicians and nursing personnel on safe and rational use of medicines.

Since computer registration of medicines takes place, either by the hospital pharmacist or by the physician, it generally would be possible for an individual hospital to monitor the use of a single medicine inside a hospital. However, since these computer systems are generally not compatible between hospitals, it is not possible to do this at national level. No reports are available on the monitoring of individual medicines.

5.2 Assessment

For medicines used inside the hospital, no assessment takes place at national level.

However, an exception exists for medicines on the list of high-cost medicines and on the list of orphan medicines of NZa (cf. section 3.1). For these medicines, therapeutic value and cost-effectiveness is taken into account (cf. section 3.1). Currently, all medicines on the list of high-cost and on the list of orphan medicines of NZa only have had a preliminary assessment; the final assessment takes place four years after being taken up on the list.

No data are available on savings achieved from pricing, rational use or cost-containment strategies of medicines used within the hospitals.

6 Interface management

Some need exists for interface management.

In some cases, health insurers and hospitals have differences in opinion on the financing of medicines. For hospitals it is favourable when expensive medicines are dispensed outside the hospital, since they will not have to finance these. However, health insurers might feel they have already paid for these medicines through the DBCs, which also includes medicines (cf. section 3.1). Moreover, for medicines which are dispensed outside the hospital, there is no incentive for hospitals to consider cost-effectiveness. Currently, options are considered to improve this situation.

Also, hospitals may receive large discounts (up to 99%) for certain branded medicines. When these are prescribed inside the hospital, its use may be continued in the out-patient sector (the general practitioner will not always switch to a cheaper alternative) where these discounts are not given. Overall, this results in the use of medicines which are too expensive.

7 Developments and outlook

Guidelines and protocols developed by medical professional bodies will play an increasingly important role in quality assurance and in ensuring cost-effectiveness. A special government board was established in April 2009, which will monitor and stimulate the development of guidelines and protocols and promote the implementation of quality and cost-effectiveness criteria in these guidelines and protocols.

For medicines on the list of high-cost medicines, plans exist to change the financing system in the future. If guidelines and protocols sufficiently take into account cost-effectiveness, these high-cost medicines may be financed as an add-on to DBCs. If for a specific treatment such a medicine is used, the hospital will be completely reimbursed by the health insurer on top of the DBC tariff. This system will also generate more data on the use of high-cost medicines. It will be possible to monitor the consumed number of DDDs per hospital, per patient or per indication.

8 References and data sources

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