PHIS Pharma Profile

DENMARK

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Authors and PHIS Representatives
The Danish Medicines Agency: Safiye Özer, Elisabeth Thomsen
The Ministry of the Interior and Health: Paul B. Schüder

Reviewers
IHHII: Gergana Andre
GÖG/ÖBIG: Nina Zimmermann, Claudia Habl, Sabine Vogler

Layout: Romana Landauer (GÖG/ÖBIG)

Development of the PHIS Pharma Profile Template
PHIS Project Leader: Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG (GÖG/ÖBIG): Sabine Vogler, Christine Leopold, Simone Gritsch, Nina Zimmermann
WP 5 (Monitoring) Leader: International Healthcare and Health Insurance Institute BG (IHHII BG): Gergana Andre

Executive Summary

Health care system

Health care provision in Denmark is to a great extent a public task, financed through taxes, and most of the services are run directly by the public authorities, i.e. the National Health Service (NHS). The vast majority of health services are therefore free of charge for the users. The coverage of the Danish residents is 100%.

The responsibility for running the National Health Service (NHS) is decentralised and mostly lies with the regional authorities (third-party payers), who work in close cooperation with the Government and the Local Authorities.

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 NHS lies with the lowest possible administrative level. Services can thus be provided as close to the users as possible.

The five Danish regions are responsible for hospital services, health insurance, general practitioners (GP) and specialists, etc. The 98 municipalities are responsible for any rehabilitation that does not take place during an in-patient stay, along with health care prevention and promotion as well as the treatment of alcohol and drug abuse.

One of the main tasks of the actors in the health system at state level, namely the Ministry of the Interior and Health (Indenrigs- og Sundhedsministeriet, IM), the National Board of Health (Sundhedstyrelsen, SST), the Danish Medicines Agency (Lægemiddelstyrelsen, DKMA), the State Serum Institute (Statens Seruminstitut SSI) and the National Institute of Public Health (Statens Institut for Folkesundhed, NHIP) is to set guidelines for the running of the health care service. The Ministry of the Interior and Health (IM) is responsible for legislation on health care. Another very central actor is of course the Danish Parliament.

The Danish health care system is based on a principle of free and equal access for all citizens.

In hospitals, all expenditure on medicines is paid by the regions (tax financed). In the out-patient health care sector, approximately 56% of the expenses is financed by the regional health insurance (tax financed), and approximately 4% is financed by the local community (mainly reimbursement paid to senior citizens or “economically weak” persons). A total of 40% of the expenditure is paid by the patients themselves (= out-of-pocket payments (OPP)). However, some people have taken out supplementary private insurance. Part of the out-of-pocket payment (OPP) is covered by this.

The payment system for general practitioners (GP) in out-patient care, acting as “gate-keeper” with regard to hospital treatment, is generally based on fee-for-service payments and partly based on a capitation system.

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 out-patient health care or social sector because of the need for specialist knowledge, equipment or intensive care and monitoring. The hospital service also gives diagnostic support to the out-patient care physicians in the form of laboratory analyses and scanning, X-ray diagnoses, etc.

In 2009 there were 55 public hospitals operating in Denmark, as well as 216 private hospitals.

Pharmaceutical system

One of the main laws in the pharmaceutical field is the Danish Medicines Act, with provisions for authorisation and control of medicines and companies which carry out pharmaceutical activities, as well as rules on reporting of adverse drug reactions and on pricing and advertising.

The Danish Pharmacy Act sets out the requirements for conducting pharmacy business and the tasks which a pharmacy is responsible for carrying out, as well as the conditions for establishing and closing pharmacy units, etc.

The main actors in the Danish pharmaceutical system are, besides the central actors mentioned above, the doctors, the patients, the pharmaceutical industry and the pharmacies. The Danish Medicines Agency's (DKMA) mission is to provide effective and safe health products, i.e. medicines, medical devices and new therapies available to society and to encourage prudent use of the products. The Danish Medicines Agency (DKMA) deals with most issues within the pharmaceutical field, including marketing authorisation of medicines and devices, licensing of pharmaceutical companies, pharmacovigilance issues, reimbursement and pricing of medicines as well as the publication of pharmaceutical consumption statistics, etc.

By the beginning of 2009 approximately 10,650 medical products, counted by different strengths and dispensing forms, were authorised in Denmark. A number of medicines are not marketed in Denmark, although they have received market authorisation.

An increase in the sales of medicines in the out-patient care sector can be observed over recent years. In hospitals, sales have also been increasing rapidly. In 2009, sales (turnover) of generics in the out-patient care sector accounted for 13% of the total sales of medicines.

The pharmaceutical industry is a significant sector in the Danish economy. Danish original manufacturers and other research-oriented pharmaceutical companies are organised in the Danish Association of the Pharmaceutical Industry (Lægemiddelindustriforeningen, Lif). It is an association of 37 member companies which represented 65% of the sales of medicines in Denmark in 2010 (Lif 2011). The leading manufacturers in Denmark are Pfizer Ltd., Nycomed Danmark Ltd., GlaxoSmithKline Pharma Ltd. and AstraZeneca Ltd.

In Denmark two major full-line wholesale companies, Nomeco Ltd and Tjellesen Max Jenne, are authorised to distribute medicines to private pharmacies and hospital pharmacies. Besides the two major suppliers, about 250 companies are licensed and inspected by the

Danish Medicines Agency to carry out wholesale activities. The wholesale activity is a multi-channel system.

Pharmacies and branch pharmacies have the monopoly on the sale of prescription-only medicine(s) (POM) to consumers.

Over-the-counter (OTC) outlets (points of sale for pharmacies organised in another shop, often a supermarket) are also allowed to deliver prescription-only medicine(s) (POMs) that have been dispatched by a pharmacy to the outlet. No pharmacists are present in such OTC outlets.

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 restricted to the hospital-only medicine(s) (HOM) category. Hospital pharmacies are not allowed to sell medicines to out-patients.

In rare cases and under special conditions a doctor can be authorised to dispense medicines.

All hospital activities including medicines are financed by the regions. Out-patient medicines are financed 2/3 by the regions through the Health Insurance and 1/3 by out-of-pocket payments. The regions activities including health care provision are financed to a large degree by a block grant from the state. Accordingly the main health expenditures are tax financed.

Pricing, reimbursement and volume control in the out-patient sector

Medicines are freely priced at both manufacturer and wholesale levels in Denmark.[1] Over the years there have been certain interventions, including periodic price freezes and pricing agreements between the state and the pharmaceutical industry.

Both reimbursement and pricing are managed by the Danish Medicines Agency (DKMA). Manufacturers/importers and wholesalers negotiate their share of the pharmacy purchasing price. They are obliged to report their pharmacy purchasing prices for all medicines on the market to the DKMA.[2]

The DKMA then calculates the pharmacy retail price (PRP) via a statutory mark-up scheme along with the reimbursement price. Product prices can be altered every two weeks. Tendering is not relevant in out-patient sector, except for vaccines and certain blood products.

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1 However, prices of reimbursable off-patent pharmaceuticals may indirectly be influenced through the reimbursement price. Pharmaceutical companies wishing to enter their products into the reimbursement system have to apply for reimbursement at the Danish Medicines Agency (DKMA).

2 Technically they only report new/altered prices.

One exception is that certain OTC medicines sold outside pharmacies are also freely priced at retail level. The DMKA is not notified of these prices and the pharmacy retail price (PRP) of such OTC may vary throughout the country.

Companies are not allowed to offer any discounts to health professionals in order to promote sales of medicines. However, discounts/rebates given to retailers and those achieved due to reduced suppliers' costs are legal but subject to strict regulation.

The Danish reimbursement system is a needs-based scheme allocating public reimbursement to those patients that have the largest consumption of prescribed medicines and who consequently have the largest expenses. This system was introduced on 1 April 2000 and is characterised by a number of aspects:

- A positive list of medicines including both prescription-only medicine(s) (POM) and over-the-counter (OTC) medicines. There is no negative list.
- Variable reimbursement rates depending on the consumption of the patient within a 12-month period and his/her age.
- OTC medicines are only reimbursed for patients with defined illnesses or for pensioners.
- Patients' out-of-pocket payments (OPP) are based on the reimbursement price. The main principles of OPP by patients for medicines have been determined by the Danish Parliament and are set out in the Danish Health Act.
- The Danish Medicines Agency (DKMA) may grant individual reimbursement to a patient for a specific non-reimbursable medicine upon application by the doctor.
- Although generic substitution is mandatory in this system, both doctors and patients may refuse it with a larger patient co-payment as a consequence.

The reference price system in Denmark is closely related to (and based on) the generic substitution scheme. The only major changes over the last five to ten years are the different ways of defining the reference price (reimbursement price) of a group.

The Reimbursement Committee (MTN) meets once a month and recommends whether medicines should be granted general reimbursement. If the DKMA agrees to follow the recommendations of the Committee, the Positive list is updated accordingly. Generics and parallel imported medicines are granted general reimbursement without application if their prices do not exceed the prices of the original (reimbursable) products.

The Danish pharmacy mark-up is regulated by law. Pharmacies receive a dispensary fee whenever they sell a prescribed product, i.e. prescription-only medicine(s) (POM) and OTC medicines sold on prescription.[3] The value-added tax (VAT) rate for medicines is the same as the standard rate (25%).

[3] Some OTC pharmaceuticals can be reimbursed for some patients that fulfil specific criteria for reimbursement of these products. Reimbursement requires prescription.

The dispensary fee is the most commonly applied fee which is added to the pharmacy retail price (PRP) of the medicine. Only the dispensary fee and the dosage dispensing fees are reimbursable according to the general reimbursement rates. Other fees are non-reimbursable and are paid by patients in the form of out-of-pocket payments (OPP) (cf. section 3.2.4.2)

Most out-of-pocket payments (OPP) are percentage based, but a flat dispensary fee for every pack is added to the reimbursement price. The applied cost limits and the price ceiling within the present needs-based system are changed once a year (cf. section 3.2.4.2.1). According to the social laws in Denmark, pensioners, people with low income, disabled people and others may be granted additional reimbursement.

The DKMA monitors monthly price developments through price indexes and average prices, maintaining two different sets of price indexes: one is based on prices per defined daily dose (DDD), and the other is based on prices per pack.

The DKMA has the possibility of monitoring prescription patterns and pharmaceutical use in detail. Each month pharmacies, hospital pharmacies, shops authorised to sell OTC and the Statens Serum Institute (SSI) send in electronically this information on their sales.

All prescriptions are also monitored by the systematic pharmaceutical system ORDIPRAX (http://www.ordiprax.dk) which is an online system where all doctors can compare their own prescribing habits with those of their colleagues in the region.

There is no formal legal source for health-economic analysis in Denmark, but several public and private institutions perform health-economic analyses. The provision of a health-economic analysis is not necessary for obtaining market authorisation but it may play a role in the reimbursement decision.

Pricing, reimbursement and volume control in the in-patient sector

In Denmark all hospital treatment in public hospitals, including medicines, is provided free of charge to the patient. 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.

The 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. Most public tenders are carried out by Amgros, a hospital purchasing agency owned by the five regions.

Manufacturers and importers of medicines may freely determine the price of each medicine. The pharmacy purchasing price 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 because Amgros has made an agreement on purchase with the manufacturer/importer. This price is not subject to VAT and dispensing fee as the medicines sold in the out-patient sector.

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

Every region in Denmark has one or more pharmaceutical and therapeutic committee(s) (PTC) that makes the relevant decisions regarding the medicines that are included in the hospital pharmaceutical formulary (HPF). The members are mainly representatives from the hospital (doctors, pharmacists). Their primary goal is to ensure the best possible treatment with medicines and to ensure the most effective utilisation of resources. The number of medicines (HOM, POM and OTC) included in a HPF can be different in each region.

The HPFs are updated once a year when the processes of new tenders are finished. All hospital wards manage their own budget for purchasing medicines. Doctors in hospitals are free to prescribe whatever medicine they wish. But the aim for the doctors is 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.

It is possible that a 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 therapeutic equivalent substance.

In May 1993 the Register of Medicinal Product Statistics was established as a publicly run register of medicines statistics with a view to the drafting of statistics and price indexes as well as to monitor the consumption of pharmaceuticals and thus to strengthen the basis for the central health authorities' decisions. The DKMA, hosting and being responsible for the Register, prepares a number of consumption analyses and statistics on the basis of data from the Register.

Monitoring of the in-patient sector is done by Amgros on a regular basis. The report 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.

When it comes to economic analysis, it is the same as in the out-patient sector. There is no formal legal source for health-economic analysis in Denmark, but several public and private institutions perform health-economic analyses.

Interface management and developments

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 medicines in a rational way so the prescription of a medicine, which is expensive in the primary care sector, is avoided.

As mentioned before it could happen 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 developed an interface management procedure for the transfer between the in-patient and out-patient care to reduce the risk of medication errors.

Since 2009 focus has mainly been pointed at the hospital medicines development. The reason is a continuous annual expenditure growth rate of 15%.

In 2009 a major public investigation of pharmaceutical prices, consumption and expenditures was made. The following report resulted in two developments. Firstly, an agreement with the pharmaceutical industry was concluded, which called for a 5 percentage points reduction of list prices of hospital medicines as of 1 January 2010 followed by a price freeze. Secondly, initiatives to strengthen the management of the consumption of hospital medicines were taken. Among these was the appointment of a common regional pharmaceutical and therapeutic committee on expensive hospital medicines (RADS).

In the out-patient sector no major reforms of the legislation framework for medicines are foreseen.

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List of abbreviations

ATC	Anatomic therapeutic chemical classification
BMG	Austrian Ministry of Health (Bundeministerium für Gesundheit)
CAST	Center for Applied Health Services research and Technology Assessment
CCOHTA	Canadian Coordinating Office for Health Technology Assessment's
CTR	Central Reimbursement Register (CTR)
DA	Danish Pharmaceutical Association (Danmarks Apotekerforening, DA)
DACEHTA	The Danish Centre for Evaluation and Health Technology Assessment
DADL	The Danish Medical Association (DADL)
DDD	Defined Daily Doses
DKK	Danish Kroner
DKMA	Danish Medicines Agency
DLI	Danish Drug Information Ltd. (Dansk Lægemiddel Information)
DRG	Diagnosis related group
DSAM	Danish College of General Practitioners (DSAM)
DSI	Danish Institute for Health Services Research (DSI).
EAHC	Executive Agency for Health and Consumers
EEA	European Economic Area
Efpia	European Federation of Pharmaceutical Industry Associations
ESP	Total consumer price
EU	European Union (EU)
GDP	Gross domestic product
GÖG/ÖBIG	Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG / Austrian Health Institute
GP	General Practitioner
IGL	Danish Generic Medicines Association

Ha	Pharmacy-only OTC medicines
HE	Health expenditure
Hf	Non-pharmacy-restricted OTC medicines for general free sale (Frihandel)
HiT	Health systems in transition
HOM	Hospital-only medicine
HPF	Hospital pharmaceutical formularies
HTA	Health technology assessment
Hx	Non-pharmacy-restricted OTC medicines, with a limited free sale, there is a maximum package per customer per day (Håndkøb)
IHHII	International Healthcare and Health Insurance Institute
IGL	Danish Generic Medicines Industry Association (Industriforeningen for Generiske Lægemidler)
IM	Ministry of the Interior and Health
INN	International Non-proprietary Name
IRF	Institute for Rational Pharmacotherapy (IRF)
Lif	Danish Association of the Pharmaceutical Industry (Lægemiddelindustriforeningen)
Mio.	Million
MTN	Reimbursement Committee
NCU	National currency unit
NHIP	National Institute of Public Health (Statens Institut for Folkesundhed)
NHS	National health service
NMEs	New molecular entities
OECD	Organisation for Economic Co-operation and Development
OPD	Out-patient departments
OPP	Out-of-pocket payment
OTC	Over-the-counter medicine

PHIS	Pharmaceutical Health Information System
PE	Pharmaceutical expenditure
PDA	Personal digital assistant
PFL	Danish Association of Parallel Importers of Pharmaceuticals (Parallelimportorforeningen af Lægemidler)
PLO	Organisation of General Practitioners in Denmark
POM	Prescription-only medicine
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy retail price
PTC	Pharmaceutical and therapeutic committee(s) (PTC)
QALY	Quality adjusted life year
RADS	Committee for Expensive Hospital Medicines
SHI	Social health insurance
SSI	Statens Serum Institute
SST	National Board of Health
SUKL	State Institute for Drug Control
THE	Total health expenditure
TPE	Total pharmaceutical expenditure
UVKL	National Committee for Evaluation of Cancer Medicines
VAT	Value added tax
VHI	Voluntary health insurance
WHO	World Health Organisation
WP	Work package

Introduction

The Pharmaceutical Health Information System (PHIS) project was a research project commissioned by the Executive Agency for Health and Consumers (EAHC) and co-funded by the Austrian Ministry of Health (BMG).

The PHIS project management was a consortium of the project leader Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (GÖG/ÖBIG) a research institute situated in Vienna, Austria, and four associated partners: the Italian Medicines Agency (AIFA), Italy, the International Healthcare and Health Insurance Institute - (IHHII), Bulgaria, SOGETI Luxembourg SA., Luxembourg and the State Institute for Drug Control (SUKL), Slovakia. Further key stakeholders of the PHIS project management were the PHIS advisory board covering EU Commission services and agencies and 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 aimed at increasing the level of knowledge and exchange of information on pharmaceutical policies, in particular on pricing and reimbursement, in the European Union. This was achieved by surveying and monitoring pharmaceutical health system information in the in-patient and out-patient sector from a public health perspective, and by developing key pharmaceutical health indicators which may be included in a European Health Information System.

The PHIS project ran 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 Monitoring

The aim of the work package “Monitoring” was to provide up-to-date country-specific information on out-patient and in-patient pharmaceutical systems in the EU Member States and beyond.

The country-specific information was compiled in different sets and for different purposes based on different templates taking into consideration a common terminology (PHIS Glossary) and a set of indicators (PHIS Indicators): e.g.

- Country reports covering information on the pharmaceutical system in the in- and out-patient sectors written by country representatives of the PHIS network (PHIS Pharma Profiles)
- Integrated flowchart of the pharmaceutical system in the in- and out-patient sectors (also part of the PHIS Pharma Profile)
- Country reports with a focus on the pharmaceutical system in the in-patient sector (national PHIS Hospital Pharma Report) and a compilation of the information in a benchmarking report (PHIS Hospital Pharma Report)

All documents together represent the PHIS Library, which has to be understood as an on-line documentation system containing up-to-date information on the pharmaceutical in- and out-patient sectors. The PHIS Library is accessible at the website of the PHIS project (http://phis.goeg.at) and is constantly updated.

PHIS Pharma Profile

The production of the country-specific PHIS Pharma Profiles was based on three steps:

1. Development of a uniform PHIS Pharma Report Template

The PHIS Pharma Profile offers a homogenous, very detailed structure for describing the pharmaceutical pricing and reimbursement system in the in- and out-patient sector of a country. The Template provides detailed guidelines and specific questions, definitions and examples needed to compile the PHIS Pharma Profile. It consists of six chapters, referring to the regulatory situation in 2010 or 2011. Three of the chapters (chapter 1 Health care system, chapter 2 Pharmaceutical system and chapter 5 Interface management and developments) are covering integrated information on the in- and out-patient sectors. Chapters 3 and 4 are dedicated entirely to the pricing, reimbursement and volume control in out-patient sector and respectively to the in-patient sector.

The methodology for developing the PHIS Pharma Profile Template was based on the review of existing surveys – country profiles developed in the PPRI project (Pharmaceutical Pricing and Reimbursement Information) and the PHIS Hospital Pharma report – and by using the common terminology (glossary) developed in Work Package 4 (Terminology) and the pharmaceutical indicators (PHIS indicators) developed in Work Package 6 (Indicators) of the PHIS project. The PHIS Pharma Profile Template was developed by the leader of work package Monitoring Ms. Gergana Andre (IHHII, Bulgaria[4]) in collaboration with the PHIS main partner (GÖG/ÖBIG). The Template was kindly reviewed by the PHIS Advisory Board members. Members of the PHIS network received the draft Template for feed-back, and had the opportunity to discuss and provide personal feed-back during a meeting.

[4] IHHII BG is a 10 years old Bulgarian think tank, independent non-governmental organisation, which provides information and analysis in health policy, healthcare management and organisation in Bulgaria. Through its network of consultants and independent research work it provides reports, early warning statements, organises debates, engages non-governmental stakeholders in health to perform proper government monitoring and enforce civic participation in the development and implementation of health policy. A significant part of the research work of IHHII is dedicated to the pharmaceutical system and market in Bulgaria. Through its reports and analyses the Institute is a reliable partner to many professional organisations in health and the public institutions. IHHII maintains the largest and the oldest health web portal in the country – www.zdrave.net – which is an online arena of information exchange and debates in health reaching at daily average 5,000 people acting in health and pharmaceutical system.

2. Collecting information and data and drafting the PHIS Pharma Profiles

The country-specific PHIS Pharma Profiles were written by members of the PHIS network. In order to get the needed information and data, experts of the in- and out-patient sectors were contacted and involved in several countries. They provided information and data in written form and during telephone conversation and personal talks. In several countries, the preparatory work for drafting the PHIS Pharma Profiles also included study visits of the authors e.g. to hospital pharmacies. Information on persons and institutions involved can be found in the “Acknowledgements” at the beginning of this PHIS Pharma Profiles. For some countries (out-dated) information on the pharmaceutical system in the in- and out-patient sectors was already available but in form of separated reports (e.g. for the out-patient sector: PPRI report; for the in-patient sector: PHIS Hospital Pharma Report). It was a challenge to integrate the two separated reports into one updated integrated description of the pharmaceutical system. The main partner (GÖG/ÖBIG) of the PHIS project offered PHIS network members to pre-fill the template with already existing information and delivered pre-filled templates for 13 countries.

3. Editorial process

The drafts of PHIS Pharma Profiles were submitted to the project management for review, which was undertaken by IHHII, Bulgaria (Work Package leader of “Monitoring”) 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, terminology (PHIS Glossary) and data provision for filling PHIS Indicators (to be filled in the PHIS database). In the course of the editorial process, the reviewers contacted the authors for providing feedback on language and content, offering suggestions for re-phrasing and change and clarified open and/or misunderstanding points.

1 Health care system

This chapter provides an overview of the country's health care system as of 2010.

1.1 Demography

The total population of Denmark is still growing with a falling population share of age 0-14 and a rising share of age above 64. The life expectancy is slightly rising. A further – and stronger – rise in the life expectancy is a stated major political goal for the future.

Table 1.1: Denmark – Demographic indicators 2000, 2005–2009

Demography	2000	2005	2006	2007	2008	2009
Total population	5,330,020	5,411,405	5,427,459	5,447,084	5,475,791	5.489.177
Population aged 0-14	981,148	1,018,146	1,015,879	1,014,153	1,009,917	1,008,086
Population aged 15-64	3,558,470	3,580,756	3,588,553	3,598,186	3,612,833	3,627,869
Population aged > 64	790,402	812,503	823,027	834,745	853,041	853,222
Life expectancy at birth	76.87*	78.26	78.43	78.40	78.77	79.00
Life expectancy at age 65	16.89	17.73	17.81	17.95	18.15	18.2

Data of 01 January of each year

Sources: EUROSTAT, *PPRI Pharma Profile Denmark 2008

1.2 Organisation

The Danish health care service can be divided into two sectors:

- The primary care sector, and
- The hospital sector.

The primary sector deals with general health problems and its services are available to all. This sector can be divided into two parts:

- one which mainly deals with treatment and care – general practitioners (GP), practising specialists, practising dentists, physiotherapists etc. (the practising sector) and district nursing;
- one which is predominantly preventive and deals with preventive health schemes, health promotion and child dental care.

Health care provision in Denmark is to a great extent a public task, financed through taxes, and most of the services are run directly by the public authorities, i.e. the National Health Service (NHS). The vast majority of health services are therefore free of charge for the users.

The basis reimbursement scheme and the social reimbursement aspect cover the whole population and all types of health care provision, except in-patient treatment. All hospital treatment is free of charge to the patient.

According to the social laws in Denmark it is possible for pensioners, people with low income and disabled people staying in their own homes to receive supplementary reimbursement covered and administered by the respective municipality.

The responsibility for running the National Health Service (NHS) is decentralised and mostly lies with the regional authorities (third-party payers), but they work in close cooperation with the Government and the Local Authorities.

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.

State

One of the main tasks for the State (the Ministry of the Interior and Health (Indenrigs- og Sundhedsministeriet, IM), the National Board of Health (Sundhedstyrelsen, SST), the Danish Medicines Agency (Lægemiddelstyrelsen, DKMA)[5], State Serum Institute (Statens Seruminstitut SSI) and National Institute of Public Health (Statens Institut for Folkesundhed, NHIP)) is to set up guidelines for the running of the health care service. The Ministry of the Interior and Health (IM) is responsible for legislation on health care.

Regions

The five Danish regions are responsible for hospital services, including psychiatry, health insurance, general practitioners (GP) and specialists, etc. They 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.

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

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 treatments in its own hospitals.

[5] Please note that since 2011 several names of the institutions have changed due to organisational changes, cf. section 5.2.

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.

Municipalities

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 that do not take place at the hospitals. Prevention includes the treatment of alcohol and drugs abuse.

1.3 Funding

This section gives an overview of the health care expenditure and the sources of funding health care.

1.3.1 Health expenditure

Table 1.2: Denmark – Health expenditure 2000, 2005–2009

Health expenditure in NCU = Mio. DKK	2000	2005	2006	2007	2008	2009
GDP	1,293,964	1,545,257	1,631,659	1,691,472	1,737,448	1,659,705
THE	106,935	146,658	156,709	164,780	(146,488)	(156,827)
- thereof public HE	88,147	122,794	131,777	139,225	(124,718)	(134,298)
- thereof private HE	18,788	23,864	24,932	25,555	(21,770)	(22,529)
HE in the out-patient sector	27,733	35,129	37,480	44,350	n.a.	n.a.
- thereof public	21,625	26,878	29,029	35,830	n.a.	n.a.
- thereof private	6,108	8,251	8,451	8,520	n.a.	n.a.
HE in the in-patient sector	56,886	45,822	49,682	59,957	n.a.	n.a.
- thereof public	53,377	43,173	46,897	56,511	n.a.	n.a.
- thereof private	3,509	2,649	2,785	3,446	n.a.	n.a.
Exchange rate (NCU per €)	7.45	7.45	7.45	7.45	7.45	7.45

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

Source: 2000-2007 and GDP from 2009: OECD 2009. Data regarding 2008-2009 is national data.

In table 1.2 data from the official OECD statistics are used. These data – except for the GDP – only reach until 2007. For 2008 and 2009 some data from national statistics are provided. These are however not to be compared to the OECD data due to differences in methods. Note that the OECD classifications underwent some major changes in 2003 making comparisons of figures before and after 2003 more or less meaningless.

In general the health expenditures share of GDP has been rising during the century while the division between public and private expenditures has been rather stable.

1.3.2 Sources of funds

Primary sector

In the primary health care sector, approximately 56% of the expenses is financed by the regional health insurance (tax financed), and approximately 4% is financed by the local community (mainly reimbursement paid to senior citizens or “economically weak” persons). A total of 40% of the expenditure is paid by the patients themselves (= out-of-pocket payments (OPP)). These figures include self-payment of non-reimbursed prescription medicines and over-the-counter (OTC) medicines.

However, some people have taken out supplementary private insurance with the insurance company "Denmark” (sygeforsikringen “Danmark”), a non-profit-making mutual insurance company specialising in health insurance as a supplement (including pharmaceutical expenditure (PE)) to the Danish National Health Service (NHS)). Part of OPP is covered by this private insurance – in 2005 this amounted to approximately 14%.

Regional and local health care

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). In the regions it is financed by four kinds of subsidies:

- block grant from the state
- state activity-related subsidy
- municipal basic contribution
- 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 following the local government reform of 2007 the municipalities 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. The basic contribution is determined by the regions. The maximum limit is fixed by statute.

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 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.

1.3.3 Out-patient care

The payment system for general practitioners (GP) and specialists in primary care in the Danish health care system is generally based on fee-for-service payments according to a three year agreement between general practitioners union and specialists unions on one side and the health insurance on the other side. The expenses of the health insurance are paid by the regions and – by the end of the day - tax financed. The services of general practitioners and specialists do in general not involve out-of-pocket payments for patients.

Out-of-pocket payments (OPP) in the out-patient sector occur in the service fields of dentists, physiotherapists, chiropodists, chiropractors and psychologists. Patients also need to co-pay for medicines in the out-patient sector, cf. section 3.2.

1.3.4 In-patient care

In Denmark all hospital treatment, including medicines given to the patients during their stay, is free of charge to the patient.

Pharmaceutical treatment is financed mainly through taxes paid to the State and passed on as a block grant to the five regions, which are then responsible for managing the health care system, including the hospitals. All expenditure on medicines in hospitals is paid by the regions.

Approximately 75% of the aggregated financing basis for the hospitals is fixed at a contribution from the State that is not activity dependent and 5% is obtained in the form of an activity-dependent subsidy from the State. The remaining 20% is financed by the municipalities, both through basic and activity-dependent contributions.

The regions decide themselves on the remunerating principle for their hospitals – typically annual framework budgets are used. However, since 2004 the Government and the regions have arranged that at least 20% of hospital resources are to be used in a way that promotes hospital activity/productivity. Remuneration per treatment is carried out with diagnosis-related group (DRG) tariffs, or through tariffs that the regions decide themselves. The productivity-dependent share of the budgets has to reach 50% of the total remuneration from 2007 onwards.

1.4 Access to health care

1.4.1 Health care professions

Table 1.3: Denmark – Doctors and pharmacists development 2000, 2005–2009

Health professionals	2000	2005	2006	2007	2008	2009
Total no. of doctors[1]	16,708	19,129	19,658	19,935	20,293	20,547
- of which GPs	3,456	3,752	3,753	3,759	3,685	4,047
- of which work in the out-patient sector	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- of which work in the in-patient sector	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of pharmacists	2,630	3,115	3,157	3,187	3,253	3,276
- of which work in community pharmacies	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- of which work in hospital pharmacies	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

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

Doctors are professional active physicians.

Pharmacists are professional active pharmacists.

Source: OECD

1.4.2 Out-patient care

Normally a patient's first contact with the health care system is with his/her general practitioner (GP) acting as "gatekeeper" with regard to hospital treatment and treatment by specialists and other health professionals working under agreements with the health care service. It is normally necessary to be referred by a GP to a hospital for medical examination and treatment unless in emergency cases or in acute illness. Thus patients usually start by consulting their GP, whose job is to ensure that they are offered the treatment they need and that they will not be treated at a more specialised level than necessary. The hospital sector deals with medical conditions, which require more specialised treatment, equipment and intensive care.

General practitioners work alone or together in small clinics – typically with 3-4 general practitioners. They are private organizations whose services to patients are paid by the health insurance according to an agreement. Expenditures of health insurance are paid by the regions.

Patients are attached to a general practitioner but may change practitioner freely with a fee.

1.4.3 In-patient care

Table 1.4: Denmark – In-patient care 2000, 2005–2009

In-patient care	2000	2005	2006	2007	2008	2009
No. of hospitals	116	201	210	227	268	271
Classified according to ownership						
– thereof public hospitals	73	59	59	58	58	55
– thereof privately owned hospitals[1]	43	142	151	169	210	216
Classified according to subtypes[1]						
– thereof general hospitals	61	49	49	48	48	45
No. of acute care beds	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
– thereof in the public sector	18,698	16,585	16,278	15,789	n.a.	n.a.
– thereof in not-for-profit privately owned hospitals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
– thereof in for-profit private hospitals	n .a.	n,a,	n.a.	n.a.	n.a.	n.a.
Average length of stay (acute care) in days	5.4	4.4	4.2	4.2	4.1	3.8
No. of hospital pharmacies	n.a.	n.a.	16	14	12	n.a.

n.a. = not available, No. = number

[1] division into “not for profit” and “for profit” privately owned hospital not possible

Source: National Board of Health, Danish National Patient Registry

There is no official definition of hospitals in Denmark at the moment, but there is 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 sub-types 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.

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.

In 2009 there were 55 public hospitals in Denmark. Most of these hospitals are large units functioning as general hospitals. Beside the public hospitals were 216 private hospitals. It should however be born in mind, that private hospitals in Denmark are most small units with only a few functions – often more correctly categorised as clinics.

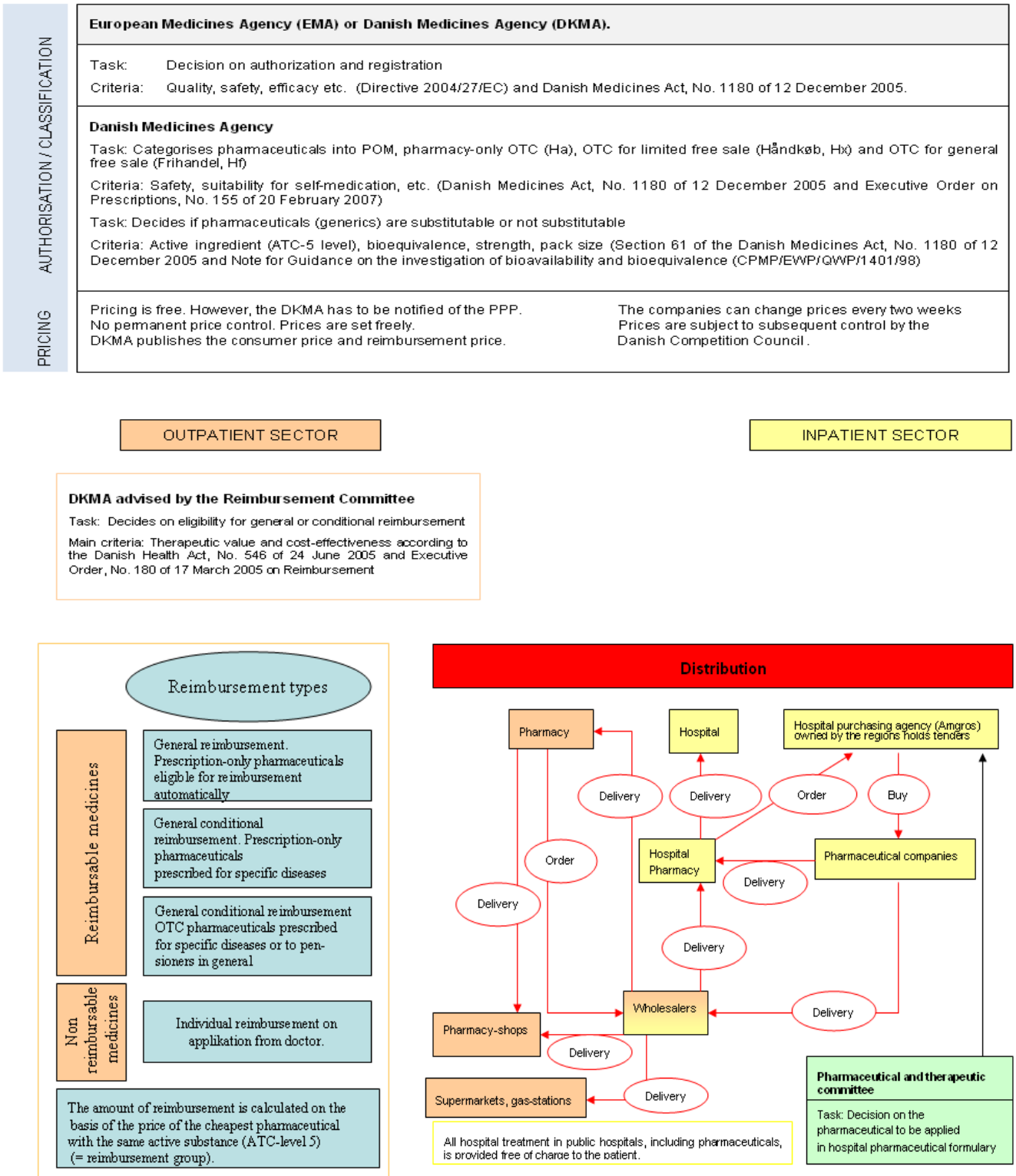
2 Pharmaceutical system

This chapter gives an introduction to the pharmaceutical system, including organisation, key statistic data, market players, and funding.

2.1 Organisation

This section describes the regulatory framework (legal basis, main authorities and their tasks) addressing both the out-patient and the in-patient sector.

Figure 2.1: Denmark – Flowchart of the pharmaceutical system, 2010



Source: Up-dated figure based on PPRI 2008

2.2 Regulatory framework

At national level the main players are the Ministry of the Interior and Health (IM), the Danish Medicines Agency (DKMA) and the Danish Parliament setting the framework of the pharmaceutical system. At regional level the five regions finance the reimbursement of medicines through nationally paid taxes, and at local level the municipalities run a supplementary reimbursement system based on social indications.

2.2.1 Policy and legislation

The main laws in the pharmaceutical field are detailed below.

The Danish Medicines Act, No. 1180 of 12 December 2005, as amended[6] contains provisions for authorisation and control of medicines and the companies which manufacture, store or otherwise carry out pharmaceutical activities. The Act also outlines rules on reporting of adverse drug reactions, prices and statistics and on advertising of medicines. Finally, the Act lays down provisions regarding the authorisation of clinical trials of medicines on humans.

The Danish Pharmacy Act, cf. Consolidated Act No. 657 of 28 July 1995, as amended,[7] sets out the requirements for conducting pharmacy business, including the conditions for being granted a licence to run a pharmacy. The Act lays down the tasks which a pharmacy is responsible for carrying out, as well as the conditions for establishing, moving and closing pharmacy units. Finally, the Act contains provisions on authority inspection and control of pharmacies.

The Danish Health Act, No. 546 of 24 June 2005, as amended,[8] sets out (in Chapter 42) the rules regulating reimbursement of medicines in Denmark.

6 http://lms-lw.lovportaler.dk/showdoc.aspx?docId=lov20051180uk-full

7 http://lms-lw.lovportaler.dk/ShowDoc.aspx?docId=lov19840279uk-full

8 http://www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=11547

2.2.2 Authorities[9]

The Ministry of the Interior and Health (IM) (**Health Care Department, Division for pharmaceuticals)** is in charge of the administrative functions related to the organisation and financing of the health care system, as well as the licensing of medicines and the pharmacy sector. Prevention and health promotion are also part of the Ministry's remit. Table 2.1 provides an overview of the Danish authorities.

The Danish Medicines Agency's (DKMA) main duties are to authorise and control medicines and companies, including pharmacies, and to monitor the economic use and consumption of medicines. The Agency has four professional divisions, detailed below.

The ***Licensing Division*** authorises human and veterinary medicines and grants market authorisations. Authorisations are granted nationally or according to a European Union (EU) procedure. The Licensing Division handles applications for variations and grants compassionate use permits for non-authorised medicines. Moreover, companies have the possibility to receive scientific advice on future applications, and the Licensing Division also deals with labelling and package leaflets. The Division publishes the List of Prices for Proprietary Medicinal Products (www.Medicinpriser.dk)[10] every two weeks, which is a detailed list of all medicines that are sold in Denmark.

The ***Consumer Safety Division*** monitors the safety of both medicines and medical devices, and it is in charge of adverse reaction reports regarding both categories. The Division is also responsible for authorising clinical trials with medicines and testing of medical devices and the Division monitors advertising of medicines and medical devices.

The ***Medicines Control Division*** is in charge of authorisation, monitoring and control of pharmaceutical companies as well as laboratory control of the quality of medicines. The Division monitors private individuals' import habits, along with illegal sales, and pharmacies and other sales outlets selling medicines. The Medicines Control Division is also in command of analytic monitoring and standardisation of biological and chemical medicines and radiomedicines. The Division controls the Danish Medicines Agency's (DKMA) laboratory. The

[9] Please note that since 2011 the following institutional changes took place:

- As of 1 March 2012 the Danish Medicines Agency and the Danish National Board of Health merged into the Danish Health and Medicines Authority (Sundhedsstyrelsen, DHMA). Some divisions in the organisation differ from the ones described in this profile.
- At the same time the managing of the Danish Register of Medicinal Product Statistics was transferred from the Danish Medicines Agency to the State Serum Institute, Division of Data Deliveries and Medicinal Product Statistics. The official name in English is now The Danish Register of Medicinal Product Statistics.
- In October 2011 the Ministry of the Interior and Health (Indenrigs- og Sundhedsministeriet , IM) became The Ministry for Health and Prevention.
- As of 1 July 2012 DSI merged with two other research institutions under the name Danish Institute for local and regional government research (KORA") http://kora.dk

[10] http://www.medicinpriser.dk/?lng=2

Division also operates the Danish Medicines Agency's (DKMA) Register of Medicinal Product Statistics.[11] Developments in the consumption of medicines are supervised and analysed on the basis of the information in the Register of Medicinal Product Statistics.

The ***Executive Secretariat*** provides services to the Chief Executive Officer and the management team of the Danish Medicines Agency. The Executive Secretariat also attends to the following tasks: cross-functional legal questions, tendering and contracts, strategy and business development, external communication including websites and campaigns, press services, secretariat services to the Council for Adverse Drug Reactions, decides on general reimbursement for medicines, issues/confirms individual patients' reimbursement requests.

The aim of the **Institute for Rational Pharmacotherapy (IRF)** is to promote the most rational use of current and new medicines with respect to both pharmacological and economical aspects and directed towards both primary and hospital care. The Institute publishes the monthly medical journal "Rational Pharmacotherapy" and arranges courses on the use of medicines, reviews new medicines on the web site[12] and supports regional medical advisers on medicines. The Institute for Rational Pharmacotherapy (IRF) provides well-balanced information to all medical doctors in Denmark. Other target groups are other professionals in the health sector and consumers of medicines.

The National Board of Health (SST) is the central professional authority in the health care field with the main task of monitoring the health care system and its actors and activities, authorising health professionals, and providing professional advice on health issues to the Minister of Health and the Interior (IM), the regions and other authorities, as well as to the population.

The Danish Centre for Health Technology Assessment (DACEHTA) carries out health technology assessments (HTA) with the aim of improving quality, standards and value for money. It is also an objective to integrate health technology assessment (HTA) principles into the running and planning of the public health service at all levels.

The five regions/the Regional Councils 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. The regions are organised in the Association of Regional Councils.

The Reimbursement Committee's (MTN) task is to advise the Danish Medicines Agency (DKMA) in cases concerning health insurance reimbursement of medicines (both general reimbursement and individual reimbursements). The MTN Committee consists of a maximum of seven people, two of whom must be general practitioners (GP). Members are appointed by the Minister of the Interior and Health (IM) after recommendation by the DKMA. One

[11] http://www.medstat.dk

[12] http://www.irf.dk

member represents the regions (the third-party payer). The members of the MTN Committee are appointed for a 4-year term and collectively possess a broad range of professional expertise. As a rule the Committee is consulted when deciding on the reimbursement status of new medicines for which the company has applied for general reimbursement and the Committee also recommends on criteria for the various types of individual reimbursement (cf. section 3.2 for details). However, the reimbursement decisions themselves are the responsibility of the DKMA alone.

The Reimbursement Committee (MTN) meets once a month and the Danish Medicines Agency (DKMA) provides a secretariat for the work of the Committee.

The Council for Adverse Drug Reactions offers general guidance to the Danish Medicines Agency (DKMA) on adverse reaction matters and makes recommendations to the Agency for improving the prevention and monitoring of adverse reactions, thereby encouraging safer use of medicines. The main tasks of the Council are to monitor and assess adverse reaction reporting in practice, and to propose recommendations and give inspiration to the DKMA information and communication tasks on adverse reactions for consumers, patients and health care professionals. The council is appointed by the DKMA and it consists of nine members representing the industry, therapists, pharmacists, patients and consumers. Meetings are held 4-6 times per year, and the DKMA provides a secretariat for the work of the Committee.

The main task of the **Licensing Committee** is to advise the Danish Medicines Agency (DKMA) on cases concerning applications for – and annulment of – market authorisations for medicines and clinical trials of medicines. The Licensing Committee consists of a maximum of 13 people appointed by the Minister of the Interior and Health (IM), on the recommendation of the DKMA. Members of the Committee are appointed for four years at a time and, collectively, possess a broad range of professional expertise. The Committee meets once or twice per month, and the DKMA provides a secretariat for the work of the Committee.

Table 2.1: Denmark – Legal basis and actors (authorities and market players) of the pharmaceutical system, 2010

Fields	Legal basis	Scope (in-patient, out-patient sector)	Authorities in English (local name, local abbreviation)	Activity / responsibility in the pharmaceutical system	Actors and interest associations in English (local name, local abbreviation)
Market authorisation	The Danish Medicines Act	In-patient and out-patient	The Danish Medicines Agency, DKMA (Lægemiddelstyrelsen, LMS)	The DKMA's main assignments are to authorise and control pharmaceuticals and companies, including pharmacies, and to monitor the economy and consumption of medicines, and to monitor the safety of medicines and medical devices, and to decide the reimbursement status of the pharmaceutical.	Pharmaceutical companies, patient organisations.
		In-patient and out-patient	The Licensing Committee (Registreringsnævnet)	Advising the DKMA on market authorisation (granting, amendments and withdrawals)* and on clinical testing.	Pharmaceutical companies, patient organisations.
Pricing / Purchasing	The Danish Medicines Act	In-patient and out-patient	The Danish Medicines Agency, DKMA (Lægemiddelstyrelsen, LMS)	The DKMA's main assignments are to authorise and control pharmaceuticals and companies, including pharmacies, and to monitor the economy and consumption of medicines, and to monitor the safety of medicines and medical devices, and to decide the reimbursement status of the pharmaceutical.	Pharmaceutical companies

Fields	Legal basis	Scope (in-patient, out-patient sector)	Authorities in English (local name, local abbreviation)	Activity / responsibility in the pharmaceutical system	Actors and interest associations in English (local name, local abbreviation)
		In-patient	The Regional Council of each of the 5 regions (De 5 regioner/ 5 Regionsråd)	Deciding which medicines to use and which (expensive) new medical treatments to implement in the hospital sector. The regions are responsible for running the hospitals and for financing medicines in the primary care sector AMGROS** purchases medicines for all public hospitals in Denmark	hospitals
Reimbursement	The Danish Health Act	Out-patient	The Danish Medicines Agency, DKMA (Lægemiddelstyrelsen, LMS)	The Danish Medicines Agency's main assignments are to authorise and control pharmaceuticals and companies, including pharmacies, and to monitor the economy and consumption of medicines, and to monitor the safety of medicines and medical devices, and to decide the reimbursement status of the pharmaceutical.	Pharmaceutical companies, patient organisations, scientific societies
			The Reimbursement Committee (Medicintilskudsnævnet, MTN)	Makes recommendations on reimbursement matters to the DKMA, e.g. on reimbursement status and on recommended criteria for individual reimbursement	

Fields	Legal basis	Scope (in-patient, out-patient sector)	Authorities in English (local name, local abbreviation)	Activity / responsibility in the pharmaceutical system	Actors and interest associations in English (local name, local abbreviation)
Promotion		In- and out-patient sector	The Danish Medicines Agency, DKMA (Lægemiddelstyrelsen, LMS)	In addition to the other assignments mentioned the Danish Medicines Agency monitors and controls advertising and promotion of medicines.	Pharmaceutical companies, health care professionals
Distribution	The Danish Medicines Act	In- and out-patient sector	The Danish Medicines Agency's (Lægemiddelstyrelsen, LMS)	The Danish Medicines Agency's main assignments are to authorise and control pharmaceuticals and companies, including pharmacies, and to monitor the economy and consumption of medicines, and to monitor the safety of medicines and medical devices, and to decide the reimbursement status of the pharmaceutical.	Pharmacies, wholesalers, pharmaceutical companies
Vigilance	The Danish Medicines Act	In- and out-patient sector	The Danish Medicines Agency's (Lægemiddelstyrelsen, LMS)	The Danish Medicines Agency's main assignments are to authorise and control pharmaceuticals and companies, including pharmacies, and to monitor the economy and consumption of medicines, and to monitor the safety of medicines and medical devices, and to decide the reimbursement status of the pharmaceutical.	Patients, pharmaceutical companies

Source: PPRI DK 2008

* The DKMA decides whether or not to consult with the committee and whether or not to follow the advice from the committee in decisions on concrete cases

** Amgros is a hospital purchasing agency owned by the 5 regions

2.3 Statistics

This section gives an overview on the number of medicines as well as on market figures and consumption data.

2.3.1 Availability of medicines

2.3.1.1 Market authorisation

Table 2.2: Denmark – Number of medicines 2000, 2005–2010

Medicines	2000	2005	2006	2007	2008	2009	2010	Method of counting[1]
Authorised	4,126	4,807	5,110	5,543	6,150	7,163	7,649	See note
On the market	3,637	4,276	4,285	4,372	4,534	4,640	4,825	See note
POM	3,536	3,600	3,618	3,692	3,812	3,892	4,041	See note
Reimbursable	2,593	2,630	2,629	2,700	2,799	2,877	2,939	See note
Generics	455	806	909	1,000	1,061	1,091	1,162	See note
Parallel traded	692	516	497	509	551	545	621	See note
Hospital-only (Begr)	48	93	128	148	156	195	199	See note

POM = prescription-only medicines, Begr = restricted to hospital use

[1] Note: All figures are given per Drug ID (name, pharmaceutical form and strength) as of 1 January. As for generics, figures represent generics marketed by members of the Danish Generic Medicines Industry Association (IGL), and the actual number may therefore be slightly higher.

Source: Danish pharmaceuticals database (KAT)

By the beginning of 2010 approximately 7,650 medicines, counted by different strengths and dispensing forms, were authorised in Denmark (cf. Table 2.2).

A number of medicines are not marketed in Denmark, although they have received market authorisation. The reasons for this are not always known, but in a number of cases Denmark has been the reference Member State for medicines where the market authorisation holder is not really interested in the Danish market, but only in the markets of the Member States involved in the procedure in question. This means that Denmark contributes to the availability of medicines in the European market as a whole.

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 pharmaceutical is to be subject to prescription and which dispensing group applies for the pharmaceutical (cf. the Danish Medicines Act, No. 1180 of 12 December 2005).

The dispensing group defines how to dispense a pharmaceutical 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) pharmaceuticals are set out in Medicinpriser (www.medicinpriser.dk), cf. Section 82 (1) (1) of the Danish Medicines Act, No. 1180 of 12 December 2005.

Types of 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”).

Types of Over-the-counter pharmaceuticals:

- sale restricted to pharmacies (dispensing group HA)
- Non-pharmacy restricted OTCE for human use (dispensing group Hf, Frihandel,)
- Non-pharmacy-restricted OTC for human use (maximum one pack per customer per day) dispensing group Hx, Håndkøb),

There are also a couple of veterinary categories.

Sector status

- Hospital-only medicine(s) (HOM) (cf. “Dispensing status” above).
- Pharmaceuticals to be dispensed via pharmacies and other outlets (and also used in hospitals).

The Danish Medicines Agency (DKMA) decides on the classification/legal status of authorised pharmaceuticals. Only few switches of classification are made on the initiative of the DKMA. Most switches are made upon application from the market authorisation holder. Regardless of the impetus behind the switch, the DKMA consults the Licensing Committee prior to making a decision.

2.3.1.2 Access to medicines

Table 2.3: Denmark – Number of new molecular entities, 1999-2009

New molecular entities	1999 – 2009	2004 – 2009
Number of new molecular entities	360	187

Source: Danish pharmaceuticals database (KAT)

The handling of an application for national market authorisation is divided into four phases: start-up phase, assessment phase, follow-up phase and closing phase,[13] which are displayed in detail (e.g. regarding guidelines and forms, case handling times, etc.) on the Danish Medicines Agency's (DKMA) web site.[14]

Denmark follows the specified time limits set out in the European Community legislation, i.e. the handling of an application takes a maximum of 210 days for national market authorisation. The duration for the follow-up phase for new applications is 90/60 days: 90 days for new full applications, and 60 days for abridged applications.

The handling of market authorisation cases and the case handling times have been discussed with industry branch organisations, because the Danish Medicines Agency (DKMA) has had a backlog of national applications for market authorisations. The DKMA has a contract with the Ministry of the Interior and Health (IM) that states the case handling times that must be adhered to for applications for market authorisations. Any delay in the case handling time is therefore placed in the initial validation phase i.e. prior to the four phases mentioned above. This means that once a case has been started, the case handling times are strictly followed. Delays in starting national applications are published on the DKMA web site[15] allowing each applicant to follow the proceedings of the backlog through a unique and confidential case number.

The Danish Medicines Agency's handling of applications for reimbursement for medicines depends on whether the application concerns medicines with an entirely new constituent or new pharmaceutical forms for medicines already eligible for reimbursement. The generic equivalent of a pharmaceutical already included in the positive list is automatically granted reimbursement status, as long as its price does not exceed the price of the original (brand name) product.

[13] The phases, including time limits, are illustrated graphically in http://www.dkma.dk/db/filarkiv/4817/fig1.ppt

[14] www.dkma.dk --> select Companies --> Authorisation of medicinal products

[15] http://www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=6738

The maximum case handling time is 90 days and it is calculated from the time when the marketing authorisation is available. However, this procedure means that a case can be handled by the Reimbursement Committee before a marketing authorisation is issued. The Reimbursement Committee can, if the criteria for general reimbursement are met, give an intended recommendation on the condition that the marketing authorisation is granted afterwards and that the dispense terms are not limited to hospitals.

Medicines with an entirely new constituent

All applications for general reimbursement from the National Health Service for medicines with an entirely new constituent will be presented to the Reimbursement Committee, which is the Danish Medicines Agency's medical scientific advisory body on questions regarding reimbursement for medicines. Before a case is presented, the Danish Medicines Agency makes a medical presentation – on the basis of the documentation submitted and selected parts of the Danish Medicines Agency's case on marketing authorisation. In the voting, the focus is particularly on the clinical effect in comparison with other medicines with the same or similar indication as well as on the adverse reaction profile in relation to those medicines, or possibly on comparative non-medication treatment. Furthermore, the medical voting should pinpoint the degree of any improvement of the clinical effect and/or adverse reaction profile in relation to the economic burden of the new medicine. In this context the DKMA will compare the medicines prices, cf. below. If a health economic analysis is enclosed in the application, it is assessed whether an equivalent health economic voting should be made, cf. section 3.3.5.2.

On the basis of a company's application, the medical presentation incl. price comparisons and a possible health economic assessment, the Reimbursement Committee prepares a written recommendation to the Danish Medicines Agency. If the Reimbursement Committee recommends that the medicine shall not be granted general reimbursement nor general conditional reimbursement or if the Reimbursement Committee recommends that the medicine be granted general conditional reimbursement, the Danish Medicines Agency will present the Committee's recommendation to the applicant for consultation before making a decision. Based on the recommendations of the Reimbursement Committee and the comments received from the company, the Danish Medicines Agency will make a decision which will be communicated to the company and made public.

Usually, case handling time of applications for National Health Service reimbursement for medicines with an entirely new constituent is 1-2 months.

New pharmaceutical forms for medicines already eligible for reimbursement

Applications for general reimbursement for a new pharmaceutical form but with the same method of administration (e.g. ointments/creams/liniments or tablets/capsules) are usually granted by the Danish Medicines Agency without presentation to the Reimbursement Committee in so far as the pharmacy retail price is not higher than the pharmaceutical forms eligible for reimbursement which are already marketed. Otherwise, the applicant is asked to state the reasons for the higher price.

Case handling times for such cases is approximately two weeks.

With regard to a new pharmaceutical form with another method of administration (e.g. parenteral instead of oral), the application will be presented to the Reimbursement Committee and follow the case progress for medicines with an entirely new constituent.

2.3.2 Prescriptions

Table 2.4: Denmark – Annual prescriptions 2000, 2005–2009

Prescriptions	2000	2005	2006	2007	2008	2009
No. of prescriptions (in volume) in Mio. DDD[16]	1,534.9	1,980	2,093	2,214	2,336	2,415
Prescriptions in value[17] (in NCU = Mio. DKK)	4,932.2	6,945	7,324	7,790	7,657	7,362

Prescription in volume = number of DDD prescribed.
Prescription in value = public expenditure of prescribed medicines.

Source: The Danish register of medicinal products statistics

The volume of prescription only medicines and over the counter pharmaceuticals with reimbursement, have increased on an average of 5.2%. From 2000 to 2007 the public expenditure to reimbursement increased on an average of 6.7%. The public expenditure has decreased slightly from 2007 to 2009.

2.3.3 Sales

In Denmark an increase in the sales of medicines (on average 4% annually by volume) in the primary care sector can be observed during the last decade. The sales volume of reimbursed medicines has even risen by approximately 5% each year in the same period. It is remarkable that the increase in sales almost ceased in 2007. From 2008 to 2009 a decrease in total expenditures in the primary sector was observed.

[16] The figures consist of the volume of prescription only pharmaceuticals and OTC with reimbursement.

[17] The figures consist of the reimbursement from the Danish Regions and municipalities.

Table 2.5: Denmark – Pharmaceutical sales 2000, 2005 –2009

Sales* (in Mio. DKK/ Mio. €) exchange rate 1€ = 7.45 DKK	**2000**	**2005**	**2006**	**2007**	**2008**	**2009**
Total sales*	11,625 / 1,560	16,402 / 2,202	17,551 / 2,356	19,079 / 2,561	20,144 / 2,704	20,678 / 2,776
– Sales in out-patient sector	9,405 / 1,262	12,003 / 1,611	12,474 / 1,674,4	13,264 / 1,780.4	13,427 / 1,802.2	13,427 / 1,802.2
– Sales at hospitals	2,220 / 298	4,399 / 590	5,077 / 681.5	5,815 / 780.5	6,717 / 901.6	7,292 / 978.8
Sales of parallel traded medicines in primary care sector	1,156.5 / 155.2	1,442 / 194	1,923 / 258.1	2,059 / 276.4	2,285 / 306.7	2,614 / 350.9
Sales of parallel traded medicines in hospital sector	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

n.a = not available

* Pharmaceutical sales (total sales including POM, OTC, reimbursable and non-reimbursable, etc.). Ex-factory prices are not publicly available.

Source: The Danish register of medicinal products statistics 2010

During previous years, total sales by value have increased by approximately 5% annually. The reason for a lower increase in the sales by value compared to the increase by volume is that many pharmaceutical patents have expired recently and many generics therefore have gained larger market shares and thus contributed to savings.

Hospital sales are expressed in terms of the procurement price, i.e. the hospital departments' pharmacy purchasing price including value-added tax (VAT). Calculation of these prices may vary depending on which hospital pharmacy supplies the product.

Sales of both parallel imported medicines and of generics benefit from the rules of substitution, i.e. the pharmacies are obliged to dispense the cheapest synonymous product (product with the same active substance).

The expenditure of parallel imported medicines has increased by 9.5% in average from 2000 to 2009. In 2009 the share of parallel traded medicines of the total sale in the primary sector was 12.3%. Only parallel traded medicines in the primary sector can be observed.

In hospitals, sales have also been increasing rapidly, with up to 15% growth in the years up to 2008. From 2008 to 2009 the rate of increase declined to 8.6%. The use of medicines for treatment of cancer and antineoplastic agents are rising in particular, including many new, expensive medicines. Due to the higher growth rates in hospital medicines, hospital accounts for 35% of total sales in 2009. In 2000 the share was 10%.

2.3.4 Consumption

When the total sales are compared to the total consumed volume, it is very important to emphasise that the major part of the pharmaceuticals applied in the in-patient sector do not have a DDD or similar values. For example during the recent years the cancer treatment has

been given a major priority in the in-patient sector. The expenditures to the medicines used in this treatment have increased dramatically but they have no DDD value.

Table 2.6: Denmark – Annual pharmaceutical consumption 2000, 2005–2009

Consumption	2000	2005	2006	2007	2008	2009
Total pharmaceutical consumption						
In packs/ million	70.8	91.4	96.2	88.1	89.2	88.9
In DDD/ million	2,035.7	2,364	2,478	2,612	2,736	2,817
Pharmaceutical consumption in the in-patient sector						
In packs/ million	7.6	10.0	10.3	10.7	10.9	11.4
In DDD/ million	73.7	86	89	92	94	99
Pharmaceutical consumption in the out-patient sector						
In packs/ million	63.2	81.4	85.9	77.4	78.4	77.5
In DDD/ million	1,962	2,278	2,389	2,520	2,642	2,718

DDD = Defined Daily Doses

Source: The Danish register of medicines statistics

In Denmark the consumption is measured in packs as well as in DDD. When it is measured in packs the amount of consumption is decreasing, however the pharmaceutical consumption is increasing when you express it in DDD. The consumption in hospitals is increasing as well.

From table 2.6 it can be observed that the number of packs varies more than the DDD. This is due to changes in pack sizes. Despite this a general increase of approximately 20 million packs can be observed from 2000 to the period 2005-2009. Especially the number of packs can be a relevant way to measure the consumption in the in-patient sector, as a comprehensive number of medicines consumed in the in-patient sector do not have a DDD value. The number of packs sold to the hospitals has been steady increasing during the period 2000 to 2009. This growth was 4.6% annually.

The annual consumption growth in the primary sector was 3.7%, when measured in DDD.

In May 1993 the *Register of Medicinal Product Statistics* was established as a publicly run register of pharmaceuticals statistics with a view to the drafting of statistics and price indexes as well as to monitor the consumption of pharmaceuticals and thus to strengthen the basis for the central health authorities' decisions. The Danish Medicines Agency (DKMA), hosting and being responsible for the Register, prepares a number of consumption analyses and statistics on the basis of data from the Register.

Individual consumption data are monitored via a database containing information on all sales taking place in pharmacies, administered by the DKMA. For each attendance it is recorded which medicine is handed over, including its pack size, strength and form, and further data stored include the prescribing general practitioner (GP), a personal identifier for the patient, age, sex, substitution at the pharmacy, reimbursement and payment, indication and dose.

The DKMA therefore has the possibility of monitoring prescription patterns and medicinal use in detail. Each month pharmacies, hospital pharmacies and shops authorised to sell OTC send in electronically this information on their sales. Regarding the hospital consumption, it is possible to link up pharmaceutical consumption by every department, but it is not possible to link up pharmaceutical consumption with the patient.

To promote more rational use of medicines, the general practitioner (GP) can follow her/his own prescription pattern in ORDIPAX,[18] a web-based, cost-free statistics programme provided by DKMA. All doctors can compare their own prescribing habits with those of their colleagues in the region. In addition, the regional health care authorities have access to ORDIPAX, with a view to – in cooperation with the GP – defining those therapeutic areas where enhanced efforts to promote more rational prescribing may be needed.

All retailers and pharmacies are obliged by law to report their sales to the Register of Medical Products managed by the Danish Medicines Agency**.**

Detailed statistics describing consumption of medicines in Denmark (Anatomic Therapeutic Chemical (ATC), age, sex, region, number of people treated, volume and expenses) are available online (http://www.medstat.dk). Consumption of medicines sold on the Internet is not monitored systematically.

2.3.5 Generics

Table 2.7: Denmark – Development of the generic shares 2000, 2005–2009

Generic share	Volume			Value		
	2005	**2007**	**2009**	**2005**	**2007**	**2009**
Shares in % of total market (in-patient/ out-patient)	25,6	30,7	36,7	9,0	9,6	8,5
Shares in % of total out-patient market	25,6	30,7	36,6	9,0	9,6	8,5
Shares in % of out-patient reimbursement market	28,7	35,0	45,5	11,3	13,5	12,8
Shares in % of out-patient off-patent market	68,3	72,7	73,7	69,2	73,2	67,4
Shares in % of the in-patient market	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

n.a. = not available

[1] Expressed in number of prescriptions

[2] Expressed in expenditure

Source: The Danish register of medicinal products statistics 2010

[18] http://www.ordiprax.dk

The use of generics is regulated in the Executive Order on Prescriptions, No. 155 of 20 February 2007. Generics are mainly used as a cost-containment tool and play an important role in the current reimbursement system

Generics are priced according to the same rules as all other medicines. However, they play a major role in the reference price system. In Denmark a reference price system was introduced in 1993 as a result of a parliamentary decision. The system is run by the Danish Medicines Agency (DKMA) and the legal framework is the Danish Health Act, No. 546 of 24 June 2005. The reference price system is closely related to (and based on) the generic substitution scheme – for reimbursable medicines the reimbursement groups are identical to the substitution groups.

If the doctor prescribes a product belonging to a reference price group other than the cheapest one and at the same time forbids generic substitution, the patient will have to pay the difference in prices between the cheapest available medicine and the one prescribed, on top of the regular co-payment. This also applies to situations where the patient opts for a more expensive product than the cheapest one at her/his own will (cf. section 3.2.3).

2.3.6 Top 10 medicines

In the out-patient sector the most consumed medicine in 2009 was the active substance simvastatin and the expenditure on paracetamol was the largest, while in the in-patient sector paracetamol was the most consumed medicine, and the largest expenditure was made on adalimumab cf. tables 2.8 and 2.9.

Table 2.8: Denmark – Top 10 active ingredients in value and volume in the out-patient sector, 2009

Position	Top active ingredients used in the out-patient sector, ranked with regard to consumption		Position	Top active ingredients used in the out-patient sector, ranked with regard to expenditure	
1	C10AA01	Simvastatin	1	N02BE01	Paracetamol
2	B01AC06	Acetylsalicylic acid	2	R03AK07	Formoterol+budesonid
3	N02BE01	Paracetamol	3	N07BA01	Nicotin
4	C08CA01	Amlodipin	4	J07BM01	Pampillomavirus
5	C03CA01	Furosemid	5	N05AH03	Olanzapin
6	C03AB01	Bendroflumethiaz.+Kal.	6	R03BB04	Tiotropiumbromid
7	C09AA02	Enalapril	7	A02BC05	Esomeprazol
8	C09AA05	Ramipril	8	R03AK06	Salmeterol+fluticason
9	N06AB04	Citalopram	9	N05AH04	Quetiapin
10	G03AA10	Gestoden and estrogen	10	N02AA05	Oxycodon

Source: The Danish register of medicinal products statistics 2010

Table 2.9: Denmark – Top 10 active ingredients in value and volume in the in-patient sector, 2009

Position	Top active ingredients used in the in-patient sector, ranked with regard to consumption		Position	Top active ingredients used in the in-patient sector, ranked with regard to expenditure	
1	N02BE01	Paracetamol	1	L04AB04	Adalimumab
2	H02AB02	Prednisolon	2	L04AB02	Infliximab
3	C03CA01	Furosemid	3	L03AB07	Interferon beta-1a
4	L02BB03	Bicalutamid	4	L04AB01	Etanercept
5	A11DA01	Thiamin (Vitamin B)	5	B02BD02	Coagulation Factor VIII
6	L02BG04	Letrozol	6	S01LA04	Ranibizumab
7	M05BA06	Ibandronsyre	7	H01AC01	Somatropin
8	L02AE03	Goserelin	8	L04AA23	Natalizumab
9	B01AC06	Acetylsalicyl acid	9	L02BG04	Letrozol
10	L03AB07	Interferon beta-1a	10	J01DH02	Meropenem

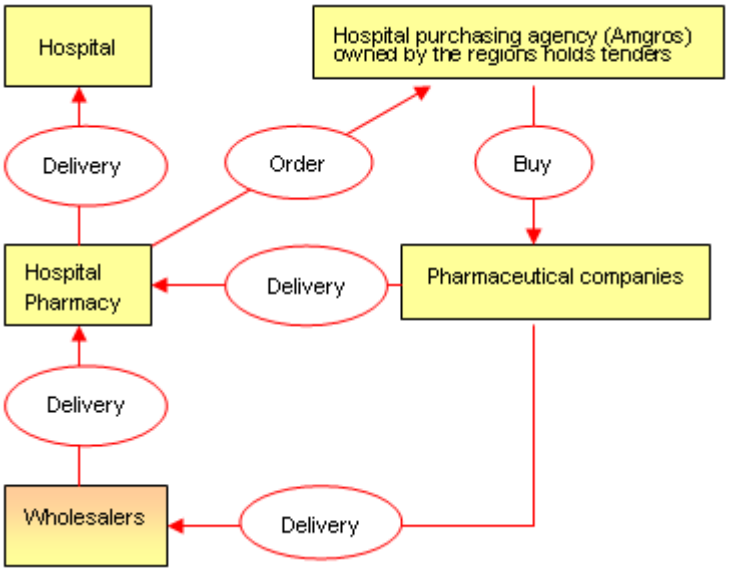
Note: Only pharmaceuticals with DDD values are included

Source: The Danish register of medicinal products statistics 2010

2.4 Market players

This section gives an overview of the key players in production, distribution and dispensing of medicines in 2010.

Figure 2.2: Flowchart, hospital delivery chain, 2010



Source: PHIS Hospital Pharma report Denmark (the figure is modified) 2009

The flowchart above describes the delivery process in Danish hospitals. The delivery chain of the out-patient sector is provided in section 2.1.

2.4.1 Industry

The pharmaceutical industry is a significant sector in the Danish economy. In 2008, pharmaceutical production amounted to € 5,551 Mio. (Efpia 2010). In 2005 264 companies – of which 189 were manufacturers and 10 parallel importers – supplied medicines in Denmark. The total export of pharmaceutical products in 2008 was DKK 41.1 billion (€ 5.5 billion) corresponding to 90% of the pharmaceutical production (Lif 2011a[19]).

The leading manufacturers in Denmark are Pfizer Ltd., Nycomed Danmark Ltd., GlaxoSmithKline Pharma Ltd. and AstraZeneca Ltd. In 2006 the parallel importer Orifarm had the largest sales among all pharmaceutical companies.[20]

In 2008, 17,019 people were directly or indirectly employed in the Danish pharmaceutical industry. The number includes people employed in the production of raw materials, production of pharmaceuticals, and wholesale (Lif 2011a).

Associations

Danish original manufacturers and other research-oriented pharmaceutical companies are organised in the Danish Association of the Pharmaceutical Industry (Lægemiddelindustriforeningen, Lif). Lif is an association of 37 member companies which represented 65% of the sales of pharmaceuticals in Denmark in 2010 (Lif 2011a). The majority of industrial medical research in Denmark is carried out by Lif-members.

The Danish Generic Medicines Industry Association (Industriforeningen for Generiske Lægemidler, IGL) is a trade association that was founded in 2002. In 2010 the association comprises 14 member companies, which are all engaged in the sale and marketing of generic medicines for the Danish market. Some of the companies manufacture generic medicines as well (IGL 2010[21]).

Medicines imported in parallel have played a role in Denmark since about 1990. Four parallel importers are members of the Danish Association of Parallel Importers of Pharmaceuticals (Parallelimportørforeningen af Lægemidler, PFL). Sales of parallel imported products in the primary care sector amounted to approximately 8% in volume and 20% in value in 2009[22].

The Ministry and the DKMA use the Lif, IGL and PFL as experts and advisory bodies for the authorities in matters related to the industry. They are sometimes represented in official committees and working parties. The industry is consulted by the Ministry of the Interior and

[19] www.Lifdk.dk (Jan 2011)

[20] www.Lifdk.dk. (2007)

[21] www.igl.dk (Dec 2010)

[22] www.medstat.dk

Health) and the DKMA in connection with preparing new bills and governing orders that affect the industry.

Licence

Not every company licensed to carry out pharmaceutical activities (i.e. manufacture, import, export, packaging, etc.) related to medicines is a member of the Lif, the IGL or the PFL. In 2007, 208 companies were authorised (and inspected by the DKMA) to carry out pharmaceutical activities (pharmacies and wholesalers excluded).

Usually, products are distributed by wholesalers, but tendering and procurement of medicines for the hospitals are largely managed by the purchasing partnership Amgros (cf. 4.1.1.1) owned by the five regions.

Table 2.10: Denmark – Key data on the pharmaceutical industry 2000, 2005–2010

Pharmaceutical industry	2000	2005	2006	2007	2008	2009	2010
Total number of companies	196	189	n.a.	166	n.a.	n.a.	208
– research-oriented	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
– generic producers	n.a	n.a	n.a	n.a	n.a	n.a	n.a.
– biotech	n.a	n.a	n.a	n.a	n.a	n.a	n.a.
Number of persons employed[1]	15,171	n.a	17,286	16,827	17,019	n.a.	n.a.

n.a. = not available

Data as of 1 January

[1] counted per head

Sources: PPRI report Denmark 2008, Efpia 2010, Efpia 2009

2.4.2 Wholesalers

The Danish wholesale activity is a multi-channel system. In Denmark two major full-line wholesale companies, Nomeco Ltd and Tjellesen Max Jenne, are authorised to distribute medicines to private pharmacies and hospital pharmacies. The full-line wholesale companies supply all medicines and other items which are demanded by pharmacies and hospitals from a range of 6,720 human medicines, of which 6,000 are prescription-only medicine(s) (POM).

Nomeco is the largest company with 570 employees. Most Danish pharmacies are customers of this wholesaler, and approximately half of them receive their supplies solely from Nomeco. Since 1998 Nomeco has been a fully owned subsidiary of the Finnish company Tamro, which is the largest distributor of medicines in the Nordic countries, Poland and the Baltic countries. Tamro is part of the German Phoenix Group – the second largest wholesaler in Europe.

Table 2.11: Denmark – Key data on pharmaceutical wholesale 2000, 2005–2010

Wholesalers	2000	2005	2006	2007	2008	2009	2010
Total number of full-line wholesale	3	3	3	3	3	2	2
Total number of importers	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total number of outlets[1]	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

Data as of 1 January

[1] 15 in 2007 (DKMA). Includes only outlets of the three major full-line wholesalers

Source: PPRI Pharma Report Denmark 2008

K.V. Tjellesen has 165 employees and an annual turnover of more than DKK 3 billion (more than € 402 Mio.)[19]. The annual turnover of Max Jenne is more than DKK 1 billion (more than € 114 Mio.) and the number of employees is 115 (Max Jenne 2007[23]). Since 2006, K.V. Tjellesen and Max Jenne have both became part of the Celesio Group (Celesio AG), the largest pharmaceutical wholesaler in Europe in June 2006. Since then the two companies have worked under joint management, but on 1 July 2009 the two companies merged to one company under the name Tjellesen Max Jenne A/S[24].

The two wholesalers are members of Megros, the Association of Pharmaceutical Wholesalers. The Ministry of the Interior and Health (IM) and the DKMA consult with Megros when preparing new bills and governing orders which affect wholesaler activity and Megros may also be represented in official committees and working parties.

Besides the two major suppliers, about 250 companies are licensed and inspected by the DKMA 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.

2.4.3 Retailers

As a rule, medicines may only be sold in pharmacies, including branches of pharmacies and licensed shops. However, some medicines may be sold in other shops. This applies to, e.g., herbal pharmaceuticals and vitamin and mineral preparations, which can be sold in any shop, and a number of over-the-counter (OTC) products, which can be sold in OTC sales outlets and in shops, providing that they have obtained authorisation from the Danish Medicines Agency (DKMA).

[23] www.maxjenne.dk (May 2007)

[24] www.Tjellesen.dk (Dec 2010)

Pharmacies and branch pharmacies have the monopoly on the sale of prescription-only medicine(s) (POM) to consumers. Similarly, there is a long list of non-prescription medicines which may only be sold in pharmacies.

At the end of 2010 there were approximately 247 pharmacies in total. In addition, there were approximately 69 branches of pharmacies, 127 pharmacy shops and almost 626 OTC sales outlets, which are all affiliated to a pharmacy. A branch pharmacy is attached to a pharmacy, is operated at the pharmacy's expense and has professional staff. A pharmacy shop is attached to a pharmacy and has qualified staff but no pharmacists. A pharmacy shop is not allowed to dispense POM.

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

2.4.3.1 Community pharmacies

The Ministry of the Interior- and Health (IM) and the Medicines Agency (DKMA) control and administer the pharmacy sector through a licensing system. At the same time it is a liberal profession, and the proprietor pharmacist owns his/her pharmacy. This means that the proprietor pharmacist is economically responsible for the financing of the pharmacy and its operation. The authorities determine the number of pharmacies and branch pharmacies as well as their location. The pharmacy structure is thus continuously evaluated.

In order to become a proprietor pharmacist a licence must be obtained from the IM, who also appoints new proprietor pharmacists. The Ministry advertises a pharmacy licence when it becomes vacant. This will typically be when the present proprietor pharmacist retires. Interested pharmacists may then apply for the licence. In order to be considered, the applicant must be versed in the operation and financial management of pharmacies, have managerial experience and possess the appropriate professional qualifications. (www.apotekerforeningen.dk)

The Minister of Health makes decisions on the establishment, closure and moving of pharmacies and branches of pharmacies. A pharmacy may be closed if

- The pharmacy license expires, is cancelled or withdrawn
- The proprietor pharmacists consents to the closure, or if
- The proprietor pharmacist is offered a license to another pharmacy within the same region

A pharmacy may also be closed if significant structural considerations speak in favour hereof and if a period of minimum 5 years has elapsed since the proprietor pharmacist was granted the license.

When a pharmacy or branch of pharmacy is established or moved, the Minister of the Interior and Health defines the area in which the pharmacy or branch of pharmacy shall be located. If no location has been specified for a pharmacy or branch of pharmacy, the Minister of Health and Prevention specifies such upon request from the proprietor pharmacist.

Community pharmacies may sell medicines, both prescription-only medicine(s) (POM) and over-the-counter (OTC), through the Internet as well.[25] However, legislation does not allow for strictly web-based pharmacies, i.e. distribution via the Internet alone.

Table 2.12: Denmark – Retailers of medicines 2000, 2005–2010

Retailers	2000	2005	2006	2007	2008	2009	2010
No. of community pharmacies[1]	330	318	322	322	320	318	316
– *Thereof: No. of private pharmacies*	330	318	322	322	320	318	316
–*Thereof: No. of public pharmacies*	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
– *Thereof: No. of hospital pharmacies for out-patients*	0	0	0	0	0	0	0
–*Thereof: No. of dispensing doctors*	n.a.	0	0	0	0	0	0
–*Thereof: No. of other POM disp., please specify*	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
Total no. of POM dispensaries	330	318	322	322	320	318	316
No. of internet pharmacies	0	0	0	0	0	0	0
No. of OTC disp., like drugstores	882	2,030	700	1,450	1,686	1,851	2,125

Disp. = dispensaries, No. = number, OTC = over-the-counter medicines, POM = prescription-only medicines, n.app. = not applicable, POM dispensaries are facilities that are allowed to sell POM to out-patients (PHIS Glossary).

Data as of 1 January

[1] The figures include pharmacies and branch pharmacies.

Source: DKMA 2010a

Pharmacists and pharmaco-economists are a main part of pharmacy staff. Apart from selling medicines, pharmacies are able to answer the majority of questions concerning medicines and their use.

Pharmacists authorised to run a pharmacy are organised in the Danish Pharmaceutical Association (Danmarks Apotekerforening, DA[26]). The IM and the DKMA use the Danish

[25] Examples are http://www.dit-apotek.dk , http://www.apoteket.dk or http://www.farmacy.dk

Pharmaceutical Association (DA) as experts and advisory bodies for the authorities in matters related to the pharmacies. The DA is also represented in official committees and working parties when relevant. The DA is consulted in connection with preparing new bills and governing orders that affect the pharmacy sector as well.

On average there are approximately 15,000 inhabitants per unit dispensing prescriptions (i.e. pharmacies and branch pharmacies) in Denmark. However, the customer base fluctuates throughout the country.

2.4.3.2 Dispensing doctors

In special cases and under special conditions the Danish Medicines Agency (DKMA) can authorise a doctor to dispense medicines and other goods bought at a named pharmacy to her/his patients (according to the Pharmacy Act). Since 2001 no doctor in Denmark has been authorised to dispense medicines and the last authorisation of this type expired in 2002.

2.4.3.3 Hospital pharmacies

In Denmark not every hospital has its own pharmacy, after a merging process starting in 2007 currently 12 hospital pharmacies are remaining. 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. Private hospital pharmacies can be established, by the Danish Medicines Agency's consent, by proprietors of private hospitals.

The twelve hospital pharmacies in Denmark differ a great deal in size. The largest hospital pharmacy is Region Hovedstadens Apotek with 480 employees[27], and one of the smallest hospital pharmacies – Sygehusapoteket Sydvestjysk Sygehus - has 17 employees[28].

However, they all deal with distribution and clinical pharmacy, and most of them maintain a service production of total parenteral 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.

All public hospital pharmacies order and buy medicines via 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. The deliveries of the medicines are done only by the wholesalers.

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[26] http://www.apotekerforeningen.dk

[27] www.regionsapoteket.dk

[28] www.sydvestjysksygehus.dk

The hospital pharmacies deliver medicines via hospital out-patient departments to a number of out-patients free-of-charge. Nevertheless, hospital pharmacies are not allowed to dispense to out-patients directly. A hospital pharmacy belonging to a regional authority is able to supply medicines and other products to the regional authority's hospitals and maternity homes and other medical institutions. Some of the hospital pharmacies' own production is sold to the other hospital pharmacies if there is a surplus in production.

2.4.3.4 Other POM dispensaries

Over-the-counter (OTC) outlets are points of sale for pharmacies organised in another shop, often a supermarket. These OTC outlets are allowed to deliver prescription-only medicine(s) (POMs) that have been dispatched by a pharmacy to the outlet.

As a rule, personnel employed at OTC outlets are not educated within the pharmacy profession. Furthermore, there are a number of delivery facilities which do not stock medicines but only receive addressed dispatches from one or several pharmacies and pass them on to the individual customer.

2.4.3.5 Other retailers

In Denmark, shops outside the pharmacy sector can obtain authorisation to sell OTC medicines suitable for sale outside pharmacies. It is the DKMA who decides whether a medicine can be sold at these so-called authorised sales outlets.

The shops must, at the minimum, keep a basic range of OTC, which is defined by the Danish Medicines Agency. The basic range of OTC includes products such as pain-relievers, cough suppressants, lozenges for a sore throat as well as nicotine chewing gums.

On 15 October 2006, it became possible for shops to obtain a distributor's authorisation exclusively covering smoking cessation products. Shops holding such an authorisation do not keep the entire basic range of OTCs.

The staff employed at authorised sales outlets are not required to have a pharmaceutical education. About 1,400 shops/companies are authorised to sell OTC products for humans, many of them are also authorised to sell OTC medicines for animals.

2.4.4 Promotion

Advertising of medicines to the general public and health professionals is regulated by the Danish Medicines Act,[29] the Executive Order on Advertising, etc., of Pharmaceuticals[30] and the Executive Order on Distribution of Free Samples of Medicinal Products,[31] which is in line with Directive 2001/83/EC. The Ministry of the Interior and Health (IM) and the Danish Medicines Agency (DKMA) are the competent authorities in charge of supervising pharmaceutical advertising activities.

The market authorisation holder or her/his representative must keep records of the number of samples supplied of each medicine. The records must be kept for at least two years and are to be available for inspection by the DKMA. Samples of medicines are only to be used by the physicians, dentists or veterinarians for treatment carried out in their professional practice.

There is no budget ceiling or special taxes on promotional spending of manufacturers. The DKMA is in charge of the monitoring of sales promotion material sent to doctors and advertisements in journals, etc.

Advertising - POM and OTC

Advertising of a medicine is to be adequate and objective and it shall not mislead or exaggerate the characteristics of the product. The advertising information must also be in accordance with the authorised summary of product characteristics.[32] These are the basic rules on advertising of medicines. There are supplementary rules on advertising to the general public and to health professionals in the Executive Order on Advertising, etc., of Pharmaceuticals.

Advertising in a media available to the general public is not allowed for prescription-only medicine(s) (POM), but companies may provide patients with product-specific information if this is personally requested by the patients or delivered by doctors or pharmacies directly to the patients (when prescribing or delivering a POM to a patient). Advertising on the Internet for POM is not allowed unless it is on a special site for health professionals.

Over-the-counter (OTC) advertising is allowed in all media. Advertising of medicines on the Internet is also allowed. It is considered to be advertising to the general public, unless it is on a special site for health professionals (i.e. doctors, dentists, veterinarians, nurses, veterinary nurses, pharmacists, pharmaco-economists or students within one of those fields) and entrance to the site is controlled by user identification and password.

Information towards doctors

[29] Act No. 1180 of 12 December 2005, as last amended by Act No. 1557 20 December 2006

[30] Executive Order No. 272 of 21 March 2007, as amended by Executive Order No. 393 of 27 April 2007

[31] Executive Order No. 1244 of 12 December 2005

[32] The Medicines Act, section 63.

Medicines sales representatives visiting doctors and pharmacies must undergo suitable training and possess sufficient specialist knowledge to enable them to provide precise and adequate information about the medicines they present. Medicines sales representatives are to place at the disposal of the people they visit the summary of product characteristics approved by the Danish Medicines Agency (DKMA) for each medicine presented, together with information on prices and reimbursement provisions.

Any documentation sent or supplied for promotional purposes to health professionals concerning a medicine must at least include information on the name of the product and common name, the name of the market authorisation holder, indications, contraindications, side-effects and hazards, dose, dosage forms, pack sizes, price and date, dispensing status and reimbursement provisions. All the information contained in the documentation shall be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form an opinion of the therapeutic value of the medicine concerned. Quotations, tables and illustrations taken from medical journals or other scientific works or similar sources and used in the documentation shall be faithfully reproduced and the precise source indicated. Infringement of these demands can be punished by means of a fine.

Sample restrictions

There are several restrictions on sending medical samples to doctors in Denmark. The rules are set out in Executive Order No. 1244 of 12 December 2005 on Distribution of Samples of Medicinal Products. Free samples of medicines are to be distributed under the conditions listed here.

- Samples of medicines shall be distributed only to physicians, dentists and veterinarians, and only in so far as the people concerned are qualified to prescribe the medicine and are permitted to use the product in their respective professions.
- Only one sample of each medicine shall be distributed each year to each physician, dentist or veterinarian. Where the medicine is available in more than one form or strength, one sample of each form and strength can be distributed.
- Each sample shall be identical with the smallest presentation on the market.
- The packaging shall be marked “Free Pharmaceutical Sample – Not for Sale”.
- Samples of medicines shall be distributed only in response to a written, signed and dated request from the recipient.
- Samples of medicines shall be distributed only by the market authorisation holder or her/his representative. Samples shall not be distributed from a pharmacy.
- Each sample shall be accompanied by the relevant summary of product characteristics.
- No samples of medicines listed in the Euphoriant Substances Act must be distributed.

Information to Patients

Patients are mostly informed by packaging inserts, by their doctors and by pharmacists. Regarding specific medicines, therapeutic groups and diseases, other pharmaceutical information is in the hands of Danish Drug Information Ltd. (DLI), which issues a pharmaceutical information handbook for patients, “Medicinhåndbogen” (Handbook of Pharmaceuticals), presenting in an easy-to-understand way a complete description of all medicines approved by the DKMA. “Medicinhåndbogen” was first published in 1985 and is now also available online.[33] It is sold from pharmacies. DLI is a private company owned by the Danish Association of the Pharmaceutical Industry (Lif).

The Institute for Rational Pharmacotherapy (IRF) hosts a web site for patients, “Medicin med fornuft”, similar to its home page for professionals,[34] providing a large amount of information on rational use of medicines. In a wider sense, the DKMA provides much web-based information to patients, e.g. on side-effects, safety, prices, reimbursement, generic substitution, counterfeit medicines, etc.[35] A National Drug Interactions Database was launched in April 2007.[36]

Many hospitals use written information based on the Handbook of Pharmaceuticals mentioned earlier.

2.5 Funding

This section provides an overview of the funding of medicines.

2.5.1 Pharmaceutical expenditure

From 2000 to 2007 the expenditures in the primary sector were steadily rising with approximately 2.1% yearly. To limit the public expenditures to reimbursement the Ministry of the Interior and Health (IM) and The Danish Association of the Pharmaceutical Industry (Lif) entered into a price agreement in 2006 which entailed a ceiling on prices. The agreement was prolonged with some modifications in 2009 and is valid until ultimo 2011. This agreement is along with the rules of generic substitution a part of the reason why there has been a curb in expenditures from 2008 to 2009.

[33] http://194.255.125.53/servlet/osp/substancelist?substancetype=medicine

[34] www.medicinmedfornuft.dk

[35] http://www.dkma.dk/1024/visUKLSArtikelBred.asp?artikelID=750

[36] http://www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=6504

Table 2.13: Denmark – Total pharmaceutical expenditure 2000, 2005–2009

Pharmaceutical expenditure[1] (in million DKK)	2000	2005	2006	2007	2008	2009
TPE	13,818	16,401	17,551	19,079	20,144	20,678
–thereof public	7,181	11,387	12,451	13,661	14,433	14,721
–thereof private	6,637	5,014	5,100	5,418	5,711	5,957
PE in the out-patient sector	11,598	12,003	12,474	13,264	13,427	13,386
–thereof public	4,962	6,989	7,374	7,851	7,719	7,429
–thereof private	6,636.3	5,014	5,100	5,413	5,708	5,957
PE in the in-patient sector	n,a,	n,a,	n,a,	n,a,	n,a,	n,a,
–thereof public	2,220	4,398	5,077	5,815	6,717	7,292
–thereof private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

NCU = national currency unit, PE = pharmaceutical expenditure, TPE = total pharmaceutical expenditure, DKK = Danish Kroner, PE = pharmaceutical expenditure, TPE = total pharmaceutical expenditure, n.a. = not available,
Note: Data are indicated as of 31 December.

1 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.

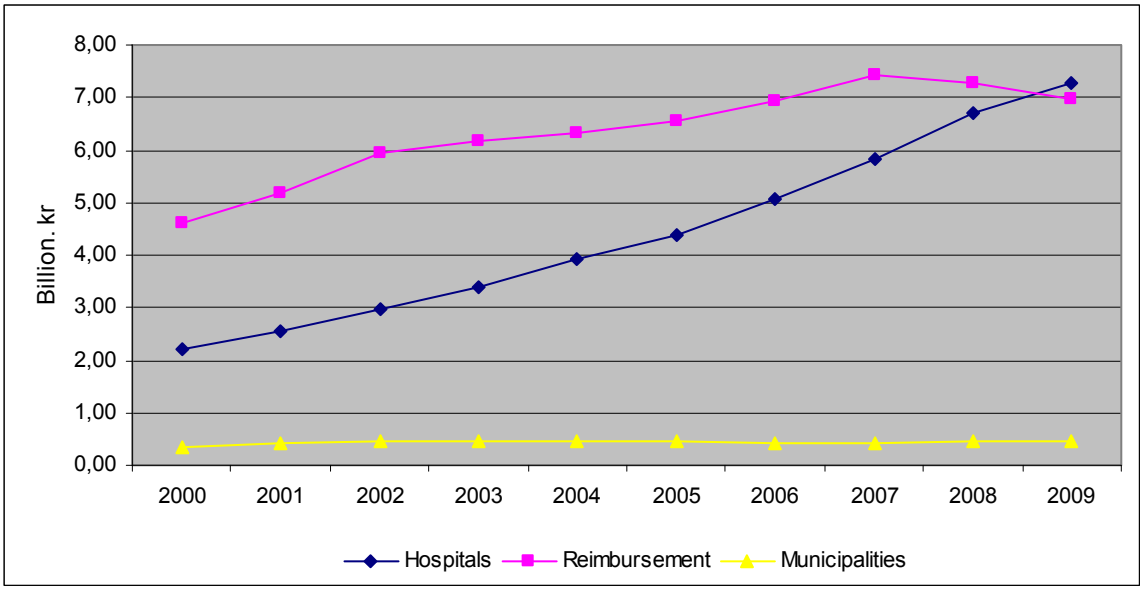
Data as of 31 December

Source: PHIS Hospital Pharma Report Denmark 2009

Pharmaceutical expenditures in the hospital sector have increased dramatically during the period 2000 to 2009. The annual average growth amounted to 14%. This is mainly caused by an intensified cancer treatment and the introduction of newer biological medicines and was the cause for a price agreement in the in-patient sector in 2009. The agreement was interred by the same parties (i.e. IM and Lif) as in 2006.

In 2009 the in-patient sector for the first time accounted for the largest amount of total public expenditures. These include of the expenses to reimbursement, hospitals and the municipalities expenditures. The development can be observed in figure 2.3.The total pharmaceutical expenditure as part of the health expenditure is 8,6% (OECD 2009). The total public pharmaceutical expenditure (PE) (in-patient and out-patient sector) is growing. The public share in the primary care sector (“regional” according to the predominant reimbursement scheme) depends on each person’s individual expenses on medicines, i.e. the higher a person’s expenditure, the higher the share of public funding. As increasingly more people are treated with a growing number of medicines, the public share is growing in the primary care sector. A minor part of public pharmaceutical expenditure (PE) is provided by the municipalities.

Figure 2.3: Denmark – Public pharmaceutical expenditures, 2000 - 2009



Source: The Danish register of medicinal products statistics 2010

2.5.2 Sources of funds

In hospitals, all expenditure on medicines is paid by the regions (tax financed).

In the primary health care sector more than half of the expenses is financed by the regional health insurance (tax financed), and approximately 4% is financed by the local community (mainly reimbursement paid to senior citizens or “economically weak” persons).

A total of 40% of the expenditure is paid by the patients themselves (= out-of-pocket payments (OPP)). These figures include self-payment of non-reimbursed prescription medicines and over-the-counter (OTC) medicines. However, some people have taken out supplementary private insurance. A part of the OPP will be covered by this insurance – in 2005 this amounted to approximately 14% (cf. section 1.3.2).

In 2010 16% of the total expenditure on medicines in the primary care sector was spent on over-the-counter (OTC) and 8% of the expenditure was for non-reimbursed prescription-only medicine(s) (POM).

3 Pricing, reimbursement and volume control in the out-patient sector

This chapter gives an overview of the pricing and reimbursement system as well as volume control mechanisms in the out-patient sector.

3.1 Pricing in the out-patient sector

3.1.1 Organisation of pricing

Medicines are freely priced at both manufacturer and wholesale levels in Denmark.[37] The basic pricing system (free pricing) has existed in Denmark for over 40 years but has been administered by the Danish Medicines Agency (DKMA) since 1994. Over the years there have been certain interventions, including periodic price freezes, pricing agreements, etc. (cf. section 3.1.3.6).

Pharmaceutical companies are obliged to report their pharmacy purchasing prices for all medicines on the market to the DKMA.[38] The DKMA then calculates the pharmacy retail price (PRP) via a statutory mark-up scheme (cf. section 3.1.5 for details) along with – for all substitutable and reimbursable products – the reimbursement price. The price list is distributed to all pharmacies and prices are the same all over the country, with minor exceptions. Pharmacy retail prices (PRP) are also published on the Internet.[39]

Product prices can be altered every two weeks when a new official price list is drawn up by the DKMA (reimbursement prices are recalculated daily within that period, however, due to lack of delivery of the cheapest products in the groups (cf. section 3.2.3 for details regarding the existing reference price system)). Consequently, in Denmark there is no such thing as pricing criteria or a set of authorities in charge of pricing decisions. However, the Competition Council is in charge of monitoring the prices of all products, including medicines.

Reimbursement decisions are based, among other things, on price meaning that the company has to set the price of a given medicine before applying for reimbursement. Both reimbursement and pricing are managed by the DKMA.

These rules cover all medicines (prescription-only medicine(s) (POM), OTC, generics, parallel imports, etc.) for which the distribution is limited to pharmacies. One exception is that certain OTC sold outside pharmacies (dispensing groups Hf and Hx) are also freely priced at

[37] However, prices of reimbursable off-patent pharmaceuticals may indirectly be influenced through the reim bursement price. Pharmaceutical companies wishing to enter their products into the reimbursement system have to apply for reimbursement at the Danish Medicines Agency (DKMA).

[38] Technically they only report new/altered prices.

[39] Cf. www.medicinpriser.dk (including English version)

retail level, and are thus subject to local competition. Consequently, the pharmacy retail price of such OTC may vary throughout the country and the DKMA is not notified of these prices.

Price information is publicly available on www.medicinpriser.dk. This website is always up to date. Only the prices of pharmaceuticals with dispensing groups Hf and Hx are not available.

3.1.2 Pricing policies

Table 3.1: Denmark – Ways of pricing of medicines, 2010

	Manufacturer level	Wholesale level	Pharmacy level
Free pricing	Free pricing for all products set by the manufacturer/ importer, cf. below Public procurement for all medicines *used* in hospitals (not only HOM but also for others)		Free pricing for certain OTC medicines which are not limited to distribution from pharmacies
Statutory pricing	Not applied		POM and those OTC medicines limited to pharmacy distribution are subject to a linear mark-up scheme[40]
Price negotiations	Manufacturers/ importers and wholesalers negotiate their share of the pharmacy purchasing price (which is set by the manufacturer/importer, cf. above).		Not applied
Discounts / rebates	N.a.	Cost-related discounts to retailers possible, cf. 3.1.4	1.72% in 2005, 2006, 2007, 2008 and 2009 to the NHS
Public procurement	➢ Mainly relevant for products used in hospitals (performed by AMGROS) ➢ Not relevant in out-patient sector, except for vaccines and certain blood products		
Institution in charge of pricing	➢ Hospital Purchasing Agency Amgros ➢ IM for pharmacy mark-up scheme ➢ (DKMA on behalf of IM for reimbursement price, cf. 3.2.1)		
Legal basis	➢ The Danish Medicines Act No. 1180 of 12 December 2005 ➢ The Danish Pharmacy Act, cf. Consolidated Act No. 657 of 28 July 1995 ➢ Executive Order No. 270 of 21 March 2007 on the Calculation of Consumer Prices of Medicinal Products ➢ Executive Order No. 272 of 21 March 2007 on Advertising, etc., of Pharmaceuticals		

DKMA = Danish Medicines Agency, HOM = hospital-only medicine(s), IM = Ministry of the Interior and Health, POM = prescription-only medicine(s), OTC = over-the-counter (medicines), NHS = National Health Service

Source: PPRI Pharma Profile Denmark 2008

[40] The total profits for all pharmacies are negotiated between the Ministry of the Interior and Health (IM) and the Danish Pharmaceutical Association (DA) every two years, and the mark-up is regulated by the Ministry during that period in order to ensure that the agreed profit level is obtained.

3.1.2.1 Statutory pricing

Statutory pricing is not applied in Denmark, with the exception of pharmacy mark-ups. To obtain the PRP, the Danish Medicines Agency DKMA adds the pharmacy mark-up (cf. section 3.1.5.2). As indicated in the rules set out in Executive Order No. 270 of 21 March 2007 on the Calculation of Consumer Prices of Medicinal Products.

Generics and parallel traded medicines are priced according to the same rules as all other medicines. However, they play a major role in the reference price system (cf. section 3.2.3 and 3.3.2).

3.1.2.2 Negotiations

Manufacturers/importers and wholesalers negotiate their share of the pharmacy purchasing price (which is set by the manufacturer/importer) (cf. section 3.1.5.1).

3.1.2.3 Free pricing

In principle, all pharmaceuticals (prescription-only medicine(s) (POM) and over-the-counter (OTC)) may be freely priced by manufacturers/importers. Anyone who markets a POM on the Danish market must notify the Danish Medicines Agency (DKMA) of the pharmacy purchasing price and of any changes to that price, per pack size, no later than 14 days prior to the price coming into force (Danish Medicines Act, No. 1180 of 12 December 2007).

To obtain the PRP, the DKMA adds the pharmacy mark-up, as indicated in the rules set out in Executive Order No. 270 of 21 March 2007 on the Calculation of Consumer Prices of Medicinal Products. However, the price setting of manufacturers/importers and wholesalers may be influenced by the reimbursement system, e.g. in the event that the product falls under the reference price system.

Since October 2001 a selected range of OTC medicines – dispensing groups Hf and Hx – may also be sold by gas stations, supermarkets and cafés provided they have obtained a licence from the DKMA. These OTC products are subject to completely free pricing at all levels, which means that the pharmacy retail price may differ between the distributors and throughout the country.

Generics and parallel traded medicines are priced according to the same rules as all other medicines.

3.1.2.4 Tendering

Tendering is not used for pharmaceuticals in the out-patient sector. Tendering is used for most of the pharmaceuticals used in hospitals. It is carried out by AMGROS, which is a hospital purchasing agency owned by the five regions, i.e. the owners of public hospitals in Denmark.

3.1.2.5 Others

There are no other pricing policies in the out-patient sector.

3.1.3 Pricing procedures

Table 3.2: Denmark – Pricing procedures, 2010

Pricing procedure	In use: yes / no	Price type[1]	Scope[2]
External price referencing	No	Not applicable	Not applicable
Internal price referencing	Yes	Reimbursement prices at pharmacy level	All medicines being part of a substitution group
Cost-plus pricing	No	Not applicable	Not applicable
Indirect profit control	Yes	Pharmacy retail price	Pharmacy profits are regulated by the mark-up scheme

[1] Price type = the level (manufacturer, pharmacy purchasing, pharmacy retail) at which the price is set.

[2] Scope = a pricing procedure does not always refer to all medicines: e.g. a pricing procedure could only refer to reimbursable medicines, whereas for Over-The-Counter medicines there is free pricing.

In Denmark medicines are freely priced, but reimbursement and pharmacy profits are regulated. For reimbursable medicines that can be substituted in pharmacies (generic substitution, cf. section 3.3.2.1), reimbursement is calculated from the lowest price of the substitution group, i.e. the reimbursement price.[41] Pharmacy profits are, as mentioned earlier, regulated by the mark-up scheme set out in Executive Order, No. 270 of 21 March 2007 on the Calculation of Consumer Prices of Medicinal Products, which is subject to amendment by the Minister of the Interior and Health. Manufacturer and wholesale profits are not regulated.

3.1.3.1 External price referencing

External price reference is not in use in Denmark.

3.1.3.2 Internal price referencing

Internal price referencing is used in a reimbursement context to determine the reimbursement price of a medicine. The rules for calculating reimbursement, including the definition of the reimbursement price, are set out in Section 150 of the Danish Health Act, No. 546 of 24.6.2005.

The reimbursement price is the lowest calculated pharmacy retail price in a reimbursement group. Reimbursement groups are a grouping of medicines that are entitled to reimburse-

[41] Pharmaceuticals are grouped by active ingredient, pharmaceutical form and strength, and approximate pack size. However, tablets and capsules and other similar forms can be substituted.

ment and can be mutually substituted (Medicines with the same active constituent in related pharmaceutical forms). Reimbursement groups ensure that the customer can get the medicine dispensed that forms the basis for the group's reimbursement price (unless substitution has not been opted for by the doctor or by the customer her/himself). In every reimbursement group a common price for reimbursement is calculated, which is the same for all medicines in the group. The reimbursement groups are updated whenever a new product is marketed or withdrawn from the market.

3.1.3.3 Cost-plus pricing

Cost-plus pricing is not used in Denmark.

3.1.3.4 (Indirect) profit control

A sort of indirect profit control for pharmacies is issued by the statutory mark-up scheme to calculate the pharmacy retail price (PRP). The total pharmacy profits are negotiated every two years and the pharmacy mark-up scheme is adjusted accordingly. The calculation of the pharmacy mark-up for each medicine (pack) is based on this scheme (cf. section 3.1.5).

3.1.3.5 Others

There are no other pricing policies.

3.1.3.6 Price agreements

The latest price ceiling was agreed upon in December 2008 in a voluntary agreement between the State and the pharmaceutical industry and is valid for a 3-year period starting in January 2009. The price ceiling concerns all reimbursable prescription medicines marketed by members of the Danish Association of the Pharmaceutical Industry (Lif). Lif member companies are manufacturers of a very large proportion of the medicines on the Danish market. The price ceiling is the price valid by 30 August 2006. However, it is possible for companies to apply for price increases in special circumstances.

Generics manufacturers and parallel importers are not members of the Industry Association Lif and are therefore not under any obligation resulting from this agreement.

The aim of the agreement is to eliminate the uncertainties regarding the implication of price increases on the rapid growth in the amount of public reimbursement. In the 3-year agreement period no major changes in the reimbursement system can be introduced without involving the Danish Association of the Pharmaceutical Industry (Lif). If new rules are introduced within the reimbursement system and these rules change the conditions within the pharmaceutical market, the agreement can be revoked.

As table 3.3 shows, Denmark has a long history of price agreements with the pharmaceutical industry. Some of these agreements have involved price cuts. Some price freezes have also been statutory.

Table 3.3: Denmark - Price freezes, price cuts and price ceilings 1995-2011

1995-1997	Agreement between the IM and Medif/Mefa (later: Lif) on price cuts for specific medicines
1997-1998	Price freeze introduced by law for specific medicines (Act No. 224 of 25 March 1997 on Temporary Price Stop on Pharmaceuticals, etc.)
1998-2000	Agreement between the IM and Lif on a price freeze for specific medicines
2000-2001	Price freeze introduced by law for specific medicines (Act No. 1031 of 23 November 2000 on Implementation of Temporary Rules on Price Stop
2001-2002	Price ceiling promised by Lif
2002-2003	A prolongation of the Lif promise
2003-2005	A prolongation of the Lif promise
2007-2008	Agreement between the IM and Lif on a price ceiling for specific medicines based on 2006 prices
2009-2011	Agreement between the IM and Lif on a price ceiling for specific medicines

Lif = Danish Association of the Pharmaceutical Industry, IM = Ministry of the Interior and Health

Sources: PPRI Pharma Profile Denmark 2008, Information by the Ministry of the Interior and Health 2010

3.1.4 Discounts / rebates

As a rule, it is not permitted to offer any discounts to health professionals in order to promote sales of medicines. However, discounts/rebates given to retailers and those achieved due to reduced suppliers' costs are legal but subject to strict regulation according to Executive Order No. 272 of 21 March 2007 on Advertising, etc. of Pharmaceuticals. Such discounts must be directly related to the retailer's ordering actions which must differ from the supplier's regular conditions for trade (cost-related discounts). The supplier may be a wholesaler, a manufacturer or an importer and the receiver may be a pharmacy or other type of retailer.

It is not mandatory for the supplier to provide these cost-related discounts/rebates but – once provided – it is mandatory to provide the discounts calculated according to the same principles to other retailers, when the cost reduction is the same.

The reduced supplier's costs may be due to fewer deliveries, larger quantities per delivery, deliveries at odd hours, agreements with a pharmacy chain instead of individual pharmacies, etc. The discount/rebate must balance the saved supplier's cost and must be given as a reduction in the price paid by the retailer – either as a fixed sum or as a percentage – and as such must be directly related to the payment for exactly those medicines (resulting in the discount/rebate).

The suppliers are obliged to publish information for the pharmacies on their web site on how they can obtain the discounts when buying medicines restricted to pharmacies. This rule aims to secure transparency and provide the pharmacies with relevant information on possible discounts/rebates. Both the retailers and the suppliers must save documentation for three years for every discount given or received, including relevant details and subject to evaluation by an accountant.

Discounts/rebates between manufacturers/importers and wholesalers are negotiated directly between the two parties and are not subject to the above-mentioned rules. Details of such discounts/rebates are not publicly known. This is also the case for discounts/rebates given to hospitals by procurement by Amgros.

As to the payers – the regions – the Danish pharmacies grant the national health insurance a permanent discount of 1.72 % on expenses, exclusive of VAT, for reimbursable medicines[42].

3.1.5 Mark-ups and taxes

This section contains a description of the wholesale and pharmacy margins and mark-ups, dispensing fees and sales taxes applied to medicines, as of 2010.

Table 3.4: Denmark – Regulation of wholesale and pharmacy mark-ups, 2010

Wholesale mark-up			Pharmacy mark-up		
Regulation	**Content**	**Scope**	**Regulation**	**Content**	**Scope***
No*	Not appl.	Not appl.	Yes	Linear mark-up	All medicines except OTC medicines which are not limited to distribution from pharmacies

OTC = over-the-counter (medicines)

* Since 2001 wholesale mark-ups are no longer regulated but freely negotiated between manufacturer and wholesaler.

Source: PPRI Pharma Profile Denmark 2008

3.1.5.1 Wholesale remuneration

The wholesale margin is not regulated by law but is negotiated individually between wholesalers and pharmaceutical companies. Wholesale margins are not publicly known. Wholesalers are allowed to grant discounts to pharmacies and are very likely to receive rebates/discounts from manufacturers. In 2006, the average gross margin of wholesalers was approximately 6% (www.girp.org).

There has been no cut in wholesale margins in Denmark, as these are negotiated between individual manufacturers/importers and wholesalers, and are not regulated at all.

3.1.5.2 Pharmacy remuneration

The Danish pharmacy mark-up is regulated by law (Executive Order, No. 270 of 21 March 2007 on the Calculation of Consumer Prices on Medicinal Products) and was – until 8 April

[42] Law on pharmacies gross profit no. 1084 of 23 December 1992 and Agreement of 3 January 2002 between the Danish Pharmaceutical Association and the minister for the Interior and Health

2007 – in a 2-year transition period. The transition led from previous 3-step-mark-up scheme (as shown in table 3.5) to a simpler scheme, consisting of only one formula (linear scheme).

Table 3.5: Denmark – Pharmacy mark-up scheme, (31 July 2006 to 8 April 2007)

Pharmacy purchasing price in DKK / €	**Pharmacy mark-up**
< DKK 30.00 / € 4.02	y × (0.293 × pharmacy purchasing price + DKK 11.82 / y × (0.293 × pharmacy purchasing price + € 1.58)
DKK 30.00 / € 4.02 ≤ pharmacy purchasing price ≤ DKK 60.00 / € 8.04	y × (0.226 × pharmacy purchasing price + DKK 13.82 / y × (0.226 × pharmacy purchasing price + € 1.85)
>DKK 60.00 / € 8.04	y × (0.160 × pharmacy purchasing price + DKK 17.82 / y × (0.160 × pharmacy purchasing price + € 2.39)

y = conscription percentage, a variable factor

Note: The mark-up percentage (y in the text above) is normally altered when an adjustment of the pharmacy profit margin is required. As of 18 July 2005, the mark-up percentage is 55% (y = 0.55).

Source: PPRI Pharma Profile Denmark 2008

The mark-up scheme, which entered into force on 12 July 2010, works on the following basis:

The constants of the formula are changed when it becomes necessary to adjust pharmacy earnings. The profit margin formula is laid down in the executive order on the calculation of consumer prices of medicines etc. Changes in the calculation of pharmacy profit margin generally take effect from the beginning of a new price period.

The conversion formula from PPP (pharmacy purchasing price) to ESP (total consumer price) is

ESP = DKK 10.00 + 1.25 x (pharmacy purchasing price + y x pharmacy purchasing price + C)

where 10.00 is the dispensing fee including VAT in DKK, y is the mark-up percentage and C is the constant. The mark-up percentage “y” (also called conscription percentage) is used to regulate the total profits of the pharmacies in order to reach the level agreed on between the Danish Pharmaceutical Association (DA) and the Ministry of the Interior and Health (IM).[43]

[43] However, on 31 July 2006 the constants in the scheme were changed instead, because adequate regulation through the mark-up percentage would have resulted in negative profits on products with a Pharmacy Pur chasing price of DKK 2.500 and over.

Table 3.6: Denmark – Pharmacy mark-up scheme, changes in the constants

Date of change	Y	C
9 April 2007	0,088	8,59
3 December 2007	0,088	6,71
28 January 2008	0,077	6,71
23 February 2009	0,083	6,71
21 September 2009	0,083	8,71
19 April 2010	0,086	8,71
12 July 2010	0,086	6,11

Note: The mark-up percentage (y in the text above) and the constant C is normally altered when an adjustment of the pharmacy profit margin is required.

Source: DKMA 2010b

The intention of this reform is to reduce the linkage between the pharmacy profit and the price of a medicine, to ensure that pharmacists do not have any incentive to dispense more expensive products, i.e. their profits are the same for all medicines. However, pharmacies do have some turnover-related expenses, so a fixed mark-up would imply that the selling of more expensive medicines generates negative profits.

Under specific circumstances pharmacies may qualify for subsidies granted by the Minister for the Interior and Health (IM). This money is taken from a fund fed by fees paid by pharmacies throughout the country.

Subsidies may be awarded in the form of special reimbursement or structural reimbursement. Special reimbursement is granted, e.g., to pharmacies that do not have the opportunity – within the scope of their normal operations – to carry out the necessary and appropriate reconstruction, relocation, etc. Structural reimbursement is given to pharmacies that do not have the opportunity to maintain a reasonable income, e.g. due to a modest turnover and a complicated distribution structure with pharmacy branches and pharmacy shops, staffed by employees with pharmaceutical education. Only few pharmacies apply for, and are granted, such subsidies.

A more common system is that of the “solidarity contribution”, whereby pharmacy revenue base – at least to some extent – is equalized between pharmacies to ensure that people in sparsely populated areas also have access to a pharmacy. The equalization scheme makes it possible to run a pharmacy in such areas. According to the Danish Pharmacy Act, the Danish Health Minister – after negotiations with the Danish Pharmaceutical Association – establishes the rules for equalization between pharmacies. The incentive to optimise the running of pharmacy is maintained since the equalization is based on turnover, not on profitsPharmacies receive a dispensary fee whenever they sell a prescribed product, i.e. POM

and OTC medicines sold on prescription.[44] The dispensary fee is added to the pharmacy retail price (PRP) of each pack and is reimbursable.

The dispensary fee is the most commonly applied fee, but pharmacies also operate with several other fees (cf. Table 3.7) which are added to the pharmacy retail price (PRP) of the medicine. Only the dispensary fee and a potential dosage dispensing fees are reimbursable according to the general reimbursement rates (cf. Table 3.10). All other fees are non-reimbursable and are paid by patients in the form of out-of-pocket payments (OPP).

Table 3.7: Denmark - Additional pharmacy remuneration fees 2010

Fee	Excluding VAT (DKK / €)	Including VAT (DKK / €)
Dispensary fee (figures from 2007, cf. below)	DKK 8.00 / € 1.07	DKK 10.00 / € 1.34
Finishing fee	DKK 17.50 / € 2.35	DKK 21.85 / € 2.93
Phone prescription fee	DKK 4.80 / € 0.64	DKK 6.00 / € 0.80
"Outside opening hours" fee	DKK 12.00 / € 1.61	DKK 15.00 / € 2.01
Delivery fee	Min. DKK 12.00 / € 1.61	Min. DKK 15.00 / € 2.01
Administration fee	DKK 10.00 / € 1.34	DKK 12.50 / € 1.68
Dosage dispensing fees	DKK 9.50 / € 1.27 (administration) DKK 35.00 / € 20.05 (preparation)	DKK 11.88 / € 1.59 DKK 43.75 / € 5.86

Notes:

- The dispensary fee is added to the pharmacy retail price (PRP) of every prescribed pack and it is reimbursable. This fee was increased during the 2-year transition period, from DKK 7.70 / € 1.03 (including VAT) to DKK 10.00 / € 1.34 (including VAT). Basing on Decree No. 237 of 24 March 2006 from 10 April 2006 to 8 April 2007 the dispensary fee was DKK 9.25 / € 1.24 (including VAT).
- The finishing fee is added whenever the medicine(s) need(s) some manipulation before dispensing, e.g. granules for oral suspension.
- The phone prescription fee is added whenever the prescription is phoned in by the doctor.
- The "outside opening hours" fee is added when the purchase takes place outside usual opening hours, i.e. between 8 pm and 8.30 am on weekdays or between 4 pm and 8.30 am on Saturdays/Sundays. Some pharmacies are open around the clock, and others have an on-call service. The fee is added for prescription-only medicine(s) (POM) not prescribed the very same day, and for over-the-counter (OTC) medicines. It is added only once per customer service.
- The delivery fee is added when the pharmacy delivers the medicines to individuals, and the delivery is not prescribed. The fee must cover the pharmacy's actual cost of the delivery, and hence there is only specified a minimum amount.
- The administration fee is added when individuals do not pay for their medicines at the time of dispensing, but have a credit arrangement with the pharmacy. The fee can be added once a month.
- The dosage dispensing fees are given to the dispensing pharmacy and the pharmacy carrying out the packaging, respectively.

Source: Executive order on calculation of consumer prices etc. on pharmaceuticals no. 836 of 28 June 2010

[44] Some OTC pharmaceuticals can be reimbursed for some patients that fulfil specific criteria for reimbursement of these products. Reimbursement requires prescription. The doctor/patient must consider whether the reimbursement will exceed the dispensary fee.

3.1.5.3 Remuneration of other dispensaries

A selection of over-the-counter (OTC) medicines can be sold from outlets other than pharmacies. These products are completely freely priced in all outlets, including pharmacies, and prices are not notified to the Danish authorities.

3.1.5.4 Taxes

3.1.5.4.1 Value-added tax

The value-added tax (VAT) rate for medicines is the same as the standard rate (25%).

3.1.5.4.2 Other taxes

There are no further taxes / fees on medicines then the above mentioned taxes / fees.

3.2 Reimbursement in the out-patient sector

This section describes the scope of the reimbursement system, the regulatory framework and the main authorities in the out-patient sector as of 2010.

3.2.1 Organisation

The predominant basic reimbursement scheme is based on the Danish Health Act, No. 546 of 24 June 2005, and Executive Order No. 180 of 17 March 2005 on Reimbursement. In addition, reimbursement is possible according to social laws.

In principle, all medicines with market authorisation are eligible for reimbursement according to the predominant scheme, provided they meet the eligible criteria (cf. section 3.2.2.1). For OTC medicines it is mandatory to define to which diseases are the conditions for the reimbursement.

Both the predominant scheme and the social reimbursement aspect cover the whole population and all institutions, except patients involved in hospital treatment. All hospital treatment is free of charge to the patient.

Decision making

The Danish Medicines Agency (DKMA) has the decision-making power to decide on reimbursement issues according to the predominant scheme. This is normally based on professional medical recommendations given by the Reimbursement Committee (MTN). Besides the Institute for Rational Pharmacotherapy (IRF) and scientific societies, the Danish Association of the Pharmaceutical Industry (Lif), the Danish Generic Medicines Industry Association (IGL), Danish Association of Parallel Importers of Pharmaceuticals (PFL), patient organisations, individual companies, etc., may potentially influence the reimbursement decision. Recommendations from professional institutions abroad, e.g. the National Institute for Clini-

cal Excellence (NICE) in England, may also be taken into consideration. The reimbursement system itself aims at promoting rational pharmacotherapy.

The price is a parameter taken into consideration, but the pricing is a company decision alone and manufacturer prices need neither to be approved by nor negotiated with Danish authorities (cf. section 3.1.1). However, to be eligible for reimbursement, a major criterion is that the price of the product is reasonable in relation to its therapeutic value.

Reimbursement application

To apply for general (automatic) reimbursement for a medicine, a company either must have market authorisation or be in the process of obtaining it. According to the Guidelines for Application for General Reimbursement for Medicinal Products of 24 April 2006, the company may apply as follows, depending on the type of authorisation procedure:

- the centralised authorisation procedure in the European Union (EU), when there is a "positive opinion";
- the mutual authorisation procedure, when 90 days have passed;
- the national authorisation procedure, when 210 days have passed.

When applying for general reimbursement, the company must state the pharmacy retail price (PRP) of the product, which is relevant to deciding whether the price is reasonable in relation to the therapeutic value (cf.3.2.2.1).

Along with the application form, the following details must be submitted: a copy of the market authorisation (when available); and a copy of the summary of product characteristics and information about expected consumption of the medicine (e.g. expected number of users) in the primary sector during the first five years after the entry to the market, distributed by sex and age (relevant age groups). In addition, pharmacological and clinical documentation must be submitted in the form of, e.g., a copy of the assessment report; comparative clinical effect studies and safety studies with regard to the pharmaceutical concerned; reprints of scientific publications and possibly reviews concerning the relevant constituent, with a brief list of the most significant content of the material enclosed and preferably with an accompanying reason for the selection. A health-economic analysis may also be enclosed to demonstrate cost-effectiveness, but this is not mandatory (cf. section 3.3.5.2).

In almost all cases the decision on reimbursement status for a given medicine is made in fewer than 90 days from the application date in accordance with the Transparency Directive (Council Directive 89/105/EEC of 21 December 1988). In a few cases it is necessary to consult the Reimbursement Committee (MTN) more than once, and in such cases the time may exceed 90 days.

Pharmaceutical companies may appeal against unfavourable decisions to the Ministry of the Interior and Health (IM), but only regarding the procedure. As far as the reimbursement decision itself is concerned, the company has the opportunity to reapply for general reimbursement to the Danish Medicines Agency (DKMA).

However, patients may still be granted reimbursement on an individual basis for products that are not eligible for general reimbursement. For individual reimbursement, the doctor prescribing treatment must apply to the DKMA and state the reasons why individual reimbursement should be granted (cf. section 3.2.2.1).

General reimbursement of generics follows the same rules as other medicines, but there is no formal reimbursement decision (i.e. no recommendation from the Reimbursement Committee (MTN) necessary). The generic or the parallel imported equivalent of a medicine already included in the positive list is automatically granted reimbursement status, as long as its price does not exceed the price of the original (brand name) product.

Change of reimbursement status

The reimbursement status of a medicine may change due to:

- new clinical studies;
- an actual use of the medicine that differs from that was estimated by the company in the application for general reimbursement - i.e. number of patients treated;
- international experience;
- experience regarding the daily clinical use, e.g. by consulting relevant scientific societies;
- evidence-based treatment recommendations, e.g. by scientific societies, the Institute for Rational Pharmacotherapy (IRF) and the Danish National Board of Health (SST);
- significant price changes;
- number of applications for individual reimbursement, including the number of individual reimbursements granted, with a view to assessing potential conditional reimbursement;
- new health-economic analyses;
- shifts in the relationship between risks and benefits of the medicine;
- other factors that may influence the relationship between the treatment value of the medicine and its price.

These are also certain issues essential to the reassessment procedure, described in 3.3.5, but these also apply to ad hoc reassessment, e.g. COX-2 inhibitors and lipid-lowering medicines (cf. section 3.2.2 for more information). There are no automatic reimbursement changes due to price changes in other countries, when patents run out, or when a competitor enters the market – although the latter normally leads to a substitution group (reference price group) being established.

A formal consultation with the market authorisation holder – and most likely the relevant scientific societies as well – always takes place prior a change of reimbursement status.

3.2.2 Reimbursement schemes

The predominant system is a needs-based reimbursement scheme allocating public reimbursement to those patients that have the largest (and well-documented) consumption of prescribed (prescription-only medicine(s) (POM) and over-the-counter (OTC)) medicines and who consequently have the largest expenses. This system was introduced on 1 April 2000.

The system is characterised by a number of aspects, listed here.

- A positive list of medicines eligible for general reimbursement or general conditional reimbursement (limited to certain diseases or patient groups) (cf. section 3.2.2.2). The list includes both prescription-only medicine(s) (POM) and over-the-counter (OTC) medicines.
- Variable reimbursement rates (cf. section 3.2.2.3) depending on:
  - The patient's consumption within a 12-month period
  - whether the patient is an adult or child under the age of 18
  - the patient's disease status, as chronically or terminally ill
- OTC medicines only reimbursed for patients with defined illnesses or for pensioners.
- Patients' out-of-pocket payments (OPP) are based on the reimbursement price
- Possibility of the Danish Medicines Agency (DKMA) granting individual reimbursement to a patient for a specific non-reimbursable medicine upon application by the doctor.

Generic substitution is mandatory and for medicines eligible for general reimbursement and the substitution groups are identical to the reimbursement groups.

A prerequisite for the functioning of the system is the Danish Medicines Agency Central Reimbursement Register (CTR) ensuring that pharmacies – when dispensing a medicine – subtract the correct reimbursement amount from the reimbursement price of the medicine that the patient purchases. All pharmacies are having online access to the Central Reimbursement Register (CTR), along with doctors and citizens. As the owner of the Register, the DKMA is required to ensure that the CTR works properly.[45]

When a patient buys a medicine eligible for reimbursement, the pharmacies report the reimbursement price of the product to the Register, which contains a record of the patient's updated balance of reimbursement prices as reported by pharmacies. Furthermore, the Register holds information on the person's reimbursement period and any individual reimbursement that has been granted (reimbursement for a specific product, raised reimbursement for a specific pack size, reimbursement for chronically ill patients and for terminally ill patients), etc. The legal framework for the system is the Danish Health Act, No. 546 of 24 June 2005 and the Order on Reimbursement No. of 17 March 2005.

[45] Order No. 205 of 17 March 2005 on the Danish Medicines Agency's Central Reimbursement Register (CTR).

All Danish citizens – independent of social or financial situation – are covered by the predominant system. The number of prescriptions reimbursed under the scheme is not available but the number of reimbursed defined daily doses (DDD) in 2009 was 2,166 Mio[46].

3.2.2.1 Eligibility schemes

General reimbursement is granted by the Danish Medicines Agency (DKMA) on the recommendation of the Reimbursement Committee (MTN), if:

- the medicine has a safe and valuable therapeutic effect on a well-defined indication; and
- the price of the product is reasonable in relation to the therapeutic value.

Unless very special circumstances exist, general reimbursement shall not be granted for a medicine if:

a) there is a considerable risk of off-label use (i.e. that the medicine will be used beyond the authorised indication, as is often the case for bisphosphonates);
b) the implementation of treatment with the medicine requires a special medical examination and diagnostic procedure, e.g. products for Alzheimer's disease;
c) the medicine is exclusively or primarily used for (a) purpose(s) for which it is not reasonable to expect reimbursement from the National Health Service (NHS), e.g. nicotine replacement products;
d) the effect of the medicine is not clinically documented, e.g. herbal medicine;
e) there is a risk that the medicine is used as a first line therapy, regardless of whether the DKMA is of a different opinion, e.g. anti-obesity products;
f) it is not clarified if or when the medicine should be used as first line therapy, e.g. some new anti-rheumatic products;
g) there is a certain risk that the medicine may be abused, e.g. sleeping remedy;
h) the medicine is primarily used in hospital treatment, e.g. anti-cancer products; or
i) the medicine is not suitable – due to its special pharmaceutical form – to be administered by the patients themselves, e.g. injection and infusion fluids.

These criteria are exclusively product specific, based on the therapeutic value of the medicine in relation to price and in comparison with other available treatment for the disease in question. To justify a high price and demonstrate cost-effectiveness, a health-economic analysis may be submitted by companies as part of the application for eligibility for reimbursement. These criteria have not been changed since the year 2000.

According to these criteria, the DKMA may limit the general reimbursement to the treatment of specific diseases or patient groups ("general conditional reimbursement"). If, e.g., a product has more than one approved indication the general reimbursement may be granted for only one of those indications, provided that this treatment alone meets the above criteria.

[46] http://ext.laegemiddelstyrelsen.dk/statistik/overvaagning/udgifter/2010-2.asp

Medicines that have been granted general reimbursement or general conditional reimbursement will be listed on the Positive List.[47]

Medicines that do not meet the criteria for general reimbursement (or general conditional reimbursement limited to certain diseases or patient groups) will not be granted general reimbursement and will not be included in the Positive List.

However, patients may still be granted reimbursement on an individual basis for products that are not eligible for general reimbursement.

According to Executive Order No. 180 of 17 March 2005 on Reimbursement, the evaluation of an application for individual reimbursement of a given product is based in particular on the therapeutic value of the medicine to the specific patient, including that the product has shown an effect on the patient or can be expected to have an effect, and that other methods of treatment have proven to be insufficient or unsuitable. If the given product falls in one of the groups a, d, g and h listed above, individual reimbursement will only be granted in rare cases.

For some major groups, e.g. medicines for the treatment of Alzheimer's disease, the Danish Medicines Agency (DKMA) has recommended criteria for obtaining individual reimbursement. Most patients meeting these criteria will be granted individual reimbursement, but other patients may also be granted the reimbursement if there are special circumstances, as the decision is always made on an individual basis.

With regard to the reimbursement eligibility schemes as defined by the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, the Danish system can be defined as "consumption-based reimbursement" since it is a needs-based reimbursement system. For further information please see sections 3.2.2.3 and 3.2.4.2.1.

3.2.2.2 Reimbursement lists

In Denmark there is a positive list containing details of all medicines (name and pharmaceutical form) eligible for reimbursement, arranged according to the Anatomic Therapeutic Chemical (ATC) classification system.[48] There is no negative list. The content of the positive list and its updating are a result of decisions on reimbursement status as well as the time required for marketing of generics, parallel imported medicines and OTC medicines (cf. 3.2.2.1).

The list is published on the Danish Medicines Agency (DKMA) web site and is updated when necessary, i.e. when new medicines are granted general reimbursement and thus enter the list, but also if a medicine is de-listed or if the reimbursement is limited to a specific disease or patient group (conditional reimbursement). In general the list is updated every two weeks.

[47] The Danish Health Act, No. 546 of 24 June 2005 and the Order on Reimbursement, No. 180 of 17 March 2005

[48] Cf. http://www.laegemiddelstyrelsen.dk/1024/visLSArtikel.asp?artikelID=816 (in Danish only).

The Reimbursement Committee (MTN) meets once a month and recommends whether medicines should be granted general reimbursement. If the DKMA agrees to follow the recommendations of the Committee, the list is updated accordingly. Generics and parallel imported medicines are granted general reimbursement without application if their prices do not exceed the prices of the original (reimbursable) products. The companies can market new medicines every two weeks (hence the bi-weekly updates).[49] Medicines are not included in the list (i.e. granted general reimbursement) if they do not meet the eligibility criteria.

All hospital treatment is free of charge. Patients in nursing homes are subject to the same rules as everybody else in the primary care sector and do not constitute a special group in a reimbursement context.

Changes

For many years there have been no fundamental or major changes to the Positive List. In 2005 the Medicines Agency started to reassess the reimbursement status of pharmaceuticals. As a result of the reassessment changes have been made in the Positive List. There have been changes concerning specific medicines or groups of medicines, e.g. lipid-lowering pharmaceuticals, COX-2 inhibitors, antihypertensives and pharmaceuticals for the treatment of acid related disorders.

Until 1998 lipid-lowering medicines were not eligible for reimbursement, except if applied for individually. In 1998 general reimbursement eligibility was granted but limited to patients with ischaemic heart disease and/or cholesterol level above a certain limit. In 2002 this limited reimbursement also included patients with apoplexy, periphery arterial insufficiency or diabetes. Reimbursement for primary prevention was only granted for individual patients based on the presence of a combination of certain risk factors and a high cholesterol level, and only as individual reimbursement. The reimbursement status was changed in 2007.

From 2004 onwards COX-2 inhibitors were no longer eligible for general reimbursement as a consequence of (initially) excessive and incorrect use, and later also as a result of the presence of known side-effects.

Cf. section 3.3.5.3 for further information about the reassessment procedure and the financial implications of the procedure.

3.2.2.3 Reimbursement categories and reimbursement rates

The current needs-based reimbursement system (consumption-based reimbursement system according to the classification of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies) and the applicable reimbursement categories/rates were determined by the Danish Parliament by the Danish Health Act, No. 546 of 24 June 2005. For every patient and for every reimbursable medicine – regardless of its eligibility for

[49] Changes to the list are published in the Weekly Journal of the Danish Medical Association (DADL) and on the Danish Medicines Agency (DKMA) web site where doctors, pharmacies, patients and companies can be informed.

general reimbursement or general conditional reimbursement or according to an individual reimbursement granted for a specific medicine – the reimbursement rates are the same. The Danish Medicines Agency decides on the reimbursement category of each medicine.

The rates are based on the patient's pharmaceutical consumption, or rather the patient's out-of-pocket payment (OPP) for medicines within a 12-month period. This period starts for each patient individually the first time a reimbursed product is dispensed.

Table 3.8: Denmark – Reimbursement categories of medicines, 2011

Reimbursement category	Reimbursement rate	Characteristic of category
General reimbursement POM	0, 50, 75, 85 (100)% of reimbursement price	The medicines meet the criteria mentioned in section 3.2.2.
General reimbursement POM, conditional	0, 50, 75, 85 (100)% of reimbursement price	Limited to specific diseases or patient groups. Do not in all cases meet the criteria mentioned in section 3.2.2.
General reimbursement OTC, conditional	0, 50, 75, 85 (100)% of reimbursement price	Limited to specific diseases or patient groups or to pensioners
Supplementary: Individual reimbursement for a specific product. 0, 50, 75, 85 (100)% of the reimbursement price. Potentially all medicines which are not eligible for general reimbursement.		

POM = prescription-only medicine(s), OTC = over-the-counter (medicines)

Source: www.dkma.dk

The reimbursement rates are 0, 50, 75 and 85% - the larger the pharmaceutical expenditure (PE), the bigger the rate will be.

Until 2000 all medicines eligible for general reimbursement were granted either 50% or 75% reimbursement (apart from insulin at 100%), and the criteria that the product had to meet were less specific than the present ones. This was a very different system, which was abandoned in favour of the present needs-based system in order to allocate the public reimbursement to the patients with the greatest need. Furthermore, the rules for deciding on a 50% or 75% rate for a given product were often difficult to administer. The choice of reimbursement rate was related to the severity of the disease, which could be difficult to decide, even without the situation where a medicine might have two reimbursable indications of differing severity.

Most medicines eligible for general reimbursement are in principle included in the reference price system (cf. section 3.2.3 for information on the principles of this system). Only for completely new medicines (new active substances or new different types/pharmaceutical forms of already existing active substances and before marketing of potential parallel imported medicines) is the pharmacy retail price (PRP) identical to the reimbursement price. For all other medicines the reported PRP may or may not be identical to the reimbursement price.

3.2.3 Reference price system

In Denmark a reference price system was introduced in 1993 as a result of a parliamentary decision. The system is run by the Danish Medicines Agency (DKMA) and the legal framework is the Danish Health Act, No. 546 of 24 June 2005. The reference price system is closely related to (and based on) the generic substitution scheme – for reimbursable medicines the reimbursement groups are identical to the substitution groups. This section should therefore be read together with section 3.3.2.1 on generic substitution.

The only major changes over the last 5 to 10 years are the different ways of defining the reference price (reimbursement price) of a group.

Reference price calculation

In 2000 a new reference price based on European prices was introduced.[50] The reimbursement was to be calculated from an average of the pharmacy purchasing prices in European Union (EU) and European Economic Area (EEA) countries, except for Liechtenstein, Luxemburg and Iceland, provided this average was lower than the Danish price. The European prices were reported to the Danish Medicines Agency (DKMA) by the pharmaceutical companies. For medicines in reimbursement groups the reimbursement level was to be calculated from the lowest average European price of the group and – if none of the products in the group had a European price – from the lowest price in the group. In case the price of a product was lower than the lowest European price, the reimbursement of that product would be calculated from its price.

As of June 2001 the reimbursement level was to be calculated from the reimbursement price defined as the average of the prices in a basket of countries.[51, 52] On April 2005 the definition of the reimbursement price for products eligible for generic substitution was changed to be the lowest price in the reimbursement group, i.e. the system based on average European prices was abandoned.[53]

The core characteristic of the system is that similar (so-called interchangeable) medicines are clustered in substitution groups. “Similar” is defined as medicines containing the same active ingredient (Anatomic Therapeutic Chemical (ATC) level 5) in the same strength and in the same or very similar pharmaceutical form (e.g. tablets and capsules together) and being

[50] By amendment of the National Social Security Act, cf. Consolidated Act, No. 509 of 1 July 1998, by Act, No. 495 of 7 June 2001.

[51] Austria, Belgium, Finland, France, Germany, Great Britain, Ireland, Iceland, Italy, Liechtenstein, the Netherlands, Norway, Sweden. Liechtenstein and Iceland were included and Greece, Portugal and Spain wee excluded from the previous country basket.

[52] By amendment of the National Social Security Act, cf. Consolidated Act, No. 509 of 1 July 1998, by Act, No. 495 of 7 June 2001.

[53] By amendment of the National Social Security Act, cf. Consolidated Act, No. 509 of 1 July 1998, by Act, No. 1431 of 22 December 2004.

sold in similar or nearly similar pack sizes). The number of medicines in a substitution group (including the number of packs) may vary from 2 to about 15.

The reference price system includes all medicines, defined as above, including parallel imported medicines. For those medicines that are eligible for reimbursement the reference price groups are identical to the substitution groups. The system is based on the grouping of synonymous medicines (according to Anatomic Therapeutic Chemical (ATC) level 5) and does not include a grouping of active substances that are different but with essentially a similar effect (analogues), e.g. statins.

Reference price updating

The reference price groups are updated whenever new medicines, new pack sizes, etc., are marketed or withdrawn from the market. There is no formal or regular review or evaluation, but occasionally situations arise whereby decisions on the grouping of some medicines are questioned, and in such cases, the decision will be reassessed.

In some cases a certain pack is the only one of that particular size (e.g. 50 tablets), in which case this specific pack is in principle included in the reference price system but in practice will not be substituted. This situation may change, e.g. two weeks later, when a synonymous product with a similar pack size is marketed. Packs may enter or leave the market and prices may change every two weeks. In 2007 the reference price system included approximately 2,400 marketed medicines (including different dispensing forms and strengths).

The reference price (= reimbursement price) is the lowest price within the substitution group, e.g. the lowest price among five packs, each of 100 tablets (original, generics or parallel imported medicines) containing the same active substance in the same strength.

Additional payments and individual reimbursement

If the doctor prescribes a product belonging to a reference price group other than the cheapest one and at the same time forbids generic substitution, the patient will have to pay the difference in prices between the cheapest available medicine and the one prescribed, on top of the regular co-payment. This also applies to situations where the patient opts for a more expensive product than the cheapest one at her/his own will.

In those rare cases where the patient is not able to use the cheaper product for medical reasons (e.g. because of an allergic reaction to the additives) the doctor can apply to the DKMA for individual raised reimbursement of the originator product (or occasionally a more expensive generic), stating the reasons why. If the case is well argued or well documented, the patient will then be granted a raised reimbursement, i.e. the reimbursement will be calculated from the price of the more expensive product instead of from the reimbursement price.

3.2.4 Private pharmaceutical expenses

The main principles of out-of-pocket payments (OPP) by patients for medicines have been determined by the Danish Parliament and are set out in the Danish Health Act. The Minister for the Interior and Health (IM) shall lay down in more detail regulations on the adjustment of the general cost limits and co-payment ceilings, also according to the Danish Health Act. The applied cost limits and the price ceiling within the present needs-based system are changed once a year.

The purpose of the needs-based system is to allocate reimbursement to the people who have the largest pharmaceutical expenditure (PE) and therefore – from a "consumption perspective" – the greatest need. At the same time, the cost-sharing objectives aim to reduce inappropriate demand and thus indirectly to support cost-containment. There have been no major changes in the level of private PE in recent years.

Much information is available to patients on the DKMA web site regarding prices, substitution groups, co-payment, etc. It is possible for a patient to calculate her/his own co-payment before visiting the pharmacy. The Institute for Rational Pharmacotherapy (IRF) edits a web site, "Medicines with sense" (http://www.medicinmedfornuft.dk) aimed at patients/consumers, offering neutral information on medicines. On the IRF web site (www.irf.dk) there is a list of recommendations for individual Anatomic Therapeutic Chemical (ATC) groups, e.g. for lipid-lowering medicines, beta-blocking agents, etc.

As patients always have to pay a variable percentage co-payment for medicines (with few exceptions), information on the current percentage co-payment balance of every person in Denmark is also available via Medicinprofilen (http://www.medicinprofilen.dk).

3.2.4.1 Direct payments

Some groups of medicines have not been granted general reimbursement as they do not meet the criteria for general reimbursement (c.f. section 3.2.2). Examples include products that are likely to be abused, antismoking medicines or products for which a special medical examination and diagnostic procedure are necessary prior to the treatment. It is not possible to state an average sum paid for those medicines.

The patient pays the full price for these medicines. However, for all medicines which are not eligible for general reimbursement the doctor can apply to the DKMA for individual reimbursement to the patient. This includes non-reimbursable OTC medicines, if prescribed by a doctor. In some cases the social laws may cover (part of) the direct payment for medicines (c.f. section 3.2.4.3).

All self-medication has to be paid fully by the patient her/himself.

3.2.4.2 Out-of-pocket payments

Table 3.9: Denmark – Out-of-pocket payments for medicines, 2011

Out-of-pocket payments	Amount	Vulnerable groups
Fixed co-payments	€ 1.34 (prescription fee), is already included in the pharmacy retail price	Maximum limit of DKK 3,555 / € 474 per 12 months for patients with a large consumption. Supplementary reimbursement schemes for disabled people and low income people and less co-payment for pensioners. No co-payment for terminally ill patients.
Percentage payments	100%. 50%, 25%, 15% and 0%	
Deductibles	An initial deductible of maximum DKK 865 / € 115,-	
Reference price system		

Source: www.dkma.dk

3.2.4.2.1 Fixed co-payments

Although out-of-pocket payments (OPP) are generally percentage based, a flat dispensary fee (DKK 10.0 / € 1.34) for every pack is added to the reimbursement price before calculating the reimbursement level, meaning that the fee is reimbursed the same way as the medicine.

The applied cost limits and the co-payment ceiling within the present needs-based system are changed once a year.

There will be a co-payment ceiling if a chronically ill patient has very high medical expenses, and her/his doctor applies for so-called reimbursement for the chronically ill. If the patient is granted a licence for the chronically ill, this will put a ceiling on her/his medical expenses. Her/his maximum co-payment will then be DKK 3,555 / € 474 stated in reimbursement prices. This applies to both pharmaceuticals with automatic reimbursement and pharmaceuticals for which the patient has been granted single reimbursement. Reimbursement for the chronically ill is not available for fertility treatment.

3.2.4.2.2 Percentage co-payments

The needs-based system is constructed around a rather large out-of-pocket payment (OPP) at the beginning of the patient's personal reimbursement period, and gradually higher reimbursement rates and corresponding lower OPP's by the end of the personal reimbursement period. Every patient has a personal reimbursement period beginning on the date when s/he bought reimbursable medicines for the first time after the introduction of the system on 1 March 2000. The reimbursement period runs for 12 months, and the next reimbursement period starts on the date when the patient buys reimbursable medicines for the first time after the previous period has expired. Such a system may also be called "consumption-based reimbursement."

Table 3.10 shows the reimbursement rates and the corresponding patient co-payment rates, along with the links to the various categories of expenses, depending on consumption. Some people never actually receive reimbursement as a result of their low consumption level, while others very quickly pass through the various categories.

Table 3.10: Denmark - Reimbursement rates and patient co-payment rates, 2011

Annual expenditure for patients in terms of reimbursement price in DKK / €[1]	**Co-payment rate in %**	**Reimbursement rate in %**
Adults		
DKK 0 - 865 / € 0 – 115	100%	0%
DKK 865 - 1,410 / € 115 - 188	50%	50%
DKK 1,410 - 3,045 / € 188 - 406	25%	75%
> DKK 3,045 / € 406	15%	85%
Children up to 18 years		
DKK 0 – 1,410 / € 0 - 188	40%	60%
DKK 1,410 – 3,045 / € 188 - 406	25%	75%
> DKK 3,045 / € 406	15%	85%
Chronically ill [2]		
DKK 0 – 16,436 (adults) or 20,260 (< 18 yrs) / € 0 - 2,191 (adults) or 2,701 (< 18 yrs)	Co-payment rates and reimbursement rates as stated above	
> DKK 16,436 or 20,260 / € 2,191 or 2,701	0%	100%
Terminally ill [3]		
DKK 0 / € 0	0%	100%
Fertility treatment[4]		
DKK 0 – 15,000 / € 0 – 2,000	100%	0
> DKK 15,000 / € 2,000	0	100%

1 Before subtraction of reimbursement

2 A chronically ill patient in this context is defined as a patient who has a large consumption of prescribed reimbursable medicines and therefore similarly large costs.

3 Includes all consumed medicines (also non-reimbursable medicines) prescribed by a doctor.

4 Starting 1 January 2011, a personal co-payment threshold of DKK 15,000 per year for medicines used in fertility treatment is introduced.

Source: www.dkma.dk

In 2011, there is an annual out-of-pocket payment (OPP) maximum of DKK 3,555 / € 474 for patients who have been granted individual reimbursement for the chronically ill. For everybody else (except terminally ill patients) there is always a co-payment of a minimum of 15% of the reimbursement price. The co-payment is slightly increased in 2011 compared to 2010.

3.2.4.2.3 Deductibles

In the predominant reimbursement scheme in Denmark there is a deductable of DKK 865 (€ 115) for adults, cf. Table 3.10 within the patient's personal reimbursement period of one year. For disabled people or parents providing for a disabled child in their own home, a monthly

deductible of maximum DKK 2,424 / € 323.2 must be paid according to the Danish Service Act.

3.2.4.3 Mechanism for vulnerable groups

According to the Danish Health Act, several mechanisms are in place to protect vulnerable population groups.

- Contrary to adults, children under the age of 18 are granted 60% reimbursement with their first filling of a prescription.
- Individual reimbursement for chronically ill people (people with an extensive, permanent and professionally well-documented need for pharmaceutical treatment, cf. Table 3.10) may be granted 100% reimbursement upon application by the doctor.
- Individual reimbursement for terminally ill people. Terminally ill patients who want to spend the end of their life in their own home or in a hospice should not be left in a worse position than patients remaining hospitalised, and are therefore granted all prescribed medicines free of charge upon application by the doctor.
- Certain over-the-counter (OTC) medicines are reimbursable for pensioners.

According to the social laws in Denmark, pensioners, people with low income, disabled people and others may be granted additional reimbursement.

Pensioners.[54,55] Health allowance may be given to pensioners to cover up to 85% of the pensioner's own expenses for reimbursable medicines, depending on the pensioner's income and personal wealth. The calculation is based on reimbursement prices. On top of this, a personal payment supplement may be given to pensioners in very difficult financial situations. However, such applications are evaluated on a case by case basis.

Reimbursement for pensioners according to the social laws also includes a reduced co-payment (fixed or percentage). However, if deemed necessary after an actual evaluation of the person's economic situation, this co-payment may be partly or fully covered as well.

People receiving cash assistance, students and low income people.[56] People belonging to these groups can apply for financial aid if they are unable to cover the pharmaceutical expenses themselves.

Disabled people[57] may be given compensation for extra expenses due to their permanently reduced functionality, and the same rules apply for parents providing for a disabled child in their own home.

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54 The Social Pensions' Act, cf. Consolidated Act, No. 484 of 29 May 2007

55 Act on highest, intermediate, increased and ordinary, anticipatory pension etc., cf. Consolidated Act, No. 485 of 29 May 2007

56 Act on Active Social Policy, cf. Consolidated Act, No. 1009 of 24 October 2005

57 The Services Act, cf. Consolidated Act, No. 58 of 18 January 2007

According to an agreement with the Danish Pharmaceutical Association (DA) patients that have been granted individual reimbursement due to chronic illness may obtain an agreement with their pharmacy to have their co-payments equally divided over the 12-month period, instead of paying a large initial co-payment.

3.3 Volume control in the out-patient sector

3.3.1 Pharmaceutical budgets

No obligatory budgetary constraints are in place for the doctors in Denmark, but doctors have to take the current reimbursement policy into consideration when prescribing. If a doctor's prescribing of medicines considerably exceeds an average level, official action will be taken by the third-party payer, i.e. the region which manages the reimbursement according to the predominant reimbursement scheme. However, this rarely occurs. According to the agreement set out by the Organisation of General Practitioners in Denmark (PLO), doctors must prescribe rationally and in a financially responsible manner, and possible sanctions are set out in that same agreement if they do not comply.

All general practitioners (GP) regularly receive an evaluation of their prescribing habits in the form of lists enumerating the amount and costs of prescribed medicines. This list should make the doctor aware of her/his prescribing habits compared to colleagues in the region but rarely is any action taken by the regions.

The prescribing procedures in the in-patient sector might influence the prescribing habits of doctors in the out-patient sector (see also section 5.1.), although it is unknown to what extent or how often exactly this occurs. It is a fact, however, that GPs may be reluctant to change medicines prescribed by hospital doctors, even though this would be the correct choice.

3.3.2 Generic policies

3.3.2.1 Generic substitution

Voluntary generic substitution of medicines has been allowed in Denmark since November 1991 (introduction of the so-called "G"-Scheme) and became mandatory in 1997 (cf. Executive Order on Prescriptions No. 155 of 20 February 2007). Obligatory generic substitution means that the pharmacist must always dispense the cheapest available product – generic or parallel import – of the same pack size, etc., unless specifically prohibited by the doctor or in the event that the patient opposes the substitution.

The Danish Medicines Agency (DKMA) decides whether a medicine qualifies for substitution. The medicines are grouped into substitution/reimbursement groups according to their Anatomic Therapeutic Chemical (ATC) classification code (whereby only ATC level 5 is considered), their formulation and their bio-equivalence (the first step), whereas single packs are clustered according to pack size and dispensing details (the second step).

In Denmark the role of generics in hospitals depend on whether the generic companies win the tenders (cf. section 4.1.2.1).

Refusing substitution

The public perception of generics is that generics are cheap pharmaceuticals and are the same as the original pharmaceutical. Generics are well accepted among patients and doctors.

Although generic substitution is well accepted, both doctors and patients may refuse it. Doctors may oppose substitution by clearly marking the prescription with "ej S" (non-“S” i.e. “no substitution”) without giving a reason for the refusal. The patient may also oppose substitution.

If the patient cannot tolerate a cheaper (generic) product, the doctor can apply to the DKMA for increased reimbursement for the more expensive (often brand name) medicine.

In any case the reimbursement (for reimbursable substitution groups) is calculated from the reimbursement price (i.e. the cheapest product in a substitution group) and the patient is obliged – on top of the normal out-of-pocket payment (OPP) – to pay the difference between the reimbursement price and the pharmacy retail price (PRP). This additional payment is not taken into account for the calculation of the patient’s 12-month co-payment ceiling. Thus, there may be strong financial incentives for the patient to demand substitution at her/his own will. However, patients who have taken out supplementary private insurance may have no or little incentive to accept substitution, as their co-payment may be partly or totally covered by this insurance.

According to the agreement between the general practitioners (GP) and the regions, doctors must prescribe rationally and include economic aspects in the decision – from both a patient and a societal perspective – but no actual consequences will follow if they do not. Neither will opposition from the patient have consequences beyond a larger patient co-payment, while pharmacies risk a fine if they do not dispense the cheapest product of the group (cf. Executive Order on Prescriptions No. 155 of 20 February 2007).

It is worth noting that generic substitution is not mandatory in cases when the price difference between the prescribed medicine and the cheaper alternative is minor. If the difference between the prescribed medicine price and the reimbursement price is irrelevant (meaning that it lies between certain limits, from DKK 5 - 20 / € 0.67 - 2.68, depending on the pharmacy retail price (PRP) of the prescribed product), the pharmacist may dispense the prescribed medicine. This “triviality limit” was introduced in 1996.

Substitution in the pharmacy

In order to assist the pharmacies in dispensing the correct medicine based on the prices in the substitution group and the “triviality limits”, every pack in a substitution group is marked with the letters A, B or C. “A” indicates that this pack is a first choice, “B” indicates that the price of the pack is within the acceptable price limits, making dispensing optional but not

mandatory, and "C" indicates a pack which as a rule should not be dispensed according to the prescription. These rules – together with rules on the pharmacy obligation to inform the patient if several smaller packs are cheaper than one large pack, are set out in the Guidelines on the pharmacies' duty to substitute and inform on cheaper combinations of similar smaller packs, No. 45 of 29 May 2006.

Pharmacies in Denmark are not allowed to substitute therapeutically.

It happens that the medicine (active substance) which is cheapest in the hospital sector is the most expensive in the primary care sector. The Drug and Therapeutic Committee 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' (GP) prescriptions.

3.3.2.2 INN prescribing

Doctors are not allowed to prescribe generically in Denmark, but have to use the name of the medicine when prescribing, irrespective of whether the medicine is an original product, a generic or a parallel imported product.

Due to a recommendation[58] by the Committee on Medicinal Product Reimbursement, the Ministry of the Interior and Health (IM) asked the Danish Medicines Agency (DKMA) to prepare a report on generic prescribing. The report "Generic prescriptions – advantages and disadvantages" of 22 November 2006 has been presented to the Ministry and to the Parliament's Health Committee. At the time of writing the DKMA does not recommend the introduction of generic prescription. One reasons for this is that the patient safety advantages which may stem from generic prescription are not documented.

3.3.2.3 Other generic promotion policies

The use of generics has been promoted through the health systems by means of generic substitution and the reference price system from the early 1990s, and both systems have become well established in Denmark over the years. They are both well-known measures of cost-containment and both present a financial incentive to the patients. The Institute for Rational Pharmacotherapy (IRF) regularly promotes generic substitution to general practitioners (GP) from the perspective of rational pharmacotherapy, and the consultants in the former counties did so too. This is an activity which presumably will continue in the new regions.

There are no financial or other incentives for doctors to encourage them to make generic substitutions, but for the patient there is normally a rather strong financial incentive. For the pharmacies there is no financial incentive due to the linear mark-up scheme.

[58] Commission Report No. 1444 of May 2004 on "Medicinal Product Reimbursement and proper use of medicinal products"

3.3.3 Claw-backs / Pay back

Claw-backs are not used in Denmark.

3.3.4 Monitoring

This section provides an overview of the programmes and methods used to evaluate the pharmaceutical policy and system, and its impact on health, access to medicines, and cost-containment. It mainly focuses on monitoring of prescriptions, price, expenditure and consumption.

3.3.4.1 Prescription monitoring

In Denmark the authorities rely on advice and recommendations – and reimbursement rules – and most doctors prescribe according to the issued guidelines. With a few exceptions, there are no obligatory guidelines which doctors must follow. Doctors are allowed to extrapolate outside registered indications – in fact, sometimes this is a necessity. The prescriptions on all reimbursed packs are monitored by the regions (with the primary objective of reimbursing pharmacists as the reimbursement is deducted at the pharmacy) and all prescriptions are also monitored by the systematic pharmaceutical system ORDIPRAX (http://www.ordiprax.dk) which is an online system where all doctors can compare their own prescribing habits with those of their colleagues in the region. The pharmaceutical statistics are very detailed and transparent. There is no annual audit of all doctors, but most doctors are offered a – voluntary – visit from fellow general practitioners (GP) organised by the regional pharmaceutical office, to give advice and recommendations on good prescribing practice.

The Danish Medicines Agency (DKMA) also administrates a database containing information on all sales taking place at pharmacies, thus allowing a detailed survey of prescription patterns.

Doctors have ample opportunity to receive detailed and valuable information on medicines. Many sources of pharmaceutical information exist, in particular information from INFOMATUM (pharmaceutical information books and an online service for a personal digital assistant (PDA)) and from the Institute for Rational Pharmacotherapy (IRF), which provides an online service where most new medicines and new studies of interest are reported. INFOMATUM Ltd. is a subsidiary company of Danish Drug Information Ltd. (Dansk Lægemiddel Information A/S, DLI).[59]

In this way, doctors receive balanced pharmaceutical information from independent sources. The Institute for Rational Pharmacotherapy (IRF) also issues a monthly 4-page pharmaceutical information journal, gives courses in pharmacotherapy for doctors and pharmacists and supports these activities with visits from the regions. Furthermore, the Institute for Rational

[59] http://www.dli.dk (in Danish only)

Pharmacotherapy (IRF) issues lists of recommendations on therapeutic areas (Den Nationale Rekommandationsliste, the National List of Recommendations) recommending which medicines to choose and in which strengths.[60] The Danish Medical Association (DADL) is represented in the board of INFOMATUM and has a seat in all levels of the governing bodies. DADL does not produce pharmaceutical information – with the exception of some articles in the Weekly Journal of the Danish Medical Association.

The scientific society of general practitioners (GP), the Danish College of General Practitioners (DSAM), has issued clinical guidelines on various therapeutic areas, e.g. heart disease, diabetes, osteoporosis, depression, etc. Not all clinical areas are covered as yet. The guidelines are sent to all GPs and are also available online (www.dsam.dk). Other scientific societies (specialists) also issue clinical guidelines on relevant subjects. None of these guidelines are revised on a regular basis, but rather only when needed.

3.3.4.2 Price monitoring

In Denmark medicines are freely priced. The pricing system as such is therefore not reviewed, but overall price development is monitored on a monthly basis. The price agreement between the Ministry of the Interior and Health (IM) and the Danish Association of the Pharmaceutical Industry (Lif) is monitored every two weeks when drawing up the price list.

The DKMA monitors monthly price developments through price indexes and average prices, maintaining two different sets of price indexes: one is based on prices per defined daily dose (DDD), and the other is based on prices per pack. Both sets of indexes contain seven subcategories of medicines, each having indexes for pharmacy retail price (PRP), the pharmacy purchasing price and patient co-payment. For reimbursable prescription-only medicine(s) (POM) there is also an index for reimbursement.

The indexes are calculated monthly, in the form of a Laspeyres index with changing weights. Prices are thus weighed according to the quantity sold the previous year. Similar to the monthly monitoring of prices, the DKMA also monitors monthly regional reimbursement. The monitoring is carried out quarterly and encompasses the developments according to the sold amount (DDD), turnover and reimbursement of reimbursable medicines. Comparisons are made with the same quarter of the previous year.

Over the years a number of committees and working groups have been established by the Ministry of the Interior and Health (IM), with participation from relevant stakeholders, e.g. central and regional authorities, professional associations and organisations, etc., and with the purpose of evaluating pricing and reimbursement policies and making recommendations on potential changes as necessary.

The latest recommendations were

- Developments in medical expenses in 1994

[60] http://www.irf.dk

- Challenges in the field of medicines in 1998
- Organisation of medicine sales in Denmark in 1999
- Reimbursement and rational use of medicines in 2004

In several cases changes to the regulations were made as a consequence of these recommendations.

3.3.4.3 Pharmaceutical expenditure monitoring

All pharmaceutical expenditures are monitored by Danish Medicines Agency. The database was established in 1993. The register is updated monthly for executive use. A public edition is updated yearly. This can be seen on the Danish Medicines Agency's homepage: http://www.medstat.dk. These data contains aggregated figures.

Each sale is registered and it is therefore possible to monitor the expenditures per region, per patient etc. In Denmark physicians have a free choice of prescription. Because of that it is not possible to monitor the pharmaceutical expenditure per diagnosis.

3.3.4.4 Consumption monitoring

Individual consumption data are monitored via a database containing information on all sales taking place in pharmacies, administered by the DKMA. For each attendance it is recorded which medicine is handed over, including its pack size, strength and form, and further data stored include the prescribing general practitioner (GP), a personal identifier for the patient, age, sex, substitution at the pharmacy, reimbursement and payment, indication and dose. The DKMA therefore has the possibility of monitoring prescription patterns and pharmaceutical use in detail. Each month pharmacies, hospital pharmacies, shops authorised to sell OTC and the Statens Serum Institute (SSI, http://www.ssi.dk) send in electronically this information on their sales.

Detailed statistics describing consumption of medicines in Denmark (Anatomic Therapeutic Chemical (ATC), age, sex, region, number of people treated, amount and expenses) are available online (http://www.medstat.dk). Consumption of pharmaceuticals sold on the Internet is not monitored systematically.

It is not possible to follow the compliance of the medicines prescribed.

3.3.5 Assessment and evaluation

3.3.5.1 Decision-making tools

There is no formal legal source for health-economic analysis in Denmark, but several public and private institutions perform health-economic analyses. Health-economic analyses are applied to assess medicines in a health technology assessment (HTA). Depending on whether clinical effectiveness has been shown to reach one or more endpoints, e.g. the overall survival, a cost-effective analysis will be performed. In cases where no overall sur-

vival or other relevant health-related endpoint has been proven, a cost analysis will be performed. If relevant, cost-benefit analyses will be included as well. The analyses are performed by health-economic institutes, e.g. the Centre for Applied Health Services Research and Technology Assessment (CAST) and the Danish Institute for Health Services Research (DSI).

The provision of a health-economic analysis is not necessary for obtaining market authorisation. The decision on issuing market authorisation is based solely on quality, safety and efficacy of the medicine and includes no economic aspects. As medicines are freely priced in Denmark the provision of a health-economic analysis is not necessary.

According to the Danish Health Act a health-economic analysis may be relevant in the reimbursement decision of a medicine. The applying company may submit a health-economic analysis to justify a high price, but this is not mandatory. A health-economic analysis as part of a reimbursement decision is only relevant for medicines containing a new active substance or a known substance in a new pharmaceutical form (different route of administration) and almost exclusively for prescription-only medicine(s) (POM) (generics and parallel imported medicines are granted reimbursement if the originator has been granted reimbursement, cf. Guidelines for Application for General Reimbursement of Medicinal Products of 13 July 2005).

The possibility of submitting a health-economic analysis as documentation to support an application for general reimbursement was introduced in 1997 by law (the “Price Freeze Act”).[61] The company itself is responsible for performing the analysis and for ensuring that this complies with the guidelines and the reporting structure.

In 1998 a set of rather broad guidelines “Guidelines for health-economic analyses of medicinal products”[62] (“Retningslinier for samfundsøkonomiske analyser af lægemidler”) were issued, and in 2004 the ”Standardised reporting structure for health-economic analyses in applications for general reimbursement”[63] (“Standardiseret rapporteringsstruktur for sundhedsøkonomiske analyser i ansøgninger om generelt tilskud til lægemidler”) was issued specifying how to structure and report a health-economic analysis.

It should be added that the number of health-economic analyses submitted to Danish Medicines Agency (DKMA) is limited. For the years 1999-2006 the DKMA received 26 analyses (of 22 medicines) and the annual number of analyses seems to be falling. Only 3-4 analyses have met the guidelines and have been performed according to “good health-economic practice”. However, only 20 analyses have been evaluated, i.e. if a medicine falls under one or more of the eligible criteria (cf. section 3.2.2.1), economic considerations are less relevant to the decision and the analysis may not be evaluated. E.g., this may be the case for products likely to be abused (cf. 3.2.2.1, subsection g).

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61 Act No. 224 of 25 March 1997 on Temporary Price Stop on Pharmaceuticals, etc.

62 http://www.dkma.dk/~/media/08161051F5B544FFBCC7627B1AF9A9D7.ashx

63 http://www.dkma.dk/~/media/00E138EADEDC4D24A263C0814918D1B9.ashx

3.3.5.2 Evaluation of measures

The provision of a health-economic analysis is not necessary for medicines.
If there will be a health-economic analysis the guidelines address the following issues:

- costs (direct costs, indirect costs, (intangible costs), discounting);
- outcome targets (intermediate outcome targets, utility-based/preference-based outcome targets, monetary outcome targets;
- design, analysis and data.

A health-economic analysis must be performed according to the guidelines and must be reported according to the standardised reporting structure, i.e. according to the following format:

- main results and summary
- introduction
- database
- analyses
- results, conclusion and discussion
- references
- appendices

Every item includes a number of questions which must be addressed by the health economist performing the analysis in order to secure a uniform performance of proper quality. The standardised reporting structure was drawn up on the basis of the Canadian Coordinating Office for Health Technology Assessment's (CCOHTA) reporting structure for health-economic evaluations. The Danish reporting structure was fitted to Danish guidelines for financial evaluation of medicines, and the questions for the analysis are based on areas that have been particularly problematic in previous Danish analyses. However, the two reporting structures are relatively similar.

The guidelines and the reporting structure are not revised on a regular basis but in connection with the preparation of the reporting structure in 2004 it was decided that there was no need to update the guidelines. However, the guidelines will be updated in accordance with new health-economic knowledge that becomes available. The DKMA is formally in charge of the evaluation of guidelines but the Agency does not have health-economic expertise. The preparation of the standardised reporting structure was therefore carried out by the Danish Institute for Health Services Research (DSI) in consultation with the two other institutions that prepared the guidelines (the University of Copenhagen and the University of Southern Denmark).

The evaluation of the analyses themselves is carried out by the Danish Institute for Health Services Research (DSI) for the DKMA. Supplementary to the guidelines and the reporting structure, the DKMA has planned the issuing of a set of guidelines for the evaluation of health-economic analyses to secure that the evaluation, too, is uniform.

The maximum value of a quality-adjusted life year (QALY) has not been applied regarding the decision on general reimbursement of a medicine. In fact, practically all analyses have been cost-effectiveness analyses and did not include QALY considerations.

3.3.5.3 Reports and results

The reimbursement status of all medicines must be reassessed regularly. The Danish Medicines Agency do so to make sure that the medicines which bear reimbursement automatically (so-called general reimbursement) satisfy the eligibility criteria, and that medicines without general reimbursement do not satisfy the criteria. The process of reassessing the reimbursement status was adopted by the Danish Parliament in 2004 based on Recommendation no. 1444 of May 2004 titled “Reimbursement and appropriate use of medicines”.

On this background, the Danish Medicines Agency has reviewed the reimbursement status of some of the medicines. An overview of the situation of the reassessment of medicines' reimbursement status is available on www.dkma.dk.

The result of the reassessment until now has led to that most of the medicines continued to be granted general reimbursement, a few lost their general reimbursement status and reimbursement for other medicines will only be granted in special circumstances.

The reimbursement change is intended to encourage general practitioners to a rational medicinal treatment, i.e. an equally effective treatment of hypertension and other cardiovascular diseases at a lower cost. As a general rule, it is rational to prescribe the less expensive medicines eligible for general reimbursement (without any reimbursement condition), and reserve the more expensive medicines with conditional reimbursement for the patients for whom the general practitioner assesses – based on an overall assessment of the patient’s pathological picture – that they can only be treated with these products. The objective is not to save money, but to provide equally efficient treatment at a lower cost.

The financial implications of the changes on 15 November 2010 within the cardiovascular products (antihypertensives) is that the savings for patients and the public sector amount to approx. DKK 300 million / around € 40 million per year, even if the change requires extra consultations to check blood pressure.

The financial implications of the changes on 15 November 2010 within the medicines for the treatment of heartburn, sour eructations or ulcers is that the estimated savings for patients and the public sector amount to DKK 140-170 million / € 18.7 – 22.5 per year.

3.4 Overview on policy measures in the out-patient sector

Table 3.11: Denmark – Policy measures in the out-patient sector, 2005–2010

Measures	Description	Year
Changes in the pricing policies (e.g. new policies or methodology and changes, external price referencing; price freezes / cuts, (obligatory) discounts	-	
Changes in the regulation of the mark-ups	-	
Changes concerning the VAT rates on medicines	-	
Changes regarding the reimbursement lists and schemes (e.g. de-listings, new reimbursement scheme)	There have been changes concerning specific medicines or groups of medicines such as lipid lowering medicines, COX-2-inhibitors, antihypertensives and medicines for acid-related disorders	2003, 2009, 2010
Changes regarding a reference price system (e.g. introduction, methodology changes conc. clustering and/or the reference price)	Changes in the country baskets. External price referencing was abandoned: reimbursement price for products eligible for generic substitution was changed to be the lowest price in the reimbursement group	2000, 2001 2005
Changes concerning OPP in the out-patient sector (e.g. introduction of a prescription fee, increase of percentage co-payments)	The introduction of the need dependant system and the basically different out-of-pocket payment	2000
Changes in the generics policies (e.g. introduction of INN prescribing, generics substitution)	-	
Changes concerning monitoring of medicines (e.g. new monitoring tools)	-	
Changes concerning evaluations and assessments (e.g. price review, reimbursement reviews)	The Danish Medicines Agency has started reassessing the reimbursement status of all medicines.	2004

conc. = concerning, OPP = out-of pocket payment, VAT = value added tax

Description = please list the major measures in the field of policy measures mentioned

Year = please list the year in which the measures were taken

Source: PPRI Pharma Profile Denmark 2008

4 Pricing, reimbursement and volume control in the in-patient sector

4.1 Pricing and procurement in the in-patient sector

4.1.1 Pricing

4.1.1.1 Framework

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

However, pharmaceutical companies are obliged to report their pharmacy purchasing prices (list prices) for all medicines on the market, including hospital medicines, to the Danish Medicines Agency (DKMA)[64]. 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[65].

The legislative framework for medicines prices is common for the out-patient and hospital sector but the pricing procedure differs.

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.

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

In 2009 a major public investigation of pharmaceutical prices, consumption and expenditures was made. The following report resulted in two developments. Firstly, an agreement with the pharmaceutical industry was concluded, which called for a 5 percentage points reduction of list prices of hospital medicines as of 1 January 2010 followed by a price freeze. Secondly, initiatives to strengthen the management of the consumption of hospital medicines were taken. Among these was the appointment of a common regional pharmaceutical and therapeutic committee on expensive hospital medicines (RADS).

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

[65] www.medicinpriser.dk

4.1.1.2 Hospital prices

The system of pricing in hospitals (of all medicines and not exclusively hospital-only medicine(s) (HOM)) differs from the system of pricing in the out-patient healthcare sector. The 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 are included in the published prices.

The pharmacy purchasing price 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.

Until 31 December 2006 some hospital pharmacies carried out their own procurement. As of 1 January 2007 Amgros[66] has been carrying out most of the public tenders on medicines. Today Amgros covers more than 98% of the medicines used by hospitals. On average, Amgros obtains a 19% discount on the pharmacy purchasing price. In 2008 the pharmaceutical turnover in hospitals was DKK 4,771 Mio./€ 636 Mio., and Amgros obtained a direct discount of DKK 888 Mio./€ 118 Mio. Amgros organises tenders 60-70 times a year and publishes the tenders at its website.

- Discounts are solely obtained through Amgros tenders and negotiations. No mandatory discounts apply.
- Amgros charges a common mark-up of 2,5% on the prices of pharmaceuticals where Amgros has obtained a discount.

As Amgros make up for more than 98 percent of all pharmaceuticals used in hospitals all public hospitals face the same price on each pharmaceutical product. There are accordingly no needs for price comparisons between hospitals.

In 2009 a major investigation into the prices and expenditures of hospital medicines were carried out resulting in a report: “Analyse af sygehusmedicin. Rapport fra arbejdsgruppen om sygehusmedicin, Maj 2009” (AAS 2009).

The investigation contained an international price comparison which showed that the Danish list prices – as well as realized prices after discounts – were higher than several other neighbouring countries.

As a result of the report the price agreement with industry mentioned in section 4.1.1.1 was made up.

[66] AMGROS is a publicly owned company which deals with tendering, negotiation, and administration of contracts with the pharmaceutical companies on behalf of the Danish hospitals.

4.1.2 Purchasing policies

4.1.2.1 Tendering

More than 98% of the medicines used in public hospitals are purchased through Amgros, which is a hospital purchasing agency owned by the five regions, i.e. the owners of public hospitals in Denmark.

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 its website[67]. The tenders usually cover more than one product. The tender process is organised on 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 (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. Amgros gains on average 19% discount on the pharmacy purchasing price (Amgros, 2008).

A lot of new and expensive medicines are only produced by one manufacturer, and therefore they are not subject to competition. Those suppliers have no incentive to bid on tenders. Amgros therefore has to purchase these medicines at the pharmacy purchasing price without receiving a discount.

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. In some cases discounts of up to 90% has been seen.

4.1.2.2 Negotiations

Amgros uses tendering to a large degree but also negotiates directly with companies.

4.1.2.3 Other purchasing policies

There are no other pricing policies.

[67] www.Amgros.dk

4.1.3 Organisation of procurement

Amgros is the hospital purchasing agency owned by the five regions, i.e. the owners of public hospitals in Denmark. Amgros holds tender and signs contracts for almost all medicines at 5th ATC level.

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.

In the tender, 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 (AAS, 2009).

4.2 Reimbursement in the in-patient sector

4.2.1 National framework

In Denmark all hospital treatment in public hospitals, including medicines, is provided free of charge to the patient. All hospital expenditures including medicine treatment are 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 1.3.2).

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 always directly relevant for hospitals since the price of medicines in the out-patient sector often differs from the prices of medicines used in the hospitals. However, hospitals in general seek to coordinate the recommendation lists of the two sectors, cf. section 4.2.2 below.

In general, hospitals do not use special budgets for specific medicines.

4.2.2 Hospital pharmaceutical formularies

Every region in Denmark has one or more pharmaceutical and therapeutic committee(s) (PTC) that makes the relevant decisions regarding the medicines 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 and new prices are known. The inclusion in the formulary will depend on an assessment of the effectiveness of the pharmaceuticals, side effects and price. Normally, the formulary will state the name of the concrete pharmaceutical to be used

as first choice. Doctors may deviate from the formulary but this will often be subject to an administrative procedure or approval.

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[68].

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 therapeutic equivalent substance instead, to prevent substantial expenses in the out-patient 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 the out-patient sector in Denmark, cf. section 3.3.2.1.

As a result of an investigation on hospital medicines in 2009, cf. Section 4.1.1.2, the regions have in 2010 formed a common pharmaceutical committee on expensive hospital medicines. The aim of the committee is to develop common recommendations list and treatment guidelines for all regions on expensive hospital medicines.

4.2.3 Pharmaceutical and Therapeutic Committees

Every region in Denmark has one or more pharmaceutical and therapeutic committee(s) (PTC).

The detailed organization, members, number of meetings etc. differ according to the decision of each region.

The decisions of the PTCs are binding in the sense that deviations normally will be subject to an administrative procedure or approval and will be monitored. In a juridical sense doctors are according to the law free to prescribe the medicines they wish.

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 out-patient 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 out-patient care sector as well.

As mentioned in section 4.2.2 the regions have in 2010 formed a common pharmaceutical committee on expensive hospital pharmaceuticals.

The role of pharmacists is briefly explained in section 4.3.1.3.

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

4.3 Volume control in the in-patient sector

4.3.1 Monitoring

This section provides an overview of the programmes and methods used to evaluate the pharmaceutical policies and system in the in-patient sector, and its impact on health, access to medicines, and cost-containment. It mainly focuses on monitoring of prices, pharmaceutical expenditure and consumption.

4.3.1.1 Price monitoring

In May 1993 the Register of Medicinal Product Statistics was established as a publicly run register of pharmaceuticals statistics with a view to the drafting of statistics and price indexes as well as to monitor the consumption of medicines and thus to strengthen the basis for the central health authorities' decisions.

The Danish Medicines Agency (DKMA) is hosting and being responsible for the Register.

With regard to the in-patient sector the register is based on reported data from hospital pharmacies on prices and consumption. Data are transformed to statistics by the agency and published regularly on the agency's website.

As of 2009 the hospital pharmacies report have been standardised to a larger extent making up for an improvement of the quality of statistics.

Prices are not monitored by government on a regularly basis. However, in 2009 an investigation showed that Danish prices were above the price level of some neighbouring countries. This led to an agreement with industry of a list price reduction of 5% as of January 1. 2010 followed by a list price freeze. The report on the investigation (ASS 2009) is mentioned in section 4.1.1.2.

The price level of hospital medicines will be analysed more regularly in the future.

However the running monitoring of prices is done by Amgros on behalf of the regions that are responsible for the expenditures of the hospital sector. This monitoring is not publicly available.

4.3.1.2 Pharmaceutical expenditure

Monitoring of the in-patient sector is done by Amgros on a regular basis. Since 2007 Amgros has been providing every quarter 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 sent to a limited group of stakeholders.

In 2009 hospital medicines prices, consumption and expenditures were subject of an investigation by a working group of members from the Ministry of the Interior and Health, the Ministry of Finance and the regions union cf. section 4.1.1.2 for more details.

4.3.1.3 Consumption monitoring

At hospital level the hospital pharmacists monitor the doctors' choice of medicines using electronic medicines modules: 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 (economically) 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 a more expensive medicine, as long as the total consumption of the ward is within the budgetary limits.

Although doctors are free to prescribe the medicine they wish several administrative procedures are in effect in hospitals in case of deviations from recommendation lists and treatment guidelines. The concrete procedures vary from region to region and hospital to hospital. Deviations are monitored and follow-up mechanisms in effect according to the decision of the region and hospital. Monitoring is an internal managing device and not in general published.

Following the 2009 public investigation of hospital medicines (cf. section 4.2.2) the development of consumption of hospital medicines has received more attention at both hospital level, regional level and state level. Further analysis of the effectiveness of the methods used in the hospitals will be carried out in the future in order to identify, describe and measure the most efficient methods of steering consumption.

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. Hospital pharmacists work with the Pharmaceutical and Therapeutic Committee (cf. section 4.2.3).

4.3.2 Assessment and evaluation

4.3.2.1 Decision-making tools

All regions use pharmaceutical and therapeutic committees to work out recommendation lists for the choice of hospital pharmaceuticals and these lists can be supplemented by treatment guidelines. The work of the committees is generally based on guidelines from scientific societies, the national cancer steering group and the committee for evaluation of cancer medicine (UVKL), the Institute for Rational Pharmacotherapia or other national recommendations.

Pharmaco-economic analyses are made by a national institute affiliated to the National Health Board (SST). Analyses are made on an ad hoc basis and cover medicines in the in-patient sector as well as the out-patient sector.

4.3.2.2 Evaluation of measures

Health Technology Assessments (HTA)

In Denmark 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[69]. The Danish Centre for Evaluation and Health Technology Assessment (DACEHTA) carries 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 levels as well as related research communities.

In cooperation with local HTA environments, the 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.

4.3.2.3 Reports and results

Health Technology Assesments (HTA) are made on an ad hoc basis. The reports are available on the SST's website[70]. External audit reports are not available.

[69] http://www.sst.dk/English/DACEHTA.aspx
http://www.sst.dk/default.aspx?lang=en

4.4 Overview of policy measures in the in-patient sector

Table 4.1: Denmark – Policy measures in the in-patient sector, 2005–2010

Measures	Description	Year
Changes in the pricing framework (e.g. change pricing regulation with relevance for the in-patient sector, change in hospital specific mark-up / VAT which is relevant for the in-patient sector)	None concerning the legislative framework. An agreement on prices were made in 2009 between government and industry	2009
Changes in procurement (e.g. establishment of new procurement agency, change in relevance of tendering vs. negotiations etc.)	The regions tendering procedures were united under Amgros in 2007	2007
Changes regarding the reimbursement lists (e.g. concerning a national hospital list, the HPF, ...)	The regions have formed a common Committee for Expensive Hospital Medicines (RADS) in 2009	2009
Changes in funding (e.g. specific budgets for specific medicines, concerning OPP in the in-patient sector)	The funding of hospital sector in general were laid down in the municipal reform of 2007	2007
Changes concerning evaluations and assess-ments	None	

HPF = hospital pharmaceutical formulary, OPP = out-of pocket payment, VAT = value added tax

Source: The Ministry of the Interior and Health

5 Interface management and developments

This concluding chapter covers information about the interface management and the most important pharmaceutical developments for the health care system.

5.1 Interface management

The hospital pharmaceutical formularies at the hospitals are coordinated with the list of recommendations for medicines in out-patient care sector. The coordination is done by the pharmaceutical and therapeutic committees (PTC) in each region. The aim is to prescribe medicines in a rational way so the prescription of a medicine, which is expensive in the out-patient 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 out-patient care sector. The PTC may therefore choose a therapeutic equivalent substance instead, to prevent substantial expenses in the out-patient 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.

An electronic patient medicines' register covering all dispensed medicines in the in-patient and out-patient sector is under development.

5.2 Developments in the out-patient and the in-patient sectors

In-patient sector:

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 working committee, 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.

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. As a result of negotiations the regions have formed a common Committee for Expensive Hospital Medicines (RADS) which is to develop common recommendations and treatment guidelines for expensive hospital medicines.

Out-patient sector:
No major changes are foreseen in the regulation of the out-patient sector concerning medicines. However a process of reassessment of the reimbursement status of all out-patient medicines was decided in 2004 and is still in progress.

The future:
The future faces several challenges related to the pharmaceutical system. These include the points listed here.

- One of the major reasons for the rising pharmaceutical expenditure (PE) is an ageing population and the uptake of new, more effective and more expensive medicines, combined with more intensive medical treatment including a rising number of different substances.

- The introduction of new innovative medicines at the optimum time, i.e. neither too early nor too late.
- A lack of relevant head-to-head clinical trials of new medicines against existing treatment.
- The so-called lifestyle medicines and the wider concept of disease as an ethical and economic challenge.
- How to evaluate “therapeutic added value”, i.e. definitions combined with useful and operational standard operation procedures.
- Promotion of relevant research in order to make new and better medicines for patients.
- Promotion of a better balance between neutral information given to doctors and patients and industry marketing initiatives.
- Focus on prevention in general, and more specifically on new medicines, e.g., the use of new vaccines, etc.

Organisational changes in 2012 (pls. note that this paragraph was included after these changes happened):

- As of 1 March 2012 the Danish Medicines Agency and the Danish National Board of Health merged into the Danish Health and Medicines Authority (Sundhedsstyrelsen, DHMA). Some divisions in the organisation differ from the ones described in this profile.
- At the same time the managing of the Danish Register of Medicinal Product Statistics was transferred from the Danish Medicines Agency to the State Serum Institute, Division of Data Deliveries and Medicinal Product Statistics. The official name in English is now The Danish Register of Medicinal Product Statistics.
- In October 2011 the Ministry of the Interior and Health (Indenrigs- og Sundhedsministeriet, IM) became The Ministry for Health and Prevention.
- As of 1 July 2012 DSI merged with two other research institutions under the name Danish Institute for local and regional government research (KORA”) http://kora.dk

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6.2 Legislation

The Danish Medicines Act, No. 1180 of 12 December 2005, www.retsinfo.dk

The Danish Pharmacy Act, No. 1180 of 12 December 2005, www.retsinfo.dk

The Danish Health Act, No. 546 of 24 June 2005, www.retsinfo.dk

6.3 Web links

The Danish Medicines Agency (DKMA). http://dkma.dk

Institute for Rational Pharmacotherapy (IRF): http://www.irf.dk

Medicine Profile: http://www.medicinprofilen.dk

The annual statistics on pharmaceuticals. http://www.medstat.dk/

Ordiprax. www.ordiprax.dk

National Board of Health (SST): http://www.sst.dk

Prices of pharmaceuticals in Denmark: http://www.medicinpriser.dk

Statistics Denmark: http://www.dst.dk

Glossary on Pharmaceutical Terms of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, http://whocc.goeg.at/Glossary/Search