Gesundheit Österreich GmbH | Executive Agency for Health and Consumers | Bundesministerium für Gesundheit | Agenzia Italiana del Farmaco AIFA | International Healthcare and Health Insurance Institute | SÚKL State Institute for Drug Control | Sogeti


# Pharmaceutical Health Information System

# PHIS Hospital Pharma Report 2009

# Denmark

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

# PHIS

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# Denmark

## PHIS Hospital Pharma Report

## Final Version, November 2009

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# Executive Summary

The responsibility of the hospital sector lies with the five regions in Denmark. Hospital treatment in public hospitals including medicines is free of charge to the patient. In both, hospital and primary care sector, pharmaceutical treatment is financed through taxes paid to the State and passed on to the five regions, which are then responsible for managing the healthcare system, including the hospitals. In the primary care sector patients pay on average one third of pharmaceutical reimbursed expenditures, while two thirds are reimbursed by the regions. Not reimbursable medicines are paid in full by patients.

Most public hospitals are general hospitals with different specialisation levels. The hospitals are responsible for specialised examinations, treatment and care of somatic and mental illnesses which it would not be more expedient to treat in the primary or social sector because of the need for specialist knowledge, equipment or intensive care and monitoring.

Apart from treating illnesses, the hospital service gives diagnostic support to the out-patient sector in the form of laboratory analyses and scanning and X-ray diagnoses etc. Furthermore, another important element is the hospitals' state of readiness in that an appropriate number of hospitals are generally manned around the clock in order to deal with acute illnesses and accidents. The total number of hospitals was 357 in 2008.

The five regions decide on which medicines to use and which (expensive) new medical treatments to implement in the hospital sector. The regions buy pharmaceuticals via public procurement. They are also in charge of funding the reimbursement of pharmaceuticals eligible for reimbursement in the primary care sector and thereby act as a third-party payer. Most of the medicines used in hospitals are purchased via tendering. The tenders are procured by Amgros, which is a hospital purchasing agency owned by the five regions.

Every region in Denmark has one or more pharmaceutical and therapeutic committee(s) (PTC) that decides which pharmaceuticals shall be included in the formulary lists. The primary goal for the PTCs is to ensure the best possible treatment with medicines and to safeguard the most effective utilisation of resources. Some of the concrete tasks of the PTCs are to select those active substances which are recommended for use in hospitals and monitor the pharmaceutical consumption in the region. Some PTCs also draw up clinical guidelines for the chosen medicines to ensure rational use, and some of these guidelines are meant to cover the primary care sector as well.

Pharmaceutical expenditure in the hospital sector is growing. The expenditure has increased by 15% each year from 2005 to 2008 – in comparison to the primary care sector where the average annual growth rate was only 4%. The government and the Regions have agreed to explore the options to reduce the growth. A task force, the committee on hospital medicines, was set up with the task to come up with proposals for initiatives to bring down the expenditure growth of hospital medicines. The report, prepared by the Danish consultant Cowi was completed in May 2009.

In June 2009 the Danish government and the Danish Association of the Pharmaceutical Industry (LIF) made an agreement on a general price reduction of 5% for medicines for hospitals followed by a price ceiling. Prices of new medicines will be set according to an international reference price ceiling. The agreement rules until the end of 2012.

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# List of abbreviations

| | |
|---|---|
| AIFA | Agenzia Italiana del Farmaco / Italian Medicines Agency |
| AMGROS | Hospital Purchasing Agency |
| ATC | Anatomic Therapeutic Chemical classification |
| BMG | Bundesministerium für Gesundheit / Austrian Ministry of Health |
| DACEHTA | Danish Centre for Evaluation and Health Technology Assessment |
| DDD | Defined Daily Doses |
| DG SANCO | Health and Consumer protection Directorate General |
| DRG | Diagnosis-related group |
| DKMA | Danish Medicines Agency |
| DKK | Danish Kroner (danske kroner) |
| EAHC | Executive Agency for Health and Consumers |
| EU | European Union |
| GÖG/ÖBIG | Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG |
| HE | Health Expenditure |
| HOM | Hospital-only medicine |
| 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 |
| LOS | Danish Medicines Agency Database |
| NCU | National Currency Unit |
| ÖBIG | Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute |
| OECD | Organisation for Economic Co-operation and Development |
| PE | Pharmaceutical Expenditure |
| PHIS | Pharmaceutical Health Information System |
| PPP | Pharmacy Purchasing Price |

| | |
|---|---|
| PPRI | Pharmaceutical Pricing and Reimbursement Information project |
| PRP | Pharmacy Retail Price |
| PTC | Pharmaceutical and Therapeutic Committee |
| SST | National Board of Health |
| 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 |

# 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 of the PHIS project management 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 is 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 (summer 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 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

The OECD definition of the term hospital and its subtypes is relevant and applied to the description in the following sections of this country-specific PHIS Hospital Pharma Report. The description on hospital pricing, reimbursement and monitoring in this Hospital Pharma Report refers to all public hospitals in Denmark.

There is no official definition of hospitals in Denmark at the moment, but there is currently one in preparation. Most public hospitals are general hospitals with different specialisation levels. There is also no clear definition of the subtypes of hospitals in Denmark; however the subtypes defined by OECD are all presented in Denmark.

The hospitals are responsible for specialised examinations, treatment and care of somatic and mental illnesses which would not be more expedient to treat in the primary or social sector because of the need for specialist knowledge, equipment or intensive care and monitoring. In 2008 there were 74 public hospitals operating in Denmark, as well as 283 private hospitals.

Apart from treating illnesses, the hospital service gives diagnostic support to the practice sector in the form of laboratory analyses and scanning, X-ray diagnoses, etc. Furthermore, another important element is the hospitals' state of readiness in that an appropriate number of hospitals are generally manned around the clock in order to deal with acute illnesses and accidents.

The hospital service plays an important role regarding the training of staff for the entire health care service and in the field of research; and it is normal in the hospital service that research results are put into clinical practice (HCD 2008).

With the local government reform the National Board of Health (SST) has been bestowed with increased leverage regarding the planning of specialist functions. There is an on-going process in which the SST – in a continuing dialogue with the medical associations and the regions – are formulating new and revised standards regarding the basic treatment and regulation regarding specialist treatment (specialised and highly specialised treatment).

This planning, which also involves the planning of emergency functions, will undoubtedly result in changes in the hospital structure. This ongoing development is part of an international and national trend towards more specialised and thus qualitatively improved treatment (HCD 2008).

## 1.2 Organisation

The health care sector in Denmark has three political and administrative levels: the State, the five regions and the 98 municipalities (national, regional and local levels). The responsibility for services provided by the health service lies with the lowest possible administrative level. Services can thus be provided as close to the users as possible.

The 98 municipalities are local administrative bodies. The municipalities have a number of tasks, of which health represents one part. In the health field, the municipalities are responsible for home nursing, public health care, school health service, child dental treatment, prevention and rehabilitation.

As the running of hospitals requires a larger population than that of the majority of the municipalities, this responsibility lies with the five regions.

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

| In-patient care | 2000 | 2004 | 2005 | 2006 | 2007 | 2008 |
|---|---|---|---|---|---|---|
| **No. of hospitals**[1] | 116 | 137 | n.a. | n.a. | n.a. | 357 |
| *Classified according to ownership* | | | | | | |
| - thereof public hospitals[2] | 73 | 62 | 59 | n.a. | n.a. | 74 |
| - thereof private hospitals[3] | 43 | 75 | n.a. | n.a. | n.a. | 283 |
| - thereof other hospitals (please specify) | n.app. | n.app. | n.app. | n.app. | n.app. | n.app. |
| *Classified according to subtypes*[1+4] | | | | | | |
| - thereof general hospitals | 61 | 52 | 49 | 49 | n.a. | n.a. |
| - thereof mental health and substance abuses hospitals | 12 | 10 | 10 | n.a. | n.a. | n.a. |
| - thereof specialty (other than mental health and substance abuse) hospitals | n.app. | n.app. | n.app. | n.app. | n.app. | n.app. |
| **No. of acute care beds** | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |
| - thereof in the public sector | 18,698 | 17,044 | 16,585 | 16,278 | 15,789 | n.a. |
| - thereof in the private sector | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |
| **Average length of stay in hospitals** | 5,4 | 4,7 | 4,5 | 4,4 | 4,3 | 4,2 |
| **No. of hospital pharmacies** | n.a. | n.a. | n.a. | 16 | 14 | 12 |
| thereof no. of hospital pharmacies that serve out-patients | 0 | 0 | 0 | 0 | 0 | 0 |

n.a. = not available, n.app. = not applicable
Note: Data are indicated as of 31 December

1 according to OECD definition and its subtypes
2 hospitals excl. clinics
3 hospitals and clinics
4 only public hospitals

Source: The National Board of Health (SST)

The regions are obliged to make agreements between themselves regarding the use of highly specialised departments with a view to ensuring the inhabitants equal access to necessary specialised treatment. This reflects the fact that the individual region cannot be expected to cover all hospital treatment in its own hospitals.

Furthermore, the regions may, after the authorisation of the National Board of Health, refer patients to highly specialised treatment abroad paid for by the state. The regions also have the possibility of referring patients to approved hospitals abroad and paying for the services themselves.

Since 1 January 1993, citizens who are in need of hospital treatment have the possibility, within certain limits, of choosing freely which hospital they wish to be treated in. The citizens may choose among all public hospitals which offer basic treatment and a number of smaller, specialist hospitals owned by associations which have agreements with the regions. If a citizen after a medical evaluation is judged to need treatment on a specialist level, he has a further choice between hospital departments which offer treatment on a highly specialised level.

From 1 July 2002, the citizens may choose among private hospitals or clinics in Denmark or abroad if the waiting time for treatment exceeds two months and the chosen hospital has an agreement with the regions' association regarding the offer for treatment. From 1 October 2007 this waiting time was reduced to one month. (HCD 2008)

The number of private hospitals and clinics was 43 in 2000, this number increased to 283 in 2008 (table 1.1). There are a few private hospitals that can offer the same treatments as the public hospitals. Most of the private hospitals and clinics are small with few employees and they only offer few medical specialties. (DDS 2009)

The number of acute care beds has decreased from 18,698 in 2000 to 15,789 in 2008. This downward trend indicates a decrease in the length of stay and an increase in admissions due to the fact that an increasing number of treatments are carried out in out-patient departments. (DDS 2009)

The regions are also responsible for the out-patient sector. The regions organise the health service for their citizens according to regional wishes and available facilities. Thus, the individual regions can adjust services within the financial and national legal limits according to needs at the different levels, enabling them to ensure the appropriate number of staff and procurement of the appropriate equipment.

The task of the state in health care provision is first and foremost to initiate, coordinate and advise. One of the main tasks is to establish the goals for a national health policy.

The Ministry of Health and Prevention (Ministeriet for Sundhed og Forebyggelse, SUM), in its capacity of principal health authority, is responsible for the legislation on health care. This includes legislation on health provisions, personnel, hospitals and pharmacies, pharmaceutical products, vaccinations, pregnancy health care, child health care and patients' rights.

The Ministry of Health and Prevention's legislation covers the tasks of the regions and the municipalities in the health area. The Ministry also sets up guidelines for the running of the health care service. This is mostly done through the National Board of Health. Moreover, the Ministry of Health and Prevention supports efforts to improve productivity and efficiency by e.g. the dissemination of experience and the professional exchange of information and by the introduction of economic incentives and activity based payment (HCD 2008).

**Dispensing status**

In connection with the granting of market authorisation, the renewal of market authorisation and under other circumstances where required, the Danish Medicines Agency (DKMA) decides whether a medicine is to be subject to prescription and which dispensing group applies for the medicine (cf. the Danish Medicines Act, No. 1180 of 12 December 2005).

The dispensing group defines how to dispense a medicine and any restrictions as to who can prescribe it. Definitions of the current valid dispensing groups applicable for prescription-only medicine(s) (POM) are set out in the Executive Order on Prescriptions No. 155 of 20 February 2007. Definitions of the current valid dispensing groups applicable for over-the-counter (OTC) medicines are set out in Medicinpriser (www.medicinpriser.dk), cf. Section 82 (1) (1) of the Danish Medicines Act, No. 1180 of 12 December 2005.

*Prescription-only medicine(s):*

- only to be dispensed once on the same prescription, unless dispensed in smaller doses at a time (dispensing group "A");
- only to be dispensed once on the same prescription, unless stated otherwise, but five times at maximum (dispensing group "B");
- only to be dispensed to (limited to) hospitals and on the same terms as those that apply to dispensing group A (dispensing group "BEGR" (= limited);
- only to be dispensed to hospitals or following prescription by specific medical specialists and the same terms apply as those for dispensing group A (dispensing group "NBS");
- dispensing subject to the provisions of Section 4 of the Executive Order No. 155 of 20 February 2007 on Prescriptions (dispensing group "A § 4") (narcotic drugs, etc.);
- only to be dispensed to hospitals and subject to the terms that apply for dispensing group "A § 4" above (dispensing group "A § 4 BEGR") (narcotic drugs, etc.);
- only to be dispensed to hospitals or following prescription by specific medical specialists and subject to the terms that apply for dispensing group "A § 4" (dispensing group "A § 4 NBS") (Narcotic drugs, etc.);
- only to be dispensed in accordance with a risk management programme, cf. Section 62 of the Danish Medicines Act, No. 1180 of 12 December 2005 (dispensing group "R").

*Over-the-counter medicines:*

- sale restricted to pharmacies (dispensing group HA)
- sale not restricted to pharmacies, human (dispensing group Hf)

- sale not restricted to pharmacies, human – maximum one pack per person per day (dispensing group Hx).

There are also a couple of veterinary categories.

*Table 1.2: Denmark – Pharmaceuticals, 2000 and 2005–2009*

| Number of pharmaceuticals | 2000 | 2005 | 2006 | 2007 | 2008 | 2009 |
|---|---|---|---|---|---|---|
| **Authorised pharmaceuticals in total** | 7,148 | 8,932 | 9,662 | 10,110 | 10,568 | 10,650 |
| - thereof hospital-only pharmaceuticals (BEGR) | 346 | 529 | 528 | 554 | 619 | 661 |

Note: data are as of 1 January.

Method of counting:
– incl. different pharmaceutical forms
– excl. different pack sizes
– incl. different dosages

Source: DKMA Database (LOS) 2009

### Hospital pharmacy

After a merging process starting in 2007 currently 12 hospital pharmacies are remaining in Denmark, meaning that not every hospital has its own pharmacy. There is at least one hospital pharmacy in every region that provides service to the public hospitals without a hospital pharmacy.

Hospital pharmacies in public hospitals can be established by the state or a regional authority. The hospital pharmacy belonging to a regional authority is able to supply medicinal products and other products to the regional authority's hospitals and maternity homes and other medical institutions. Private hospital pharmacies can be established, by the Danish Medicines Agency's consent, by proprietors of private hospitals. (PHA 1984)

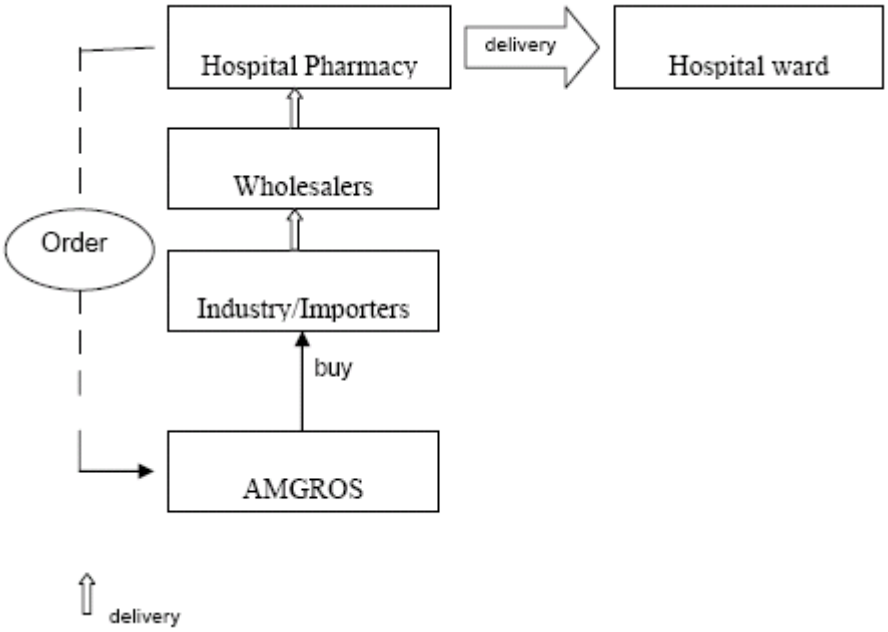
Hospital pharmacies supply their own hospitals in terms of distribution and clinical pharmacy, but some of the hospital pharmacies' own production is sold to the other hospital pharmacies if there is a surplus in production. The hospital pharmacies deliver free-of-charge medicines to a number of out-patients via hospital out-patient departments. Nevertheless, hospital pharmacies are not allowed to also dispense to out-patients directly.

Hospital pharmacies only provide medicines for hospitalised patients and – via out-patient departments – to those patients who, to a limited extent, are given medicines either as the beginning of a medical treatment or because the medicines in question are (hospital-only medicine(s) (HOM). Hospital pharmacies are not allowed to sell medicines like OTC to patients.

The twelve hospital pharmacies differ a great deal in size. However, they all deal with distribution and clinical pharmacy, and most of them maintain a service production of total par-

enteral nutrition, cytostatics, and some antibiotics. A few of them have the proper facilities to deal with the production of authorised and ex tempore medicines, both sterile and not sterile.

*Figure 1.1: Denmark – Flowchart on the delivery chain, 2009*




Source: DKMA 2009

All public hospital pharmacies order and buy medicines via the hospital purchasing agency's (Amgros) electronic purchasing system. Amgros is a purchasing partnership owned by the five regions, and is the leading organisation in Denmark in terms of tendering and procurement of medicines. Amgros puts together tenders to the Danish hospitals on behalf of the Danish hospital pharmacies regarding medicines that are expected to be consumed within a given period (cf. section 2.2.). The deliveries of the medicines are done only by the wholesalers. Figure 1.1 shows the delivery chain of the medicines.

Two major full-line wholesale companies, Nomeco Ltd and Tjellesen Max Jenne, are authorised to distribute medicines to private pharmacies and hospital pharmacies. Most Danish pharmacies are customers of Nomeco.

Besides the two major wholesalers, about 250 companies are licensed to carry out wholesale activities. These represent a variety of wholesalers: large and small, supplying many products or just one or a few, and including wholesalers dealing with veterinary products alone (PPRI Profile DK 2008).

Some of the hospitals produce annual reports, which are available on the hospitals websites (cf. section 8.1).

## 1.3 Funding

The Danish healthcare system is based on a principle of free and equal access for all citizens. Thus, the vast majority of health services in Denmark are free of charge for the users.

For financing of the majority of the regional and local health care expenditure, the state imposes a health care contribution tax. The health care contribution is 8% on taxable income (HCD 2008).

Health care in the regions is financed by four kinds of subsidies: A block grant from the state, a state activity-related subsidy, a municipal basic contribution and a municipal activity-related contribution. The state block grant constitutes the most significant element of financing - approximately 75%. In order to give the regions equal opportunities to provide health care services, the subsidy is distributed by a number of objective criteria that reflect expenditure needs (e.g. demography and social structure of each region).

Furthermore, part of the state financing of the regions is an activity-related subsidy. The activity pool may constitute up to 5% of the health care expenditure of the regions. The purpose of the pool is to encourage the regions to increase the productivity of hospitals.

A novelty is that the municipalities following the local government reform of 2007 contribute to financing health care. When considering the local health care tasks (preventive treatment, care and rehabilitation), the municipalities have acquired a more important role within health care. The purpose of the local contributions is to encourage the municipalities to initiate efficient preventive measures for their citizens with regard to health issues.

Local financing consists partly of a basic contribution and partly of an activity-related contribution (productivity). Together they constitute approximately 20% of total financing of health care in the regions.

The basic contribution is determined by the regions. The maximum limit is fixed by statute (DKK 1,500 / € 202 per inhabitant at the price and wage level of 2003). The municipalities (min. 2/3 of the municipalities in the region) are able to veto a region's proposal to increase the contribution in excess of the price and wage development. The local basic contribution is initially fixed at DKK 1,000 / € 134 per inhabitant.

The activity-related contribution depends on how much the citizens use the regional health services. It will primarily reflect the number of hospitalisations and out-patient treatments at hospitals as well as the number of services from general practitioners. In this way the municipalities that succeed in reducing the need for hospitalisation, etc. by improving the efficiency through preventive treatments will be rewarded.

As a part of the activity-related contribution to the regions, the regions have to reallocate the contributions to the hospitals. In 2007, in accordance with the agreement between the government and Danish Regions concerning the economy of the regions, 50% of the hospital budgets depended on activity-related contribution.

Under the Health Care Reimbursement Scheme services are provided by self employed professionals such as general practitioners, specialists, dentists, etc. who are licensed by the state. These services are provided in accordance with collective agreements between the regions and the relevant unions. Collective agreements include prices of individual services which are covered by the Health Care Reimbursement Scheme (HCD 2008).

*Table 1.3: Denmark – Health and pharmaceutical expenditure, 2000 and 2004–2008*

| Expenditure (in million DKK) | 2000 | 2004 | 2005 | 2006 | 2007 | 2008 |
|---|---|---|---|---|---|---|
| **Total health expenditure (THE)** | 113,500 | 123,400 | 126,900 | 130,500 | 137,400 | 145,500 |
| - thereof THE public | 96,000 | 103,600 | 106,700 | 109,700 | 116,200 | 123,700 |
| thereof THE private | 17,500 | 19,900 | 20,200 | 20,900 | 21,200 | 21,800 |
| **THE in hospitals (HOSHE)** | 74,612 | 81,145 | 84,018 | 86,482 | 88,413 | 95,500 |
| thereof HOSHE public | 72,412 | 78,245 | 80,918 | 83,282 | 85,213 | 92,200 |
| thereof HOSHE private | 2,200 | 2,900 | 3,100 | 3,200 | 3,200 | 3,300 |
| **Total pharmaceutical expenditure (TPE)[a]** | 11,382 | 15,236 | 16,061 | 17,219 | 18,627 | 19,565 |
| - thereof TPE public | 4,962 | 6,797 | 6,989 | 7,374 | 7,851 | 7,719 |
| - thereof TPE private | 4,200 | 4,515 | 4,674 | 4,768 | 4,961 | 5,129 |
| **Pharmaceutical expenditure in hospitals (HOSPE)** | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |
| - thereof HOSPE public | 2,220 | 3,924 | 4,398 | 5,077 | 5,815 | 6,717 |
| - thereof HOSPE private | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |

DKK = Danish Kroner, 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.

[a] The definition of pharmaceutical expenditure in the primary care sector is not identical with the definition in the hospital sector. PE in the primary care sector comprises the pharmacy retail prices, while the PE in the hospital sector comprises the internal settling prices between hospital wards and the suppliers. (AAS 2009)

Source: SST 2009 and DKMA (Medicinal Product Statistics, www.medstat.dk) 2008

Total pharmaceutical expenditure (hospital and primary care sector) is growing, especially in the hospital sector. The expenditure has been increasing by 15% every year from 2005 to 2008 (cf. table 1.3). The public share in primary care sector has been growing until 2008; in 2008 there was a slight reduction.

# 2 Pricing

## 2.1 Organisation

### 2.1.1 Framework

Manufacturers and importers of pharmaceutical products may freely determine the price of each medicinal product.

However, pharmaceutical companies are obliged to report their pharmacy purchasing prices (PPP) for all medicines on the market, including hospital medicines, to the Danish Medicines Agency (DKMA)[1]. The price is included in the Danish Medicines Agency Pricelist; the price list is distributed by the DKMA to all pharmacies. The prices can be altered every two weeks when a new official price list is drawn up by the DKMA. This occurs very occasionally for hospital-only medicines. The official prices are available on the DKMA's website[2].

The five regions owning the public hospitals decide on which medicines to use and which (expensive) new medical treatments to implement in the hospital sector. The regions buy medicines via public procurement. They are also in charge of funding the reimbursement of medicines eligible for reimbursement in the primary care sector and thereby act as a third party payer.

Most of the medicines used in hospitals are bought via public procurement. Since 1 January 2007 most public tenders are carried out by Amgros I/S which is a hospital purchasing agency owned by the five regions.

### 2.1.2 Hospital prices

The PPP for hospital-only medicines (HOM) that pharmaceutical companies notify to the DKMA does not correspond to the actual prices that hospitals pay for the medicines. The prices of hospital medicines are lower than in the out-patient sector if Amgros has made an agreement on purchase with the manufacturer/importer. This price as well as the wholesale margin and the ex-factory price are not publicly known. This price is not subject to VAT and dispensing fee as the medicines sold in the out-patient sector. To make comparison between the prices of HOM and the rest of the medicines easier both the dispensing fee and VAT is included in the published prices.

[1] Executive order on the price list and delivery conditions, No. 59 of 29 January 2009 (www.retsinfo.dk)

[2] www.medicinpriser.dk

## 2.2 Pricing policies

### 2.2.1 Procurement

98 percent of the medicines used in public hospitals are purchased through Amgros. Amgros holds tender under the EU rules and signs contracts for almost all medicines at 5th ATC level. Amgros organises tenders 60-70 times a year and publishes the tenders at their website[3]. The tenders usually cover more than one product (cf. AAS). The tender process is an electronic system which the companies can access on Amgros' website. In 2009 160 suppliers participated in 77 tenders.

The company with the best offer wins the contract. The criteria specified in the tender documentation can vary case by case. In tenders containing many products the relevant criteria for accepting a tender may be the price, in other tenders the criteria may be other than only the price e.g. packaging, aspects of patient safety, easy to handle etc (cf. AAS 2009).

The contracts run for typically 1-2 years and the contract price is fixed for this period (cf. AAS 2009). The medicines that are not contracted for are purchased at the official pharmacy purchasing prices (PPP). AMGROS gains on average 20 percent discount on the PPP (AMG 2008).

In 2007 the pharmaceutical turnover in hospitals amounted to about DKK 4 billions / € 538 Mio. and AMGROS obtained a direct discount of DKK 946,2 Mio. / € 127 Mio (AMG 2008). However, the prices achieved in the individual contracts between Amgros and the suppliers are not open to the public.

A lot of new and expensive medicines are only produced by one manufacturer, and are therefore not subject to competition. Those suppliers have no incentive to bid on tenders. Amgros therefore has to purchase these medicines at the PPP without having any legal means to receive a statutory discount.

Representatives of the hospital pharmacies and clinical experts with specialty within the respective field are involved in the procurement process. Sometimes representatives from the regions are also involved. This team participates in the preparations of the tender documents and also in the evaluation of the tenders received (AAS 2009).

A number of medical companies offer a discount/rebate on medicines which have an overlap between the hospital sector and the primary care sector, to ensure faster penetration into the primary health care market as a knock-on effect.

[3] www.amgros.dk

### 2.2.2 Others

There are no other pricing policies for HOM besides procurement as, for instance, the standard mark-up scheme for pharmacies (cf. PPRI DK Profile 2008, section 3.5) does not apply.

The tendered price is the settlement price, no further negotiations take place during price validity.

# 3 Reimbursement

## 3.1 National hospital reimbursement procedure

In Denmark all hospital treatment in public hospitals, including medicines, is provided free of charge to the patient. In both hospital and primary care sectors, medicine treatment is funded by taxes paid to the State and passed on as block grant to the five regions, which are then responsible for managing the health care system, including the hospitals (cf. section 1.3; PPRI Profile DK 2008, sections 4.4.1 and 4.4.2).

All hospital wards manage their own budget for purchasing medicines. The aim is for the doctors to prescribe those medicines that are on the standard list of medicines regularly used in the ward. The positive list used in the out-patient sector is not relevant for hospitals since the price of medicines in the out-patient sector often differs from the prices of medicines used in the hospitals.

## 3.2 Hospital pharmaceutical formularies

Every region in Denmark has one or more pharmaceutical and therapeutic committee(s) (PTC) that makes the relevant decisions regarding the pharmaceuticals that are included in the hospital pharmaceutical formulary (HPF). The hospital pharmacies take care of administration and the preparation of the HPFs. The HPFs are updated once a year when the processes of new tenders are finished.

The number of medicines (HOM, POM and OTC) included in a HPF can be different in each region e.g. this number is some 700 in Region Sjælland[4].

The members of the PTC are mainly hospital doctors (clinical pharmacologists and doctors in the respective field), hospital pharmacists, representatives from the hospital management and representatives from the primary care sector. The primary goal for these committees is to ensure the best possible treatment with medicines and to ensure the most effective utilisation of resources. Some of the concrete tasks of the committees are to select those active substances which should be recommended for use in hospitals and monitor the pharmaceutical consumption in the region. Some committees also draw up clinical guidelines for the chosen medicines to secure rational use, and some of these guidelines are meant to cover the primary care sector as well (cf. AAS).

It is possible that the medicine (active substance) which is the least expensive in the hospital sector is the most expensive in the primary care sector. The PTC may therefore choose a

[4] https://www.sundhed.dk/Fil.ashx?id=7361&ext=xls&navn=Rekommandationer_14_maj_2009.xls

therapeutic equivalent substance instead, to prevent substantial expenses in the primary care sector due to (initially) prescribing by hospital doctors in the hospital ambulatories and a (subsequent) overspill effect from the general practitioners' prescriptions. Basically speaking, generic substitution is mandatory in Denmark.

# 4 Consumption of pharmaceuticals

All hospitals provide consumption data to the Danish Medicines Agency DKMA (cf. tables 4.1 and 4.2). It is possible to quantify pharmaceutical consumption by every department, but it is not possible to link up pharmaceutical consumption with the patient.

*Table 4.1 Denmark – Pharmaceutical consumption, 2000 and 2004–2008*

| Pharmaceutical consumption | 2000 | 2004 | 2005 | 2006 | 2007 | 2008 |
|---|---|---|---|---|---|---|
| **Annual pharmaceutical consumption in total (in 1,000)** | | | | | | |
| in packs | 70,774 | 85,950 | 91,395 | 96,240 | 88,888 | 90,017 |
| in DDD (Defined Daily Doses) | 1,889,563 | 2,305,396 | 2,399,314 | 2,525,388 | 2,653,133 | 2,780,433 |
| In other measures units (e.g. unit doses) | n.app. | n.app. | n.app. | n.app. | n.app. | n.app. |
| **Annual pharmaceutical consumption in hospitals (in 1,000)** | | | | | | |
| in packs | 7,605 | 9,511 | 9,969 | 10,300 | 10,665 | 10,876 |
| in DDD | 75,422 | 86,437 | 89,585 | 92,949 | 96,162 | 98,848 |
| In other measures units (e.g. unit doses) | n.app. | n.app. | n.app. | n.app. | n.app. | n.app. |

DDD = Defined Daily Doses, n.app. = not applicable

Source: Register of Medicinal Product Statistics at the Danish Medicines Agency, www.medstat.dk

*Table 4.2 Denmark – Top 10 pharmaceuticals by pharmaceutical expenditure and consumption in hospitals, 2008*

| 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[5] |
|---|---|---|---|
| 1 | C03CA01: Furosemide | 1 | L04AB04: Adalimumab |
| 2 | N02BE01: Paracetamol | 2 | L03AB07: Interferon beta-1a |
| 3 | H02AB06: Prednisolone | 3 | L04AB02: Infliximab |
| 4 | L02BB03: Bicalutamide | 4 | L04AB01: Etanercept |
| 5 | L02BA01: Tamoxifen | 5 | B02BD02: Coagulation factor VIII |
| 6 | B05BB01: Electrolytes | 6 | L01XC03: Trastuzumab |
| 7 | A11DA01: Thiamine | 7 | L02BB03: Bicalutamide |
| 8 | B03XA02: Darbepoetin alfa | 8 | H01AC01: Somatropin |
| 9 | L02AE03: Goserelin | 9 | S01LA04: Ranibizumab |
| 10 | M05BA06: Ibandronic acid | 10 | J06BA02: Immunoglobulins |

Source: Register of Medicinal Product Statistics at the Danish Medicines Agency

[5] In the hospital sector, the hospitals mix cytostatics to specific patients. These mixtures are reported unspecified to the Register of Medicinal Product Statistics. Therefore the top10 in expenditures would likely have contained more cancer drugs if reported to the register specified.

# 5 Evaluation

## 5.1 Monitoring

Monitoring of the national in-patient sector is done by Amgros on a regular basis. Every quarter Amgros makes a market monitoring report, which contains the development of the total pharmaceutical expenditure in hospitals and the expenditure per region, per ATC code and per diagnosis. The report is not publicly available. It is send to a limited group of stake-holders.

At hospital level the hospital pharmacists monitor the doctors' choice of medicines: The medicines have been included in the medicine module of the digital patient files' as so-called standard prescriptions, which makes it easy for the individual doctor to pick the (economi-cally) most advantageous medicines. The hospital pharmacy often runs the procedure and at the same time assists the wards by directly substituting with the recommended cheaper generic product that has been purchased by Amgros. In case where the ward orders a medicine therapeutically equivalent to the one already on the recommended list, the hospital pharmacy will contact the ward in order to make a possible change to the recommended medicine. In spite of this procedure it is still possible for the ward to order an expensive medicine, as long as the total consumption of the ward is within the budgetary limits.

The role of the hospital pharmacists is besides the traditional area of activity as ordering, distribution and service production of medicines also quality control and clinical pharmacy such as the ensuring of a rational and secure use of medicines. Hospitals pharmacists' works with the Pharmaceutical and Therapeutic Committee (cf. 3.2).

In Denmark the role of generics in hospitals depend on whether the generic companies win the tenders (cf. 2.2.1).

Doctors in hospitals are free to prescribe whatever medicine they wish. No prescribing guidelines are in place.

## 5.2 Assessment

In Denmark health technology assessments (HTA) is typically done prior to the introduction of new health technology in the health care system in connection with changes in the use of an already existing technology. The purpose of the HTA is to establish a well-documented and comprehensive overview of the consequences of the new technology in the healthcare system[6]. The Danish Centre for Evaluation and Health Technology Assessment (DACEHTA) is carrying out the HTA. The centre is situated as an entity within the National Board of Health (SST). DACEHTA primarily targets health professionals and decision-makers at all

[6]http://www.sst.dk/English/DACEHTA.aspx

levels as well as related research communities. The HTA reports are available on the SST's website[7].

In cooperation with local HTA environments, the Danish Centre for Evaluation and Health Technology Assessment (DACEHTA) has developed a flexible decision support tool, a mini-HTA, which can be used by hospital managements locally and regionally when contemplating the introduction of new health technology.

Mini-HTA is intended as a flexible and dynamic tool adaptable to local conditions and the current requirements of decision-makers – which means that it can relatively easily be incorporated into local and regional budget and planning processes. Where the problem or the application extends beyond a specific local context, however, the mini-HTA cannot replace a full-size HTA (cf. HT 2005).

# 6 Interface management

The hospital pharmaceutical formularies at the hospitals are coordinated with the list of recommendations for medicines in primary care sector. The coordination is done by the pharmaceutical and therapeutic committees (PTC) in each region. The aim is to prescribe pharmaceuticals in a rational way so the prescription of a medicine, which is expensive in the primary care sector, is avoided.

It happens that the medicine (active substance) which is the cheapest in the hospital sector is the most expensive in the primary care sector. The PTC may therefore choose a therapeutic equivalent substance instead, to prevent substantial expenses in the primary care sector due to (initially) prescribing by hospital doctors in the hospital ambulatories and a (subsequent) overspill effect from the general practitioners' prescriptions.

The regions have also made a procedure for the shift between the in-patient and out-patient care to reduce the risk of medication errors.

[7] http://www.sst.dk/default.aspx?lang=en

# 7 Developments and outlook

Pharmaceutical expenses at the hospitals rose by 15% annually in the last couple of years. The government and the regions have agreed to explore options and initiatives to reduce the growth. A task force, the committee on Hospital Medicines, was set up early in 2009

- to analyse the market for hospital medicines and the reasons for the growth of expenditures;
- to describe the attempts to control expenditure made at hospital level;
- to make a comparison of several countries on
    - the organisation on the purchase of hospital medicines,
    - the price mechanism for hospital medicines,
    - the actual prices paid for hospital medicines.

This builds the basis for proposals for initiatives to bring down the expenditure growth of hospital medicines. The report from the committee was finished in May, and approved by the Danish government on 25 May 2009 (AAS 2009).

In the report the committee has stated two main recommendations:

1. To establish a price control system for hospital medicines. The preferred model of the committee is an international reference price model for budget-heavy medicines following the outline of the Norwegian model.
2. To work on the establishing of clinical consensus among regions on recommendations and medical treatment guidelines for medicines in hospital use. In this way the basis for the tendering procedures on hospital medicines will be strengthened.

The commission report was followed up by negotiations between the Danish government and the Danish Association of the Pharmaceutical Industry (LIF) which led to an “Agreement on price-cap and price reductions for medicines for hospitals” on 4 June 2009. The agreement is valid until the 31 December 2012. The agreement replaces the introduction of a price control system for hospital medicines by legislation.

The main elements of the agreement are the following:

- an immediate price freeze on hospital-only medicines;
- a price reduction of 5% on hospital-only medicines as of 1 January 2010;
- a price ceiling until the end of 2012;
- a reference price system for new hospital-only medicines in Denmark saying that their price cannot exceed the average price of the medicine in Sweden, Norway, Finland, UK, Ireland, Germany, The Netherlands, Belgium and Austria.

The second recommendation of the committee has been followed up in negotiations between government and the regions organisation.

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