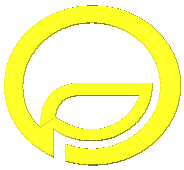

Pharmaceutical Pricing and Reimbursement Information

DENMARK

February 2008

Commissioned by
European Commission, Health and Consumer Protection Directorate-General and
Austrian Ministry of Health, Family and Youth

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Pharma Profile

Final, February 2008

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Executive summary

Background

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. Of the total expenditure on health care in Denmark in 2005, public expenditure constituted a little more than 84% and private expenditure a little less than 16%.

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).[1] 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 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 the hospitalisation period, along with preventive treatment and promotion and treatment of alcohol and drug abuse.

General practitioners (GP) act as gatekeepers and they are predominantly remunerated via fee-for-service payments and partly via a capitation system.

One of the main tasks for the actors in the health system at state level (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 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. Another very central actor is of course the Danish Parliament.

Pharmaceutical system

One of the main laws in the pharmaceutical field is the Danish Medicines Act, with provisions for authorisation and control of pharmaceuticals 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 third central act, the Danish Health Act, sets out rules on

[1] The five regions were established on 1 January 2007 as a consequence of a new local government reform to replace the former 15 counties at the regional level. At the same time, several of the former 271 municipalities merged to form 98 municipalities.

various issues within the health care system, including those regulating reimbursement of pharmaceuticals in Denmark.

The main actors in the Danish pharmaceutical system are, besides the central actors mentioned above, the doctors, the patients, the industry and the pharmacies. The Danish Medicines Agency's (DKMA) mission is to make effective and safe health products, i.e. pharmaceuticals, 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 authorisation of products and professionals, pharmacovigilance, reimbursement, pricing, statistics on pharmaceutical consumption, etc.

The pharmaceutical industry is a significant sector in the Danish economy. In 2006 the country‘s pharmaceutical export amounted to almost € 5 billion. Approximately 166 companies are authorised and inspected by the Danish Medicines Agency (DKMA) to carry out pharmaceutical activities (pharmacies and wholesalers excluded). Over the years the consumption of generics has gradually grown and in 2006 amounted to 39% of the total consumption in the primary care sector, measured in volume. For parallel imported pharmaceuticals the figure was 9%. The total number of wholesalers in Denmark is approximately 250, of which three are major wholesale companies providing a full product range. The wholesale system is a multi-channel system.

In Denmark pharmaceuticals are mainly sold through pharmacies or branch pharmacies, which have the monopoly on the sale of prescription-only medicine(s) (POM) to consumers. There are 267 pharmacies in total (in 2006) and 55 branches of pharmacies, approximately 130 pharmacy shops and 700 over-the-counter (OTC) sales outlets, which are all affiliated to one of the pharmacies. Furthermore 1,450 retailer shops are authorised to sell a limited number of over-the-counter (OTC) pharmaceuticals.

The 14 hospital pharmacies in Denmark provide pharmaceuticals for hospitalised patients. The hospital pharmacies order and buy pharmaceuticals via the hospital purchasing agency’s (AMGROS) electronic purchasing system.

In 2005 there were 18,600 medical doctors. There are no dispensing doctors in Denmark.

The associations of the various types of pharmaceutical companies (research-based, generics, parallel imported pharmaceuticals, wholesale) and the associations of pharmacies and doctors are consulted by the Ministry of the Interior and Health (IM) and the Danish Medicines Agency (DKMA) when preparing new bills and governing orders affecting their respective areas, and they may be represented in official committees and working parties as well. The same applies to the umbrella patient organisations.

Total pharmaceutical expenditure (TPE) in 2005 was € 1,602 Mio., equalling 11.5% of the total health care expenditure and € 405 per capita. The public share was 70% and the private share was 30% of the total pharmaceutical expenditure (TPE).

Pricing

All pharmaceuticals at manufacturer and wholesale levels are freely priced. The wholesale margin is not regulated by law, but rather is negotiated individually between wholesalers and

pharmaceutical companies. Pharmaceutical companies must report their pharmacy purchasing prices (PPP) for all pharmaceuticals on the market to the Danish Medicines Agency (DKMA). The Danish Medicines Agency (DKMA) then calculates the pharmacy retail price (PRP) via a linear mark-up scheme set out in the Executive Order on the Calculation of Consumer Prices of Medicinal Products. The Danish Medicines Agency (DKMA) also calculates the reimbursement price for all reimbursable products which are eligible for generic substitution.

The price list is distributed by the Danish Medicines Agency (DKMA) to all pharmacies. There are no pricing criteria and there is no price approval or price negotiation, etc. for any pharmaceuticals. The prices can be altered by the company every two weeks when a new official price list is drawn up by the Danish Medicines Agency (DKMA). The total pharmacy profits are negotiated every two years, and the pharmacy mark-up scheme is adjusted accordingly.

This pricing system has existed for many years. Over the years, however, there have been certain interventions or agreements between the authorities and one or more of the industry associations. These arrangements have included periodically price freezes, price cuts and price ceilings.

Over-the-counter (OTC) products that may be sold by authorised retailers, e.g. supermarkets, are subject to completely free pricing at all levels, which means that – contrary to other pharmaceuticals – the pharmacy retail price (PRP) may differ between the distributors and throughout the country.

In Denmark, as a rule it is not allowed to offer any discounts to health professionals in order to promote sales. However, discounts given to retailers and due to reduced suppliers' costs are legal but subject to strict regulation according to the Executive Order on Advertising, etc. of Pharmaceuticals. The discounts must be directly related to the retailer's ordering behaviour which must differ from the supplier's regular conditions for trade (cost-related discounts).

A tendering process is undertaken for most of the pharmaceuticals used in hospitals. Tendering is carried out by the hospital purchasing agency, AMGROS, owned by the regions, i.e. the owners of public hospitals in Denmark. The prices in the contracts that AMGROS makes with the suppliers are not open to the public.

Reimbursement

The predominant system is characterised by the following aspects:

- a positive list including both prescription-only medicine(s) (POM) and over-the-counter (OTC) pharmaceuticals;
- variable reimbursement rates (a needs-based system) depending on the consumption of the patient within a 12-month period and disease status as chronically or terminally ill;
- over-the-counter (OTC) pharmaceuticals are only reimbursed for patients with defined illnesses or for pensioners;
- patients' out-of-pocket payments (OPP) are based on the reimbursement price (reference price system);

- the Danish Medicines Agency (DKMA) may grant individual reimbursement to a patient for a specific non-reimbursable pharmaceutical at the request of the doctor.

Reimbursement from the regions, with the Regional Councils as the third-party payer, constitutes a considerable proportion of pharmaceutical expenditure (PE). The reimbursement amount is deducted from the price by the pharmacy. The regions only grant reimbursement for eligible pharmaceuticals and in cases when the patient has been granted individual reimbursement for a given pharmaceutical. If the pharmaceutical is eligible for general reimbursement, anybody (or anybody suffering from specific diseases) can be granted reimbursement.

The criteria for general reimbursement are set out in the Executive Order on Reimbursement. The Danish Medicines Agency (DKMA) evaluates whether the pharmaceutical has a safe and valuable effect on a well-defined indication and whether the price of the product is proportionate to the therapeutic value. As a rule, a pharmaceutical is not eligible for general reimbursement if there is an imminent risk that the product will be used for purposes other than the authorised use, if the pharmaceutical is primarily being used for purposes for which reimbursement cannot be expected from the State, or if there is an imminent risk of abuse of the product, etc.

If a pharmaceutical is not subject to general reimbursement, the doctor may apply to the Danish Medicines Agency (DKMA) for individual reimbursement on behalf of the patient. If granted, the reimbursement will be the same as for pharmaceuticals eligible for general reimbursement. The Danish Medicines Agency (DKMA) must consider whether the pharmaceutical carries special therapeutic significance for the patient and whether other relevant therapies have been found to be inadequate or inappropriate in that specific case.

The reimbursement system is needs based. The amount of reimbursement depends on the patient's overall annual expenses for pharmaceuticals eligible for reimbursement (general and individual). Up to a certain level, the patient pays all the costs of her/his reimbursable pharmaceuticals. When this level is reached, the National Health Service (NHS) offers a percentage reimbursement which increases with increasing consumption.

Products that are identical in terms of active substance, pharmaceutical form and strength (original, parallel imported and generics) may have very different prices. To encourage doctors and patients to choose the cheapest alternative, the percentage reimbursement for a pharmaceutical is calculated on the basis of the reimbursement price. The reimbursement price is either the actual price of the pharmaceutical or the price of the cheapest alternative with the same constituents. The reference price system is closely related to the system of generic substitution.

Social criteria are not part of the predominant reimbursement scheme, except for some over-the-counter (OTC) pharmaceuticals that are eligible for reimbursement to pensioners. According to the social laws, however, vulnerable population groups may be given additional reimbursement, e.g. it is possible for pensioners, people with low incomes, and disabled people staying in their own home to receive supplementary reimbursement covered and administered by the respective municipality.

According to a decision by the Danish Parliament, the Danish Medicines Agency (DKMA) has started reassessing the reimbursement status of all pharmaceuticals over a 5-year period. All pharmaceuticals will be reviewed to ensure that products that have been granted general reim-

bursement still meet the eligibility criteria and, conversely, that pharmaceuticals which have not been granted general reimbursement still do not meet these criteria.

Rational use of pharmaceuticals

There are no obligatory budgetary constraints for doctors in place in Denmark, but doctors have to take the current reimbursement policy into consideration when prescribing. The authorities rely on advice and recommendations. If a doctor's pharmaceutical prescribing considerably exceeds an average level, official action may be taken by the third-party payer, i.e. the region which manages the reimbursement according to the predominant reimbursement scheme. All general practitioners (GP) regularly receive an evaluation of their prescribing habits in the form of lists enumerating the amount and costs of prescribed pharmaceuticals. Doctors have ample opportunity to receive detailed and valuable information on pharmaceuticals from a number of sources including, e.g., the Institute for Rational Pharmacotherapy (Institut for Rationel Farmakoterapi, IRF).

All hospital wards manage their own budget for purchasing pharmaceuticals. The aim is for the doctors to prescribe only those pharmaceuticals which have been recommended by the Drugs and Therapeutics Committees.

Advertising through 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 prescription-only medicine(s) (POM) to a patient). Over-the-counter (OTC) advertising is allowed in all media, and advertising of pharmaceuticals on the Internet is also allowed.

There is no formal legal basis for health-economic analyses in Denmark but several public and private institutions perform such analyses. According to the Danish Health Act, a health-economic analysis may be relevant in the reimbursement decision of a pharmaceutical (primary care sector). The applying company may submit a health-economic analysis to justify a high price, but this is not mandatory.

Generics are used mainly as a cost-containment tool and play an important role in the current reimbursement system, i.e. the reference price system. Generic substitution in Denmark is closely related to the reference price system. For reimbursable pharmaceuticals the reimbursement groups are identical to the substitution groups, and the reference price system is based on the system of generic substitution. Generic substitution is mandatory for pharmacies, but doctors and patients are allowed to reject substitution.

In order to follow trends in the consumption of pharmaceuticals, data on consumption are monitored via a database, managed by the Danish Medicines Agency (DKMA), containing information on all sales taking place in pharmacies. For each patient it is known which pharmaceutical was handed over, including its pack size, strength and form. Further data stored include the prescribing general practitioner (GP), a personal identifier for the patient, age, sex, substitution at the pharmacy, reimbursement, payment, indication and dose. The Danish Medicines Agency (DKMA) therefore has the possibility to monitor prescription patterns and pharmaceutical use in detail. Each month pharmacies, hospital pharmacies, shops selling pharmaceuticals and the State

Serum Institute (SSI) submit electronically information on their pharmaceutical sales. A very detailed set of statistics describing consumption of pharmaceuticals in Denmark (Anatomic Therapeutic Chemical (ATC) classification, age, sex, region, number of people treated, amount and expenses) is available online.

Current challenges and future developments

The Danish Medicines Agency (DKMA) is experiencing – similar to authorities in many other countries – several challenges relating to the pharmaceutical system. A constant issue over several years is the rising pharmaceutical expenditure (PE), linked to an ageing population and the uptake of new, more effective and more expensive pharmaceuticals combined with more intensive medical treatment and including a rising number of different substances. Another challenge is trying to introduce new innovative pharmaceuticals at the optimum time, i.e. neither too soon nor too late.

Other ethical and economic challenges include the lack of relevant head-to-head clinical trials of new pharmaceuticals against existing treatment, along with the so-called lifestyle pharmaceuticals. In addition, among other things, definitions combined with useful and operational standard operation procedures are needed on how to evaluate “therapeutic added value”.

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Abbreviations

AMGROS	Hospital Purchasing Agency
ATC	Anatomic Therapeutic Chemical classification
CAST	Centre for Applied Health Services Research and Technology Assessment
CCOHTA	Canadian Coordinating Office for Health Technology Assessment
COPD	Chronic Obstructive Pulmonary Disease
CTR	Danish Medicines Agency Central Reimbursement Register
DACEHTA	Danish Centre for Health Technology Assessment
DADL	Danish Medical Association (Lægeforeningen)
DA	Danish Pharmaceutical Association
DDD	Defined Daily Dose
DKK	Danish Kroner (Danske Kroner)
DKMA (LMS)	Danish Medicines Agency (Lægemiddelstyrelsen)
DLI	Danish Drug Information Ltd. (Dansk Lægemiddel Information A/S)
DRG	Diagnosis-Related Group(s)
DSAM	The Danish College of General Practitioners
DSI	Danish Institute for Health Services Research
GDP	Gross Domestic Product
GGE	General Government Expenditure
GÖG/ÖBIG	Austrian Health Institute (Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG)
GP	General Practitioner
Ha	Pharmacy-restricted over-the-counter (OTC) pharmaceuticals
HE	Health Expenditure
Hf	Non-pharmacy-restricted over-the-counter (OTC) human pharmaceuticals
HiT	Health Systems in Transition
HOM	Hospital-Only Medicine(s)
HTA	Health Technology Assessment
Hx	Non-pharmacy-restricted over-the-counter (OTC) human pharmaceuticals (maximum 1 package per customer per day)
IGL	Danish Generic Medicines Industry Association
IM	The Ministry of the Interior and Health (Indenrigs- og Sundhedsministeriet)
IRF	Institute for Rational Pharmacotherapy (Institut for Rationel Farmakoterapi)
Lif	Danish Association of the Pharmaceutical Industry
Mio.	Million
MTN	Reimbursement Committee

n.a.	Not available
n.app.	Not applicable
NHIP	National Institute of Public Health (Statens Institut for Folkesundhed)
NHS	National Health Service
NICE	National Institute for Clinical Excellence
OECD	Organisation for Economic Co-operation and Development
OPP	Out-of-Pocket Payment
OTC	Over-The-Counter (pharmaceuticals)
PDA	Personal Digital Assistant
PE	Pharmaceutical Expenditure
PFL	Danish Association of Parallel Importers of Pharmaceuticals
PLO	Organisation of General Practitioners in Denmark (Praktiserende Lægers Organisation)
POM	Prescription-Only Medicine(s)
PPP	Pharmacy Purchasing Price
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy Retail Price
QALY	Quality-Adjusted Life Year
SSI	State Serum Institute (Statens Seruminstitut)
SST	National Board of Health (Sundhedsstyrelsen)
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
VAT	Value-Added Tax
WHO	World Health Organization

Introduction

The Pharmaceutical Pricing and Reimbursement Information (PPRI) project is a 31-month project (2005-2007) commissioned by the Health and Consumer Protection Directorate-General (DG SANCO) of the European Commission (EC) and co-funded by the Austrian Federal Ministry of Health, Family and Youth (Bundesministerium für Gesundheit, Familie und Jugend, BMGFJ). The project was coordinated by the main partner Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG (GÖG/ÖBIG) and the associated partner World Health Organization (WHO) Regional Office for Europe. The PPRI project has established a network of 46 participating institutions (competent authorities and other relevant organisations) in the field of pharmaceuticals.

The PPRI project seeks to increase transparency and knowledge and facilitate the exchange of experience in the field of pharmaceuticals by:

- establishing and maintaining a network of relevant institutions in the field of pharmaceuticals in the enlarged European Union (EU), in order to facilitate a regular exchange of information and allow a process of learning from each other;
- producing country reports on pharmaceutical pricing and reimbursement systems, the "PPRI Pharma Profiles";
- developing indicators for the comparison of pharmaceutical pricing and reimbursement information;
- providing a comparative analysis on pharmaceutical pricing and reimbursement in the European Union (EU); and
- disseminating the outcomes of the project.

The PPRI Pharma Profiles are country-specific reports that provide detailed descriptions of the countries' pharmaceutical systems and policies. The profiles are written by PPRI participants (country experts from the competent authorities, medicines agencies, social insurance institutions, research institutes) and edited by experts coordinating the PPRI project.

This Pharma Profile is one of the many PPRI Pharma Profiles, which all are available on the PPRI web site at http://ppri.oebig.at. The information and data provided in the PPRI Pharma Profiles refer, in general, to the year 2006.

In order to improve readability and allow for comparisons between countries, the structure of the Pharma profiles follows a template, which was developed by the project coordination team and the PPRI participants. The template is based on a large needs assessment of both national and international stakeholders. In addition to the template a glossary was developed to facilitate the writing process and the readability. The 70-page PPRI Pharma Profile Template and the PPRI Glossary are available on the PPRI web site.

1 Background

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. According to the Organisation for Economic Co-operation and Development (OECD), of the total expenditure on health care in Denmark in 2005, public expenditure constituted approximately 84% and private expenditure approximately 16% (OECD 2005).

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 Danish health care service can be divided into two sectors:

- primary care sector, and
- 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;
- the other part, which is predominantly preventive, deals with preventive health schemes, health care and child dental care.

Normally the patient's first contact with the health care system is with the 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 general practitioner (GP) to a hospital for medical examination and treatment unless it is a matter of an accident or acute illness. This means that patients usually start by consulting their general practitioner (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.

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).

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), 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.

Table 1.1: Denmark - Key figures on the health care system 1995, 2000-2005

Variable	1995	2000	2001	2002	2003	2004	2005	Source
Total population	5,215,718[1]	5,330,020	5,349,212	5,368,354	5,383,507	5,397,640	5,411,405	Statistics Denmark
Life expectancy at birth, total	75.3	76.9	77.0	77.2	77.5	77.6	77.9	OECD
Life expectancy at birth, females	77.8	79.3	79.3	79.5	79.9	79.9	80,2	OECD
Life expectancy at birth, males	72.7	74.5	74.7	74.8	75.1	75.2	75,6	OECD
GDP in Mio. DKK	1,019,545	1,293,964	1,335,611	1,372,737	1,400,689	1,459,399	1,551,967	OECD
GDP in Mio. €	136,661	173,598	179,223	184,743	188,467	196,156	208,267	OECD
GGE in Mio. DKK	606,983	697,890	728,015	753,047	774,504	803,836	819,184	Statistics Denmark
GGE in Mio. €	81,361	93,629	97,691	101,345	104,212	108,042	109.931	Statistics Denmark
THE in Mio. DKK[2]	82,841	106,935	114,368	120,265	127,412[4]	134,817[4]	141,432[4]	OECD
THE in Mio. €[9]	11,104	14,346	15,349	16,185	17,144[4]	18,121[4]	18,980[4]	OECD
Public HE in Mio. DKK	68,364	88,147	94,546	99,744	107,336[4]	113,698[4]	118,945[4]	OECD
Public HE in Mio. €	9,164	11,826	12,687	13,424	14,442[4]	15,282[4]	15,962[4]	OECD
Private HE in Mio. DKK	14,477	18,788	19,823	20,521	20,076[4]	21,119[4]	22,486[4]	OECD
Private HE in Mio. €	1,941	2,521	2,660	2,762	2,701[4]	2,839[4]	3,018[4]	OECD
Total no. of hospitals[5]	92	73	66	68	67	62	n.a.	SST
No. of hospital beds (acute and non-acute care)[6]	25,496	22,742	22,421	22,225	21,457	20,646	n.a.	SST
Total no. of doctors[7]	15,750	16,822	17,003	17,296	17,677	17,965	18,616	SST
No. of visits to GPs per patient per year[8]	3.0	3.2	3.2	3.1	3.1	3.1	3.1	SST, Statistics Denmark
Exchange rate (DKK per €)	7.46038[10]	7.4538	7.4522	7.4305	7.4320	7.4400	7.4518	Austrian National Bank, 2006

GDP = gross domestic product, GGE = general government expenditure, GP = general practitioner, HE = health expenditure, THE = total health expenditure, SST = National Board of Health, OECD = Organisation for Economic Co-operation and Development

1 1995 data are actually data from 1 January 1996.

2 OECD Health database

3 Break in series

4 Estimate

5 This is the sum of somatic and psychiatric hospitals.

6 There is no distinction between acute and non-acute care beds.

7 The total workforce of doctors, including the unemployed; there is no distinction between part-time and full-time employment; data are from 1 January each year.

8 The number of visits is the sum of visits to GPs and GP home visits; the full population is used as the denominator.

9 Synthesised exchange rate used: 1 € = 7.46038 DKK

The five Danish regions are responsible for hospital services, including psychiatry, health insurance, general practitioners (GP) and specialists, etc. The 98 municipalities are responsible for any rehabilitation that does not take place during hospitalisation, including preventive treatment and promotion and treatment of alcohol and drug abuse.

The payment system for general practitioners (GP) in primary care in the Danish health care system is generally based on fee-for-service payments and partly based on a capitation system.

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 invoicing principle for their hospitals – typically annual framework budgets are used. However, since 2004 the Government and the regions have arranged that at least 20% the 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 is to reach 50% of the total remuneration from 2007 onwards.

Table 1.2: Denmark - Diseases with highest morbidity and the leading causes of mortality 2005

No.	Top 5 diseases with highest morbidity (1 = most common)	ICD-10 code	No.	Top 5 leading causes of mortality (1 = most common)	ICD-10 code
1	Loss of hearing	H91	1	Chronic ischaemic heart disease	I 25
2	Abdominal and stomach pain	R10	2	Cancer, colon	C18
3	Pneumonia	J18	3	Chronic Obstructive Pulmonary Disease (COPD)	J44
4	Diseases of the knee joint	M23	4	Stroke	I64
5	Cataract	H25	5	Cancer, bronchial and lung	C34
Source: National Hospital Register (SST 2005a)			Source: National Causes of Death Register (SST 2005b)		

2 Pharmaceutical system

2.1 Organisation

This section describes, on one hand, the Danish regulatory framework (legal basis, main authorities and their tasks), and on the other hand, the pharmaceutical market (data, key players) (cf. Figure 2.1).

2.1.1 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 pharmaceuticals through nationally paid taxes, and at local level the municipalities run a supplementary reimbursement system based on social indications.

2.1.1.1 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[2] contains provisions for authorisation and control of pharmaceuticals 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 pharmaceuticals. Finally, the Act lays down provisions about authorisation of pharmaceutical trials on humans.

The Danish Pharmacy Act, cf. Consolidated Act No. 657 of 28 July 1995, as amended,[3] 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.

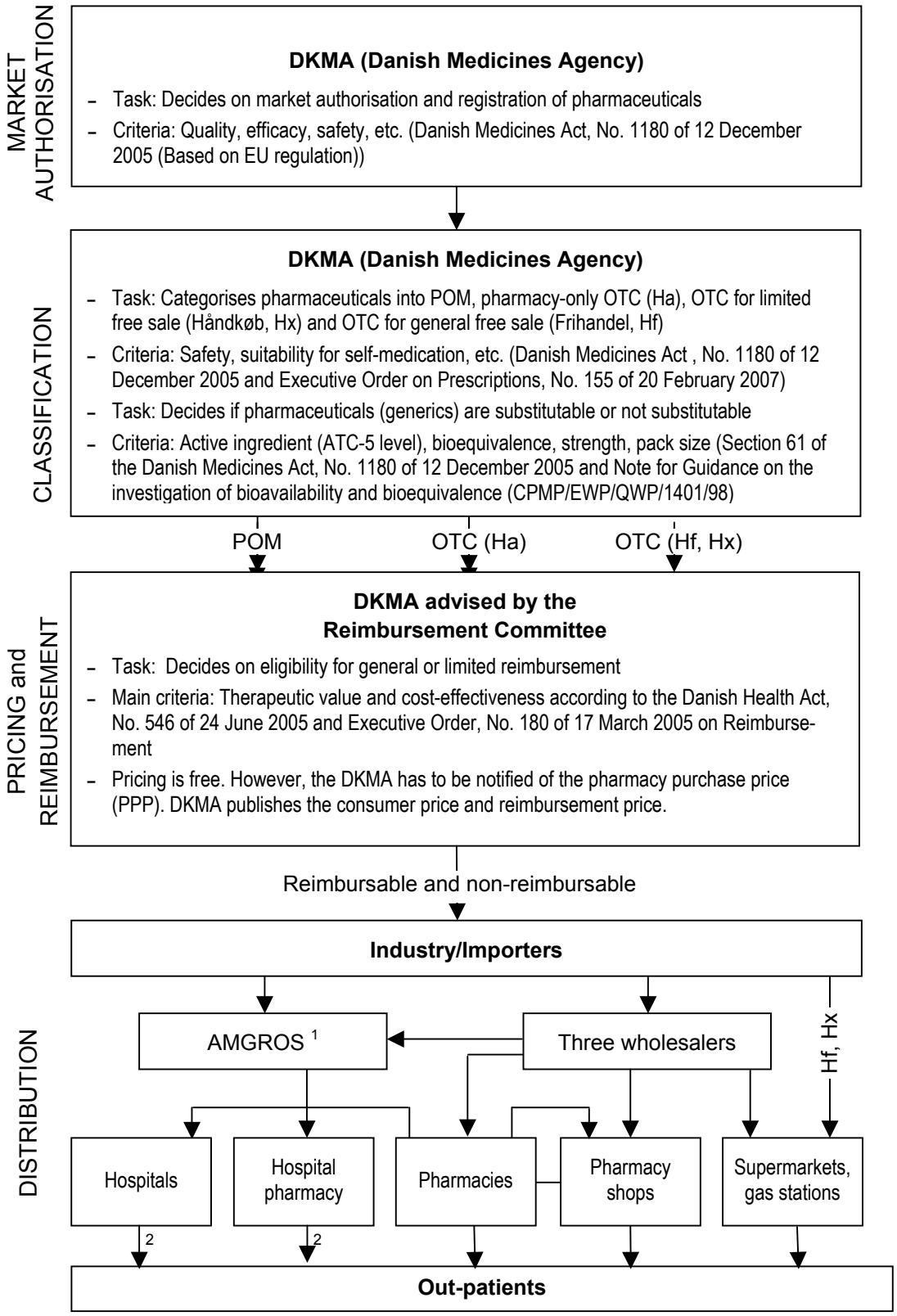
The Danish Health Act, No. 546 of 24 June 2005, as amended,[4] sets out (in Chapter 42) the rules regulating reimbursement of pharmaceuticals in Denmark.

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

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

[4] http://www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=11547

Figure 2.1: Denmark - Flowchart of the pharmaceutical system



[1] Procurement only. No actual physical handling of pharmaceuticals,

[2] Hospital treatment for non-hospitalised patients

EU = European Union, OTC = over-the-counter (pharmaceuticals), POM = prescription-only medicine(s), Ha = Pharmacy-restricted over-the-counter (OTC) pharmaceuticals, Hx = Non-pharmacy-restricted over-the-counter (OTC) human pharmaceuticals (maximum one pack per customer per day), Hf = Non-pharmacy-restricted over-the-counter (OTC) human pharmaceuticals, ATC = Anatomic Therapeutic Chemical classification

Source: DKMA 2007

2.1.1.2 Authorities

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 approval of pharmaceuticals 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.

Table 2.1: Denmark - Authorities in the regulatory framework of the pharmaceutical system 2006

Name in local language	Name in English	Description	Responsibility
Indenrigs- og Sundheds-ministeriet (IM)	Ministry of the Interior and Health	The health care department of the IM drafts legislation, issues rules and regulations, and exercises authority. It also draws up planning proposals within health care and local political areas	Responsible for legislation and governing health care
Lægemiddel-styrelsen (LMS)	Danish Medicines Agency (DKMA)	Medicines Agency (subordinate to the IM).	In charge of market authorisations, classification, vigilance, pricing, reimbursement, pharmaceutical consumption and market surveillance
Registrerings-nævnet	The Licensing Committee	Advisory committee to the DKMA on market authorisation (granting, amendments and withdrawals) and on clinical trials This is a separate body from the DKMA	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
Medicintilskuds-nævnet (MTN)	The Reimbursement Committee	Advisory committee to the DKMA on reimbursement issues This is a separate body from the DKMA.	Makes recommendations on reimbursement matters to the DKMA, e.g. on reimbursement status and on recommended criteria for individual reimbursement
Bivirkningsrådet	Council for Adverse Drug Reactions	Advisory council to the DKMA on adverse drug reaction issues.	Makes recommendations on questions regarding adverse reactions to pharmaceuticals
Institut for Rationel Farmakoterapi (IRF)	Institute for Rational Pharmacotherapy (IRF)	Independent institute under the DKMA	Promotion of the most rational use of pharmaceuticals with respect to both pharmacological and economical aspects Directed towards both primary care sector and hospital sector

Sundheds-styrelsen (SST)	National Board of Health	National agency for health, (subordinate to the IM) The Danish Centre for Health Technology Assessment (DACEHTA) is an independent centre within the SST	The SST is the advisory and monitoring authority on health care issues DACEHTA performs health technology assessments (HTA) mainly aimed at the hospital sector
De 5 regioner/ 5 Regionsråd	The Regional Council of each of the 5 regions	The regions are the third-party payers AMGROS is a hospital purchasing agency owned by the 5 regions	The regions are responsible for running the hospitals and for financing pharmaceuticals in the primary care sector AMGROS purchases pharmaceuticals for all public hospitals in Denmark

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

- The ***Licensing Division*** authorises human and veterinary pharmaceuticals 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 pharmaceuticals. Moreover, companies have the possibility to receive scientific advice on future applications, and the Licensing Division also deals with labelling and package leaflets.
- The ***Consumer Safety Division*** monitors the safety of both pharmaceuticals 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 pharmaceuticals and testing of medical devices, and the Division monitors advertising of pharmaceuticals and medical devices.
- The ***Inspection, Laboratory and Enforcement Division*** is in charge of authorisation, monitoring and control of pharmaceutical companies as well as laboratory control of the quality of pharmaceuticals. The Division monitors private individuals' import habits, along with illegal sales, and pharmacies and other sales outlets selling pharmaceuticals. The Inspection, Laboratories and Enforcement Division is also responsible for analytic monitoring and standardisation of biological and chemical pharmaceuticals and radio-pharmaceuticals. The Division controls the Danish Medicines Agency's (DKMA) laboratory.
- The ***Pharmacoeconomic Division*** decides on general reimbursement for pharmaceuticals, issues/confirms individual patients' reimbursement requests and operates the Danish Medicines Agency's (DKMA) Register of Medicinal Product Statistics.[5] The Division publishes the List of Prices for Proprietary Medicinal Products every two weeks, which is a detailed list of all pharmaceuticals that are sold in Denmark. Developments in the consumption of pharmaceuticals are supervised and analysed on the basis of the information in the Register of Medicinal Product Statistics.

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

The aim of the **Institute for Rational Pharmacotherapy (IRF)** is to promote the most rational use of current and future pharmaceuticals 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 pharmaceuticals, reviews new pharmaceuticals on the web site[6] and supports regional medical advisers on pharmaceuticals. The Institute for Rational Pharmacotherapy (IRF) provides well-balanced information to all medical doctors in Denmark. Secondary target groups are other professionals in the health sector and consumers of pharmaceuticals.

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 pharmaceuticals to use and which (expensive) new medical treatments to implement in the hospital sector. The regions buy pharmaceuticals via public procurement. They are also in charge of funding the reimbursement of pharmaceuticals eligible for reimbursement in the primary care sector and thereby act as a third-party payer. The regions are drawn together 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 pharmaceuticals (both general reimbursement and individual reimbursements). The Reimbursement Committee (MTN) 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 Danish Medicines Agency (DKMA). One member represents the regions (the third-party payer). The members of the 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 pharmaceuticals for which the company has applied for general reimbursement, and the Committee also recommends on criteria for the various types of individual reimbursement (cf. 4.2.2 for details). However, the reimbursement decisions themselves are the responsibility of the Danish Medicines Agency (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

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

pharmaceuticals. 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 Danish Medicines Agency's (DKMA) information and communication tasks on adverse reactions for consumers, patients and health care professionals. The council is appointed by the Danish Medicines Agency (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 Danish Medicines Agency (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 pharmaceuticals and clinical testing of pharmaceuticals. 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 Danish Medicines Agency (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 Danish Medicines Agency (DKMA) provides a secretariat for the work of the Committee.

Process of market authorisation

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,[7] which are displayed in detail (e.g. regarding guidelines and forms, case handling times, etc.) on the Danish Medicines Agency's (DKMA) web site.[8]

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, as shown in the graphic illustration: 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 Danish Medicines Agency (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[9] allowing each applicant to follow the proceedings of the backlog through a unique and confidential case number.

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

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

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

2.1.2 Pharmaceutical market

2.1.2.1 Availability of pharmaceuticals

By the beginning of 2006 approximately 9,142 pharmaceutical products, counted by different strengths and dispensing forms, were authorised in Denmark (cf. Table 2.2).

A number of pharmaceuticals 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 pharmaceuticals 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 pharmaceuticals in the European market as a whole.

Table 2.2: Denmark - Number of pharmaceuticals 1995, 2000-2006[1]

Pharmaceuticals	1995	2000	2001	2002	2003	2004	2005	2006
Authorised	2,568	4,231	4,621	5,138	5,918	6,822	7,853	9,142
On the market	1,918	2,779	2,937	3,166	3,474	3,769	4,142	4,346
POM*	2,090	3,230	3,487	3,852	4,506	5,311	6,224	7,393
Reimbursable*	3,884	4,109	3,967	3,946	3,945	4,034	4,083	3,987
Generics*	2,426	2,852	1,514	1,186	1,366	1,600	1,881	2,137
Parallel traded	61	220	245	274	376	473	646	851
Hospital-only (Begr)	48	218	282	349	405	435	478	518

POM = prescription-only medicine(s); Begr = restricted to hospital use

[1] as of 1 January

Note: All figures are given per DrugID (name, pharmaceutical form and strength) as of 1 January. However, figures marked with * indicate number of marketed packs of pharmaceutical products, which is the only way the data are available. As for generics, the figures represent packs marketed by members of the Danish Generic Medicines Industry Association (IGL), and the actual number may therefore be slightly higher.

Source: The figures marked with * are from the statistics on pharmaceuticals (DKMA 2007b). The rest of the figures are from internal reports from the Danish pharmaceuticals database.

2.1.2.2 Categorisation

Pharmaceuticals in Denmark may be categorised according to the following three perspectives:

- dispensing status
- reimbursement status (primary care sector only)
- sector status.

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.

Prescription-only medicine(s):

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

Over-the-counter pharmaceuticals:

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

There are also a couple of veterinary categories.

Reimbursement status (primary care sector only)

According to the predominant reimbursement scheme there are three categories of general reimbursement (cf. Section 144 of the Danish Health Act, No. 546 of 24 June 2005), as listed here.

- General reimbursement for prescription-only medicine(s) (POM) is granted whenever the pharmaceutical is prescribed.
- Limited reimbursement for prescription-only medicine(s) (POM). Reimbursement is granted only for specific diseases. If the pharmaceutical is prescribed for other diseases, it is not reimbursable (unless the patient has been granted individual reimbursement for the product (cf. 4.2.1 and 4.2.3)).
- Limited reimbursement for some over-the-counter (OTC) pharmaceuticals. Reimbursement is given only when the pharmaceutical is prescribed for a pensioner or for people suffering from specific diseases (cf. 4.2.1).

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 Danish Medicines Agency (DKMA). Most switches are made upon application from the market authorisation holder. Regardless of the impetus behind the switch, the Danish Medicines Agency (DKMA) consults the Licensing Committee prior to making a decision (cf. 2.1.1.2).

2.1.2.3 Market data

In Denmark an increase in the sales of pharmaceuticals (on average 5% annually by volume) in the primary care sector can be observed over recent years. The sales volume of reimbursed pharmaceuticals has even risen by approximately 8% each year (DKMA 2007b).

During previous years, total sales by value have increased by approximately 3% 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.

In 2006, sales of generics in the primary care sector accounted for 15% of the total sales of pharmaceuticals and 39% of the volume sold (cf. 5.5 for more information on generics). These figures have been growing steadily over recent years. Parallel imported products accounted for approximately 16% of the total sales and 9% of the volume sold in the primary care sector. These proportions are fairly constant.

Hospital sales are expressed in terms of the procurement price, i.e. the hospital departments' pharmacy purchasing price (PPP) including value-added tax (VAT). Calculation of these prices varies a good deal and depends on which pharmacy supplies the product.

Sales of both parallel imported pharmaceuticals and of generics benefit from the rules of substitution, i.e. the pharmacies are obliged to dispense the cheapest product when several pharmaceuticals have the same active ingredient (cf. 5.5.1).

In hospitals, sales have also been increasing rapidly, with up to 15% growth. The use of pharmaceuticals for treatment of cancer and antineoplastic agents are rising in particular, including many new, expensive pharmaceuticals.

Table 2.3: Denmark - Market data 1995, 2000-2005

Pharmaceutical industry in Mio. DKK / Mio. €	**1995**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**
Pharmaceutical sales (total sales including POM, OTC, reimbursable and non-reimbursable, etc.)							
Sales at ex-factory price level[1,3]	n.a.	5,389/ 723	5,775/ 775	6,430/ 865	6,662/ 896	6,793/ 913	n.a.
Sales at wholesale price level[1,3]	n.a.	5,784/ 776	6,195/ 831	6,889/ 927	7,113/ 957	7,256/ 975	n.a.
Sales at PRP level[1]	7,136	9,405/ 1,262	9,992/ 1,341	10,935/ 1,472	11,291/ 1,519	11,573/ 1,556	11,935/ 1,602
Sales at hospitals	n.a.	2,220/ 298	2,565/ 344	2,970/ 400	3,384/ 455	3,926/ 528	4,399/ 590
Sales of generics in primary care sector	n.a.	n.a.	749/101	936/126	1,074/ 145	1,429/ 192	1,573/ 211
Sales of generics in hospital sector	n.a.	n.a.	168/23	196/26	205/28	189/25	167/22
Sales of parallel traded pharmaceuticals in primary care sector	n.a.	n.a.	1,190/ 160	1,299/ 175	1,420/ 191	1,370/ 184	1,442/ 194
Sales of parallel traded pharmaceuticals in hospital sector	n.a.	n.a.	42/6	26/2	33/4	86/12	124/17
Exports and imports							
Total pharmaceutical exports[2]	12,700	24,096/ 3,232	28,246/ 3,790	30,374/ 4,088	32,189/ 4,331	32,640/ 4,387	38,249/ 5,133
Total pharmaceutical imports[2]	n.a.	7,676/ 1,030	9,140/ 1,227	10,564/ 1,422	11,296/ 1,520	11,409/ 1,533	13,112/ 1,760

[1] Primary care sector

[2] Finished products

[3] Sales at ex-factory price level and sales at wholesale price level are not directly available but are calculated from sales at PRP level (DKMA 2007b) and figures from a table on "Composition of consumer price for medicines in Denmark", Tal og data 2007 (Lif).

POM = prescription-only medicine(s), OTC = over-the-counter (pharmaceuticals), PRP = pharmacy retail price, n.a. = not available

Sources: Exports and Imports: Tal og data 2007 (Lif 2007), all other figures DKMA 2007b

Table 2.4: Denmark - Top 10 best-selling pharmaceuticals, by active ingredient 2005

Position	Pharmaceutical, by active ingredient
1	Olanzapine
2	Esomeprazol
3	Paracetamol
4	Budesonid
5	Formoterol and budesonid in combination
6	Venlafaxine
7	Salmeterol and fluticason in combination
8	Metoprolol
9	Lamotrigine
10	Atorvastatine

Note: Data are given for primary care sector, sales measured in pharmacy purchasing prices (PPP)

Source: DKMA 2007a

2.1.2.4 Patents and data protection

Patents and data protection are two different legal instruments. The former provides for an exclusive right to an invention, whereas the latter protects the data submitted to the regulatory authorities from being referred to by a third party.

Patent matters are dealt with by the Danish Patent and Trademark Office, whereas the Danish Medicines Agency (DKMA) acts as the national competent authority in relation to matters involving data protection.

With regard to access and public health issues, there is no explicit provision for compulsory licensing, parallel import and “government use” on patented products within the national legislation, apart from a provision which implements article 126a in Directive 2001/83/EC (as amended). It follows from this provision that “in the absence of a market authorisation or of a pending application for a medicinal product authorised in another Member State in accordance with this Directive, a Member State may, for justified public reasons, authorise the placing on the market of the said medicinal product.”

It is not unusual for originator companies to try to prevent generic products from entering the market by referring to the provisions on data protection stemming from Directive 2001/83/EC (as amended). More specifically, originators occasionally seek an agreement with the competent authority that their product or a line extension of it shall benefit from data protection and therefore generics applications referring to their product will be rejected.

On the basis of a claim of patent infringement, court cases are initiated with a request for injunction against the marketing, etc., of the generic product, in an attempt to prolong data protection. If an injunction is issued, the generic pharmaceutical cannot be marketed or must be withdrawn from the market and the originator de facto obtains more protection by keeping a competitor away from the market.

The same effect may be obtained by summoning both the national competent authority and the generic competitor to appear in court, claiming that the legal basis for granting the market authorisation to the latter suffers from procedural/legal errors.

2.1.3 Market players

2.1.3.1 Industry

The pharmaceutical industry is a significant sector in the Danish economy. In 2005, pharmaceutical production amounted to € 4,877 Mio. (Efpia 2006). In 2005, 264 companies – of which 189 manufacturers and 10 parallel importers – supplied pharmaceuticals in Denmark. The total export of pharmaceutical products in 2006 was DKK 39.5 billion corresponding to 7 percent of the total Danish export and making the pharmaceutical industry the second largest exporting sector in Denmark (Lif 2007[10]).

In 2006, 17,286 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 2007).

Danish original manufacturers and other research-oriented pharmaceutical companies are organised in the Danish Association of the Pharmaceutical Industry (Lægemiddelindustriforeningen, Lif). The Danish Association of the Pharmaceutical Industry (Lif) is an association of 42 member companies which represented 55% of the sales of pharmaceuticals in Denmark in 2006 (Lif 2007). The majority of industrial medical research in Denmark is carried out by the Danish Association of the Pharmaceutical Industry's (Lif) members.

In 2006 the sale of brand name original products in the primary care sector was approximately 50% in volume and 62% in value (DKMA 2007b).

The Danish Generic Medicines Industry Association (Industriforeningen for Generiske Lægemidler, IGL) is a trade association that was founded in 2002. In 2007 the association comprises 11 member companies, which are all engaged in the sale and marketing of generic pharmaceuticals for the Danish market. Some of the companies manufacture generic pharmaceuticals as well (IGL 2007[11]).

The sale of generics (prescription-only medicine(s) (POM) and over-the-counter (OTC) pharmaceuticals) in the primary care sector amounted to approximately 39% in volume and 15% in value in 2006. In the proportion of the market where substitution of pharmaceuticals with generics is an option, the sale of generics constitutes approximately 85% (DKMA 2007b).

Pharmaceuticals 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 Pharmaceuti-

[10] www.Lifdk.dk (May 2007)

[11] www.igl.dk (May 2007)

cals (Parallelimportorforeningen af Lægemidler, PFL). The sale of parallel imported products in the primary care sector amounted to approximately 9% in volume and 16% in value in 2006 (DKMA 2007b).

The Ministry (IM) and the Danish Medicines Agency (DKMA) use the Danish Association of the Pharmaceutical Industry (Lif), the Danish Generic Medicines Industry Association (IGL) and the Danish Association of Parallel Importers of Pharmaceuticals (PFL) as experts and advisory bodies for the authorities in matters related to the industry. The Danish Association of the Pharmaceutical Industry (Lif), the Danish Generic Medicines Industry Association (IGL) and the PFL are sometimes represented in official committees and working parties. The industry is consulted by the Ministry of the Interior and Health (IM) and the Danish Medicines Agency (DKMA) in connection with preparing new bills and governing orders that affect the industry.

The leading manufacturers in Denmark are Pfizer Ltd., Nycomed Danmark Ltd., GlaxoSmith-Kline Pharma Ltd. and AstraZeneca Ltd. In 2006 the parallel importer Orifarm had the largest sales among all pharmaceutical companies.[12]

Usually, products are distributed by wholesalers, but tendering and procurement of pharmaceuticals for the hospitals are largely managed by the purchasing partnership AMGROS, owned by the five regions.

Not every company licensed to carry out pharmaceutical activities (i.e. manufacture, import, export, packaging, etc.) related to pharmaceuticals is a member of the LIF, the Danish Generic Medicines Industry Association (IGL) or the Danish Association of Parallel Importers of Pharmaceuticals (PFL). At the time of writing 166 companies in total are authorised (and inspected by the DKMA) to carry out pharmaceutical activities (pharmacies and wholesalers excluded).

Table 2.5: Denmark - Key data on the pharmaceutical industry 1995-2005[1]

Pharmaceutical industry	1995	2000	2001	2002	2003	2004	2005
Total no. of companies[13]	167	196	n.a.	n.a.	n.a.	n.a.	189
- 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
No. of people employed[2]	14,323	15,171	n.a	n.a	n.a	n.a	17,286[3]

[1] as of 1 January

[2] counted per head

[3] 2006

n.a. = not available

Source: ÖBIG 2003, Lif 2007

[12] LIF 2007

[13] Only the actual number is available: 166 companies in 2007 (DKMA).

2.1.3.2 Wholesalers

In Denmark three major full-line wholesale companies, Nomeco Ltd., K.V. Tjellesen Ltd. and Max Jenne Ltd., are authorised to distribute pharmaceuticals to private pharmacies and hospitals. The number of branches of each is 8, 4 and 3, respectively (DKMA). The full-line wholesale companies supply all pharmaceuticals and other items which are demanded by pharmacies and hospitals from a range of 6,720 human pharmaceuticals, of which 6,000 are prescription-only medicine(s) (POM).

Nomeco is the largest company with 570 employees. Most Danish pharmacies are customers at Nomeco, 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 pharmaceuticals in the Nordic countries, Poland and the Baltic countries. Tamro is part of the German Phoenix Group – the second largest wholesaler in Europe. Nomeco has an anuual turnover of more than DKK 10 billion (more than € 1,340 Mio.) (Nomeco 2007[14]).

K.V. Tjellesen has 165 employees and an annual turnover of more than DKK 3 billion (more than € 402 Mio.) (Tjellesen 200715). 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[16]). 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.

The three wholesalers are members of Megros, the Association of Pharmaceutical Wholesalers. The Ministry of the Interior and Health (IM) and the Danish Medicines Agency (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.

In 2006 the average gross margin of wholesalers was approximately 6%, and the total revenue of pharmaceuticals wholesalers (without value-added tax (VAT)) was € 1,346 Mio. (Girp, 2007[17]).

Besides the three major suppliers, about 250 companies are licensed and inspected by the Danish Medicines Agency (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. No specified data are available (DKMA).

The wholesale activity is a multi-channel system.

[14] www.nomeco.dk (May 2007)

[15] www.tjellesen.dk (May 2007)

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

[17] www.girp.org (May 2007)

Table 2.6: Denmark - Key data on pharmaceutical wholesale 1995-2005[1]

Wholesalers	1995	2000	2001	2002	2003	2004	2005
Total no. of wholesale companies	3	3	3	3	3	3	3
Total no. of outlets[2]	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

[1] as of 1 January

[2] Only the actual number is available: 15 in 2007 (DKMA). Includes only outlets of the three major full-line wholesalers

Source: DKMA 2007

2.1.3.3 Pharmaceutical outlets / retailers

As a rule, pharmaceuticals may only be sold in pharmacies, including branches of pharmacies and licensed shops. However, some pharmaceuticals 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 over-the-counter (OTC) sales outlets and in shops, providing that they have obtained authorisation from the Danish Medicines Agency (DKMA).

The legal basis for the pharmacy sector is listed here:

- The Danish Pharmacy Act, cf. Consolidated Act No. 657 of 28 July 1995
- The Danish Medicines Act, No. 1180 of 12 December 2005
- Executive Order No. 1215 of 7 December 2005 on pharmacies and pharmacy staff
- Executive Order No. 993 of 5 October 2006 on sale of pharmaceuticals out of pharmacies
- Executive Order No. 994 of 5 October 2006 on sale of pharmaceuticals
- Executive Order No. 270 of 21 March 2007 on Calculation of Consumer Prices of Medicinal Products
- Executive Order No. 272 of 21 March 2007 on Advertising, etc. of Pharmaceuticals.

2.1.3.3.1 Pharmacies

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

A **pharmacy** must be run by a pharmacist who has received permission from the Government to run a pharmacy at a certain location. The pharmacy staff are pharmacists and pharmacoeconomists. Apart from selling pharmaceuticals, pharmacies are able to answer the majority of questions concerning pharmaceuticals and their use.

At the end of 2006 there were approximately 267 pharmacies in total. In addition, there were approximately 55 branches of pharmacies, 132 pharmacy shops and almost 700 over-the-counter (OTC) sales outlets, which are all affiliated to one of the pharmacies. 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 (pharmacoeconomists).

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 profits are distributed nationwide among pharmacies in order to partially level out the earnings, irrespective of the size of the population that the pharmacy supplies. This system aims at ensuring that the population in sparsely populated areas also has access to a pharmacy, thus a kind of solidarity contribution.

On average there are approximately 17,000 inhabitants per unit dispensing prescriptions (i.e. pharmacies and branch pharmacies) in Denmark. However, the customer base fluctuates throughout the country.

Over-the-counter (OTC) outlets are points of sale for pharmacies organised in another shop, often a supermarket. These over-the-counter (OTC) outlets may sell non-prescription pharmaceuticals suitable for sale outside of pharmacies, e.g. non-pharmacy-restricted over-the-counter (OTC) human pharmaceuticals (Hf) and pharmacy-restricted over-the-counter (OTC) pharmaceuticals (Ha) (cf. 2.1.2.2). At present there are 700 such over-the-counter (OTC) outlets in Denmark. The Danish Medicines Agency (DKMA) decides which pharmaceuticals may be sold in over-the-counter (OTC) outlets. Furthermore, these over-the-counter (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 over-the-counter (OTC) outlets are not educated within the pharmacy profession. Furthermore, there are a number of delivery facilities which do not stock pharmaceuticals but only receive addressed dispatches from one or several pharmacies and pass them on to the individual customer.

Over-the-counter (OTC) dispensaries include pharmacy shops, retail shops and others. The right to sell a limited range of pharmaceuticals in retail shops entered into force on 1 October 2001.

Table 2.7: Denmark - Retailers of pharmaceuticals 1995, 2000-2006[1]

Retailers	1995	2000	2001	2002	2003	2004	2005	2006
No. of community pharmacies[2]	337	331	330	329	328	327	322	322
No. of private pharmacies	337	331	330	329	328	327	322	322
No. of public pharmacies	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
No. of hospital pharmacies for out-patients	0	0	0	0	0	0	0	0
No. of other POM dispensaries	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
Total no. of POM dispensaries[1]	337	331	330	329	328	327	322	322
No. of Internet pharmacies	0	0	0	0	0	0	0	0
No. of OTC dispensaries (OTC outlets / retailer shops with limited sales of OTC pharmaceuticals)	977	882	1,829	1,851	1,957	2,031	2,030	700 / 1,450[3]

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

[1] as of 1 January

[2] The figures include pharmacies and branch pharmacies. In January 2006 there were 269 pharmacies and 53 branch pharmacies

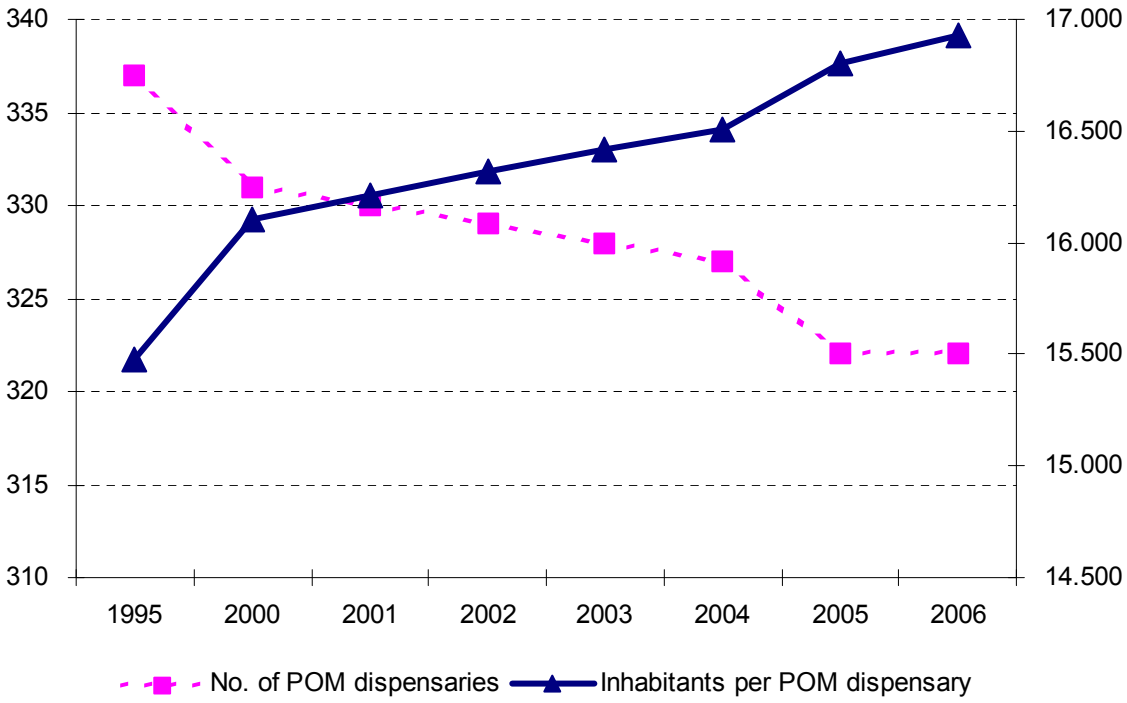
[3] 2007

Source: Review of pharmacy management. DKMA 1995, 2002-2005. DKMA.

Pharmacists authorised to run a pharmacy are organised in the Danish Pharmaceutical Association (Danmarks Apotekerforening, DA[18]). The Ministry (IM) and the Danish Medicines Agency (DKMA) use the Danish Pharmaceutical Association (DA) as experts and advisory bodies for the authorities in matters related to the pharmacies and the Danish Pharmaceutical Association (DA) is represented in official committees and working parties when relevant. The Danish Pharmaceutical Association (DA) is consulted by the Ministry of the Interior and Health (IM) and the Danish Medicines Agency (DKMA) in connection with preparing new bills and governing orders that affect the pharmacy sector.

[18] Http://www.apotekerforeningen.dk

Figure 2.2: Denmark - Number of retail pharmacies, POM dispensaries and number of inhabitants per POM dispensary 1995 and 2000–2006



POM = Prescription only medicine
Source: DKMA 2007

2.1.3.3.2 Other pharmacy outlets

Shops not included in the pharmacy sector can obtain authorisation from the Danish Medicines Agency (DKMA) for the sale of over-the-counter (OTC) pharmaceuticals suitable for sale at locations other than pharmacies. Approximately 1,450 shops have been granted authorisation. The DKMA decides which pharmaceuticals can be sold at such authorised sales outlets.

As a minimum, these shops must offer a certain range of products (basic range), as set out by the Danish Medicines Agency (DKMA). The basic range includes, e.g., painkillers, expectorants for the treatment of coughs and compressed lozenges for the treatment of sore throats, as well as nicotine chewing gum. The staff at authorised sales outlets do not have pharmaceutical education.

2.1.3.3.3 Internet pharmacies

Community pharmacies may sell pharmaceuticals, both prescription-only medicine(s) (POM) and over-the-counter (OTC), through the Internet.[19] However, legislation does not allow for strictly web-based pharmacies, i.e. distribution via the Internet alone.

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

2.1.3.3.4 Dispensing doctors

In special cases and under special conditions the Danish Medicines Agency (DKMA) can authorise a doctor to dispense pharmaceuticals 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 pharmaceuticals and the last authorisation of this type expired in 2002.

2.1.3.4 Hospitals

Until 31 December 2006 Denmark had 16 hospital pharmacies. On 1 January 2007 three of the hospital pharmacies in the region of Copenhagen were merged, reducing the total number to 14 hospital pharmacies. The hospital pharmacies supply their own hospitals in terms of distribution and clinical pharmacy, but some of the hospital pharmacies' own production is sold to the other hospital pharmacies if there is a surplus in production. The hospital pharmacies deliver free-of-charge pharmaceuticals to a number of out-patients via the hospital ambulatory unit.

The 14 hospital pharmacies differ a great deal in size. However, they all deal with distribution and clinical pharmacy, and most of them maintain a service production of total parenteral nutrition, cytostatics, and some antibiotics. A few of them have the proper facilities to deal with the production of authorised and ex tempore pharmaceuticals, both sterile and not sterile.

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

Formulary lists are prepared for all Danish hospital pharmacies. Every region has a Drug and Therapeutic Committee that makes the decisions regarding the pharmaceuticals that are included in the formulary lists. The hospital pharmacies take care of administration and the preparation of the formulary lists.

The members of the Drug and Therapeutic Committees are mainly hospital doctors and hospital pharmacists, but often representatives from the primary care sector are also involved in promoting the use of the recommended pharmaceuticals in both sectors. The primary goal for the Committees is to select those active substances which should be recommended for use in hospitals. Some Committees also draw up clinical guidelines for the chosen pharmaceuticals to secure rational use, and some of these guidelines are meant to cover the primary care sector as well.

It happens that the pharmaceutical (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.

All the hospital pharmacies order and buy pharmaceuticals via the hospital purchasing agency's (AMGROS) electronic purchasing system. AMGROS is a purchasing partnership owned by the five regions, and is the leading organisation in Denmark in terms of tendering and procurement

of pharmaceuticals. AMGROS puts together tenders to the Danish hospitals on behalf of the Danish hospital pharmacies regarding pharmaceuticals that are expected to be consumed within a given period. A number of medical companies offer a discount/rebate on pharmaceuticals 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 (cf. 3.2.4 and 3.4.1). Pharmaceutical companies are not allowed to offer discounts/rebates in the primary sector in the same way as in the secondary sector.

The hospital pharmacies may be part of a hospital or an independent institution in the hospital sector. The financing may vary but in every case the running of the pharmacy constitutes part of the total hospital sector budget.

2.1.3.5 Doctors

The Danish Medical Association's (Lægeforeningen, DADL) objectives are to unite Danish doctors in order to protect the interests of the medical profession, and to serve as the body through which the influence of the medical profession may be exercised on general social issues in the best interest of health and the health care system.

While the Danish Medical Association (DADL) is on the one hand a lobby organisation for Danish doctors, on the other hand it is also used by the national health administration, the Ministry (IM), and the private sector as an expert and advisory body for the authorities on medical matters and is represented in a number of official committees and working parties. The Danish Medical Association (DADL) is, e.g., consulted by the Ministry of the Interior and Health (IM) and the Danish Medicines Agency (DKMA) in connection with preparing new bills and governing orders that affect doctors' activities.

The Danish Medical Association (DADL) has produced a pharmaceutical policy paper that in general describes the Association's views and recommendations on the pharmaceutical field, as expressed, e.g., in official consultations and as a result of participating in committees and expert groups, etc. It is the opinion of the Association that the authorities in general are very receptive to its views and that they willingly participate in conferences, meetings, etc., arranged by the Danish Medical Association (DADL).

Denmark's pharmaceutical policy is not binding for the individual doctor prescribing pharmaceuticals. The National Board of Health (SST) issues clinical guidelines on specific therapeutic areas on a regular basis but the Danish Medical Association (DADL) has no official agreements with the authorities on pharmaceutical prescribing. The Danish Medical Association (DADL) has an agreement with the pharmaceutical industry on conditions for sponsored activities (research, courses, etc.), with a view to strengthening and maintaining doctors' integrity.

The Organisation of General Practitioners in Denmark (Praktiserende Lægers Organisation, PLO), as part of the Danish Medical Association (DADL), however, has made an agreement with the Regional Councils (the third-party payer) on including economic aspects when prescribing pharmaceuticals (Landsoverenskomst om almen lægegerning, Art. 101A.1: "The doctor is

obliged to assist the regional councils to have a responsible economy regarding those expenses that depend on the doctor's prescribing of pharmaceuticals").[20]

Prescribing is one of the most important therapeutic tools for doctors. It is therefore of paramount importance that doctors have access to pertinent, updated and balanced pharmaceutical information. This information should be easily at hand and preferably available at the time of prescribing.

Doctors obtain information from many sources, in particular from journals; guidelines; colleagues; opinion leaders; neutral pharmaceutical information organisations, e.g. the Institute for Rational Pharmacotherapy (IRF), which is an organisation much similar to (although smaller than) the National Institute for Clinical Excellence (NICE) in England; to a certain degree from the Doctors Association, INFOMATUM, issuing pharmaceutical treatment handbooks; and not least from the pharmaceutical industry. It is not always easy to separate relevant pharmaceutical information from purely commercial recommendations.

It is important to note that doctors' prescribing habits are also to a certain degree governed by the reimbursement policy. All doctors (with very few exceptions) are allowed to prescribe any marketed pharmaceutical, although some restrictions apply to opoids and some hypnotics. Doctors are not required to follow official recommendations or prescribing guidelines (cf. 5.2).

2.1.3.6 Patients

The choice of which pharmaceutical to prescribe is made by the doctor – often in cooperation with the patient, in order to secure through concordance the highest degree of compliance.

The prices and the patient percentage co-payment are the same in every pharmacy. The prices may only vary from one pharmacy to another where freely prices over-the-counter (OTC) pharmaceuticals are concerned (including those eligible for reimbursement). E.g., in the group Hf (Non-pharmacy-restricted OTC human pharmaceuticals) and Ha (Pharmacy-restricted OTC), cf. 2.1.2.2, the prices may vary from one retailer, i.e. in gas stations, supermarkets and other licensed dispensaries to another.

Danish patients obtain information on their medication from the prescribing doctor and the dispensing pharmacist. Furthermore, the Danish Medicines Agency (DKMA) offers extensive information on the prices of pharmaceuticals, the patient percentage co-payment and the possibility of generic substitution, their content including benefits and any potential risks via an Internet platform known as "Medicinpriser".[21]

In Denmark there are a large number of patient associations. Some of the largest ones, e.g. the Danish Heart Foundation, the Danish Cancer Society, and the Danish Diabetes Association, are rather influential. There is a sporadically recurring debate regarding industry influence through

[20] http://www.laeger.dk/portal/page/portal/LAEGERDK/LAEGER_DK/POLITIK/POLITIKPAPIRER/POLITIKPAPIRER_LAEGEFORENINGEN/LAEGEMIDDELPOLITIK/L%C3%A6gemiddelpolitik%20-%20endelig%20_3_.pdf

[21] http://www.medicinpriser.dk

patient organisations via sponsoring. This may be an issue in terms of general reimbursement decisions (cf. 5.3).

Most patient associations are organised within the umbrella organisation Danske Patienter (Danish Patients) which represents more than 700,000 members and covers practically all patient interests. Also the Danish Consumer Council (Forbrugerrådet) – a body independent of public authorities and commercial interests – represents the interests of patients (and consumers in general).

2.2 Funding

2.2.1 Pharmaceutical expenditure

There has been an increase in the sales of pharmaceutical products – each year the volume sold increases by approximately 5% in the primary care sector, which means that the third-party payers, i.e. the regions, face growing expenses for reimbursement.

The total public pharmaceutical expenditure (PE) (hospital and primary care sector) is growing (cf. Table 2.8). The public share in the primary care sector ("regional" according to the predominant reimbursement scheme) depends on each person's individual expenses on pharmaceuticals, i.e. the higher a person's expenditure, the higher the share of public funding (cf. 4.2.4 for details). As increasingly more people are treated with a growing number of pharmaceuticals, the public share is growing in the primary care sector. A minor part of public pharmaceutical expenditure (PE) is provided by the municipalities (cf. 4.2.2).

Pharmaceutical expenditure (PE) is also growing in the hospital sector. The total expenditure on pharmaceuticals as a share of gross domestic product (GDP) is rising as well.

Table 2.8: Denmark - Total pharmaceutical expenditure (TPE) 1995, 2000-2005

Pharmaceutical expenditure (PE)	1995	2000	2001	2002	2003	2004	2005
TPE in Mio. DKK	7,126[1]	11,626	12,557	13,905	14,675	15,499	16,334
TPE in Mio. €	n.a.	1559.7	1685.0	1871.3	1974.6	2083.2	2192.0
TPE as a % of THE	n.a.	10.9	11.0	11.6	11.5	11.5	11.5
TPE per capita in DKK	n.a.	2,181	2,348	2,590	2,726	2,871	3,019
TPE per capita in €	n.a.	292.6	315.1	348.6	366.8	385.9	405.1
Public PE as a % of TPE	n.a.	61.6	64.7	67.3	68.4	69.4	70.0
Private PE as a % of TPE	n.a.	38.4	35.5	32.7	31.6	30.6	30.0

GDP = gross domestic product, TPE = total pharmaceutical expenditure, PE = pharmaceutical expenditure, THE = total health expenditure

[1] Only figures from the primary care sector available.

Sources: DKMA 2007a, DKMA 2007b, The Health Sector in figures 2006, Statistics Denmark.

2.2.2 Sources of funds

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

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 pharmaceuticals and over-the-counter (OTC) pharmaceuticals.

However, some people have taken out supplementary private insurance in with Health Insurance "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 the out-of-pocket payment (OPP) is covered by this private insurance – in 2005 this amounted to approximately 14%.

In 2005 16% of the total expenditure on pharmaceuticals 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).

2.3 Evaluation

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. The routine annual statistics contain the sale of human pharmaceuticals in Denmark, grouped according to active substances (Anatomic Therapeutic Chemical (ATC) classification) (cf. 5.6), and analyses on specific groups of pharmaceuticals or specific issues are performed on an ad hoc basis.

E.g. the Danish Medicines Agency (DKMA) provides the State Serum Institute (SSI) with very detailed analyses on the consumption of antibiotics used in State Serum Institute (SSI) monitoring of bacterial resistance to antibiotics. The State Serum Institute (SSI) publishes an annual report (in Danish) on this topic.

To promote more rational use of pharmaceuticals, the general practitioner (GP) can follow her/his own prescription pattern in Ordiprax,[22] a web-based statistics programme. In addition, the regional health care authorities have access to Ordiprax, with a view to – in cooperation with

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

the general practitioner (GP) – defining those therapeutic areas where enhanced efforts to promote more rational prescribing may be needed (cf. 5.2).

The Medicine Profile (Medicinprofilen)[23] is an overview of pharmaceuticals dispensed from the pharmacy according to prescriptions written for individual patients. Only the patient her/himself and the doctor(s) are automatically authorised to obtain access to a patient's personal profile and in this way the doctor can obtain useful information on present and previous pharmaceutical treatment.

The DKMA also 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 pharmaceuticals, each having indexes for pharmacy retail price (PRP), the pharmacy purchasing price (PPP) 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 Danish Medicines Agency (DKMA) also monitors monthly regional reimbursement. The monitoring is carried out quarterly and encompasses the developments according to the sold amount (defined daily dose (DDD)), turnover and reimbursement of reimbursable pharmaceuticals. 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
- Challenges in the field of pharmaceuticals in 1998
- Organisation of pharmaceutical sales in Denmark in 1999
- Reimbursement and rational use of pharmaceuticals in 2004

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

Denmark has received two "opening letters" from the European Commission with respect to non-compliance with the Transparency Directive (Council Directive 89/105/EEC) and Article 28 and 30 of the Treaty: Opening letter No. 2005/4686 of 10 April 2006 on the Danish Legislation on Reimbursement of Pharmaceuticals and Opening letter No. 2006/2349 of 23 March 2007 on Reimbursement for Pharmaceuticals bought outside Denmark. The Danish Government has

[23] http://www.medicinprofil.dk

sent its reply to both letters and a meeting has been held with the Commission on the subject of the first matter. It is the position of the Danish Government that the Danish rules and practice are in compliance with the European Union (EU) regulation.

Legal actions with respect to decisions made on reimbursement are rarely brought against the Danish Medicines Agency (DKMA). On 19 December 2006, however, the Danish High Court ruled on a case brought by the company MSD against the Ministry of the Interior and Health (IM) and the DKMA. In this case the High Court ruled in favour of the IM and the DKMA with respect to the interpretation of the rules on reimbursement.

3 Pricing

3.1 Organisation

Pharmaceuticals are freely priced at both manufacturer and wholesale levels in Denmark.[24]

Pharmaceutical companies are obliged to report their pharmacy purchasing prices (PPP) for all pharmaceuticals on the market to the Danish Medicines Agency (DKMA).[25] The Danish Medicines Agency (DKMA) then calculates the pharmacy retail price (PRP) via a mark-up scheme (cf. 3.5.2 for details) along with – for all substitutable and reimbursable products (cf. 4.1 and 4.3) – the reimbursement price. The price list is distributed to all pharmacies and prices are the same all over the country, with minor exceptions.

Product prices can be altered every two weeks when a new official price list is drawn up by the Danish Medicines Agency (DKMA) (reimbursement prices are recalculated daily within that period, however, due to lack of delivery of the cheapest products in the groups (cf. 4.3 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 pharmaceuticals.

Reimbursement decisions are based, among other things, on price (cf. 4.2), meaning that the company has to set the price of a given pharmaceutical before applying for reimbursement (cf. Figure 2.1). Both reimbursement and pricing are managed by the Danish Medicines Agency (DKMA) (cf. 3.2.3).

These rules cover all pharmaceuticals (prescription-only medicine(s) (POM), over-the-counter (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, cf. 2.1.2.2) are also freely priced at retail level, and are thus subject to local competition (cf. 3.5.3). Consequently, the pharmacy retail price (PRP) of such OTC may vary throughout the country and the Danish Medicines Agency (DKMA) is not notified of these prices.

3.2 Pricing policies

The basic pricing system (free pricing, cf. Table 3.1) 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. 3.6.3).

[24] 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).

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

Table 3.1: Denmark - Ways of pricing pharmaceuticals

	Manufacturer level	Wholesale level	Pharmacy level
Free pricing	Free pricing for all products set by the manufacturer/ importer, cf. below Public procurement for all pharmaceuticals *used* in hospitals (not only HOM but also for others)		Free pricing for certain OTC pharmaceuticals which are not limited to distribution from pharmacies
Statutory pricing	Not applied		POM and those OTC pharmaceuticals limited to pharmacy distribution are subject to a linear mark-up scheme[26]
Price negotiations	Manufacturers/importers and wholesalers negotiate their share of the PPP (which is set by the manufacturer/importer, cf. above).		Not applied
Discounts / rebates	N.a.	Cost-related discounts to retailers possible, cf. 3.6.1	1.72% in 2005, 2006 and 2007 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. 4.3)		
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 (pharmaceuticals), PPP = pharmacy purchasing price, NHS = National Health Service

Source: DKMA

3.2.1 Statutory pricing

Statutory pricing is not applied in Denmark, with the exception of pharmacy mark ups. The applicable pharmacy retail prices (PRP) are calculated by the Danish Medicines Agency (DKMA), using a linear mark-up scheme and distributed to all pharmacies (cf. 3.5.2). Pharmacy retail prices (PRP) are also published on the Internet.[27]

3.2.2 Negotiations

Manufacturers/importers and wholesalers negotiate their share of the pharmacy purchasing price (PPP) (which is set by the manufacturer/importer) (cf. 3.5.1).

[26] 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.

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

3.2.3 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, however, notify the Danish Medicines Agency (DKMA) of the pharmacy purchasing price (PPP) and of any changes to that price, per pack size, no later than 14 days prior to the price coming into force (cf. Section 77 of the Danish Medicines Act, No. 1180 of 12 December 2007). To obtain the pharmacy retail price (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 (cf. 4.3).

Since October 2001 a selected range of over-the-counter (OTC) pharmaceuticals – dispensing groups Hf (non-pharmacy-restricted human use OTC pharmaceuticals) and Hx (non-pharmacy-restricted human use OTC (maximum 1 package per customer per day)) – may also be sold by gas stations, supermarkets and cafés provided they have obtained a licence from the Danish Medicines Agency (DKMA). These OTC products are subject to completely free pricing at all levels, which means that the pharmacy retail price (PRP) may differ between the distributors and throughout the country. This system of free pricing has been interrupted periodically by price freezes/price cuts (cf. 3.6.3).

3.2.4 Public procurement / tendering

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.

3.3 Pricing procedures

In Denmark pharmaceuticals are freely priced, but reimbursement and pharmacy profits are regulated. For reimbursable pharmaceuticals that can be substituted in pharmacies (generic substitution, cf. 5.5.1), reimbursement is calculated from the lowest price of the substitution group, i.e. the reimbursement price (cf. 4.3).[28] 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.

[28] 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.

Table 3.2: Denmark - Pricing procedures

Pricing procedure	In use: Yes / No	Level of pricing[29]	Scope
Internal price referencing	No (indirectly)	(Reimbursement prices)	(Reimbursable pharmaceuticals subject to generic substitution)
External price referencing	No	(Reimbursement prices)	(Used to be applied, between November 2000 and March 2005, for calculation of reimbursement prices)
Cost-plus pricing	No	Not applicable	Not applicable
Other, e.g. indirect profit control	Yes	PRP	Pharmacy profits are regulated by the mark-up scheme

PRP = pharmacy retail price

Source: DKMA

3.3.1 External price referencing

External price referencing is only relevant in a reimbursement context. From 30 October 2000 until 1 April 2005, European average prices were used as reference prices in the reimbursement calculations. For more information cf. 4.3.

3.3.2 Internal price referencing

Between June 1993 and November 2000, and again from 1 April 2005, internal price referencing has been used in a reimbursement context to determine the reimbursement price of a pharmaceutical (cf. 4.3). 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.

3.3.3 Cost-plus pricing

Cost-plus pricing is not used in Denmark.

3.3.4 (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 pharmaceutical (pack) is based on this scheme (cf. 3.5.2).

[29] The brackets indicate that the price referencing is related to the reimbursement price, i.e. the price from the reimbursement is calculated, and not the actual pharmacy retail price (PRP).

3.4 Exceptions

3.4.1 Hospital-only medicine(s)

The system of pricing in hospitals (of all pharmaceuticals and not exclusively hospital-only medicine(s) (HOM)) differs from the system of pricing in the primary care sector. Some hospital pharmacies even carried out their own procurement until 31 December 2006. As of 1 January 2007 AMGROS I/S[30] has been carrying out most of the public tenders on pharmaceuticals. On average, AMGROS obtains a 22-23% discount on the pharmacy purchasing price (PPP). In 2005 the pharmaceutical turnover in hospitals was DKK 3,294 Mio./€ 442 Mio. and AMGROS obtained a direct discount of DKK 771 Mio./€ 103 Mio.

The prices in the contracts that AMGROS makes with the suppliers are not open to the public.

3.4.2 Generics

Generics are priced according to the same rules as all other pharmaceuticals. However, they play a major role in the reference price system (c.f. 5.5 and 4.3 for more information).

3.4.3 Over-the-counter pharmaceuticals

Over-the-counter (OTC) pharmaceuticals that are only allowed to be sold in pharmacies are priced the same way as other pharmaceuticals. Certain over-the-counter (OTC) pharmaceuticals that are not limited to distribution from pharmacies but may be sold from retail shops (e.g. gas stations) are freely priced at all levels (pharmacy purchasing price (PPP), pharmacy retail price (PRP)) and are subject to local competition, meaning that the pharmacy retail price (PRP) may vary throughout the country.

3.4.4 Parallel traded pharmaceuticals

Parallel traded pharmaceuticals are priced according to the same rules as all other pharmaceuticals, but they play a role in the reference price system (cf. 4.3 for more information).

3.5 Margins and taxes

Table 3.3 shows that wholesale profits are not regulated in Denmark but are negotiated between manufacturers and wholesalers. Pharmacy mark ups, on the contrary, are statutorily regulated.

[30] 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.

Table 3.3: Denmark - Regulation of wholesale and pharmacy mark ups 2007

Wholesale mark up			Pharmacy mark up		
Regulation (yes / no)	**Content**	**Scope**	**Regulation (yes / no)**	**Content**	**Scope**
No	Not appl.	Not appl.	Yes	Linear mark up	All pharmaceuticals except OTC pharmaceuticals which are not limited to distribution from pharmacies

OTC = over-the-counter (pharmaceuticals)

Source: DKMA

3.5.1 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).

3.5.2 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 2007 – in a 2-year transition period. The transition led from the 3-fold mark-up scheme (as shown in Table 3.4) to a simpler scheme, consisting of only one formula (linear scheme).

Table 3.4: Denmark - Pharmacy mark-up scheme (31 July 2006 to 8 April 2007)

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

PPP = pharmacy purchasing price, 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: DKMA 2007

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).[31]

The new mark-up scheme, which entered into force on 8 April 2007, works on this basis:

0.088 × PPP + C, whereby C is a constant amount.

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

To avoid this, the new mark up contains a small pharmacy purchasing price (PPP)-dependent part (8.8%), intended to cover the turnover-related charges for the pharmacies.[32] In future, when the Ministry of the Interior and Health (IM) has to adjust the mark up, this will be carried out through the constant C.

Pharmacies receive a dispensary fee whenever they sell a prescribed product, i.e. prescription-only medicine(s) (POM) and OTC pharmaceuticals sold on prescription.[33] 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 3.5) which are added to the pharmacy retail price (PRP) of the pharmaceutical. Only the dispensary fee and the dosage dispensing fees are reimbursable according to the general reimbursement rates (cf. Table 4.2). All other fees are non-reimbursable and are paid by patients in the form of out-of-pocket payments (OPP).

[31] 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 Purchasing price of DKK 2.500 and over.

[32] The turnover-related expenses are: settlement between pharmacies (3.9%); sector charge (2.88%); and a rebate/discount for the National Health Service (NHS) (1.72%). (Source: Danish Pharmacists Association.)

[33] 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.

Table 3.5: Denmark - Additional pharmacy remuneration fees 2006

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 pharmaceutical(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) pharmaceuticals. It is added only once per customer service.
- The delivery fee is added when the pharmacy delivers the pharmaceuticals 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 pharmaceuticals 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: DKMA 2007

3.5.3 Remuneration of other dispensaries

As mentioned earlier, a selection of over-the-counter (OTC) pharmaceuticals can be sold from outlets other than pharmacies. These products are completely freely priced in all outlets, including pharmacies.

3.5.4 Value-added tax

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

3.5.5 Other taxes

There are no other taxes.

3.6 Pricing-related cost-containment measures

3.6.1 Discounts / Rebates

As a rule, it is not permitted to offer any discounts to health professionals in order to promote sales of pharmaceuticals. 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 pharmaceuticals (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 pharmaceuticals 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 (cf. 3.4.1). Regarding pharmacies, there is a sort of solidarity contribution (cf. 2.1.3.3.1 for details).

3.6.2 Margin cuts

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.

Regarding the statutorily regulated pharmacy mark ups, the situation is different. Although there were no actual margin cuts, the variable factor "y" (cf. 3.5.2) used to be negotiated between the Ministry of the Interior and Health (IM) and the Danish Pharmaceutical Association (DA) on a regular (often bi-annual) basis, to reflect the economic situation of pharmacies. During recent years the variable factor "y" ranged, i.e., between 0.55 (18 July 2005 to 8 April 2006) and 0.697 (20 August 2001 to 28 April 2002).

3.6.3 Price freezes / Price cuts

The latest price ceiling was agreed upon on 15 December 2006 in a voluntary agreement between the State and the pharmaceutical industry and is valid for a 2-year period starting in January 2007. The price ceiling concerns all reimbursable prescription pharmaceuticals marketed by members of the Danish Association of the Pharmaceutical Industry (Lif). Lif member companies are manufacturers of a very large proportion of the pharmaceuticals 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. There are no sanctions if a company does not follow the agreement, as it is voluntary.

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 2-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 3.6 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 3.6. Denmark - Price freezes, price cuts and price ceilings 1995-2008

1995-1997	Agreement between the IM and Medif/Mefa (later: Lif) on price cuts for specific drugs
1997-1998	Price freeze introduced by law for specific pharmaceuticals (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 pharmaceuticals
2000-2001	Price freeze introduced by law for specific pharmaceuticals (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 pharmaceuticals

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

Source: DKMA

3.6.4 Price reviews

In Denmark pharmaceuticals 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.

4 Reimbursement

4.1 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 (cf. 4.2.2).

In principle, all pharmaceuticals with market authorisation are eligible for reimbursement according to the predominant scheme, provided they meet the eligible criteria (cf. 4.2.3). For over-the-counter (OTC) pharmaceuticals it is also mandatory to define to which diseases the reimbursement will be limited.

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.

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) (cf. 2.1.1.2). 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 Clinical 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. 3.2). However, to be eligible for reimbursement, a major criterion is that the price of the product is reasonable in relation to the therapeutic value (cf. 4.2.1).

To apply for general (automatic) reimbursement for a pharmaceutical, a company either must have market authorisation or be in the process of getting 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. 4.2.1).

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 pharmaceutical (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. 5.4).

In almost all cases the decision on reimbursement status for a given pharmaceutical 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.

General reimbursement of generics follows the same rules as other pharmaceuticals, 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 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.

The reimbursement status of a pharmaceutical may change due to:

- new clinical studies;
- an actual use of the pharmaceutical 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 limited reimbursement;
- new health-economic analyses;
- shifts in the relationship between risks and benefits of the pharmaceutical;
- other factors that may influence the relationship between the treatment value of the pharmaceutical and its price.

These are also certain issues essential to the reassessment procedure, described in 4.6.5, but these also apply to ad hoc reassessment, e.g. Cox-2 inhibitors and lipid-lowering pharmaceuticals (cf. 4.6.1 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 (cf. 4.3).

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.

4.2 Reimbursement schemes

4.2.1 Predominant reimbursement scheme

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)) pharmaceuticals 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 pharmaceuticals eligible for general reimbursement or general reimbursement **limited** to certain diseases (cf. eligibility criteria in 4.2.3). The list includes both prescription-only medicine(s) (POM) and over-the-counter (OTC) pharmaceuticals.
- Variable reimbursement rates (a needs-based system, cf. Table 4.2) depending on:
  - the consumption of the patient 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 (cf. 4.4).
- OTC pharmaceuticals only reimbursed for patients with defined illnesses or for pensioners.
- Patients' out-of-pocket payments (OPP) are based on the reimbursement price (cf. 4.3 and 4.2.4 for details).
- Possibility of the Danish Medicines Agency (DKMA) granting individual reimbursement to a patient for a specific non-reimbursable pharmaceutical upon application by the doctor.

Generic substitution is mandatory and for pharmaceuticals eligible for general reimbursement and the substitution groups are identical to the reimbursement groups (cf. 4.3).

A prerequisite for the functioning of the system is the Danish Medicines Agency Central Reimbursement Register (CTR) ensuring that pharmacies – when dispensing a pharmaceutical – subtract the correct reimbursement amount from the reimbursement price of the pharmaceutical that the patient purchases. All pharmacies are have online access to the Central Reimbursement Register (CTR), along with doctors and citizens. As the owner of the Register, the Danish Medicines Agency (DKMA) is required to ensure that the Central Reimbursement Register (CTR) works properly.[34]

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

When a patient buys a pharmaceutical 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.

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 2006 was 1,951 Mio.

4.2.2 Supplementary reimbursement schemes

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.

Pensioners.[35,36] Health allowance may be given to pensioners to cover up to 85% of the pensioner's own expenses for reimbursable pharmaceuticals, depending on the pensioner's income and personal wealth. The calculation is based on reimbursement prices. On top of this, a personal pay supplement may be given to pensioners in very difficult financial situations. However, such applications are evaluated on a case by case basis.

People receiving cash assistance, students and low income people.[37] People belonging to these groups can apply for financial aid if they are unable to cover the pharmaceutical expenses themselves.

Disabled people[38] 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.

4.2.3 Eligibility criteria

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

- the pharmaceutical has a safe and valuable therapeutic effect on a well-defined indication; and

[35] The Social Pensions' Act, cf. Consolidated Act, No. 484 of 29 May 2007

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

[37] Act on Active Social Policy, cf. Consolidated Act, No. 1009 of 24 October 2005.

[38] The Services Act, cf. Consolidated Act, No. 58 of 18 January 2007

- 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 pharmaceutical if:

a) there is a considerable risk of off-label use (i.e. that the pharmaceutical will be used beyond the authorised indication, as is often the case for bisphosphonates);

b) the implementation of treatment with the pharmaceutical requires a special medical examination and diagnostic procedure, e.g. products for Alzheimer's disease;

c) the pharmaceutical 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 pharmaceutical is not clinically documented, e.g. herbal medicine;

e) there is a risk that the pharmaceutical is used as a first line therapy, regardless of whether the Danish Medicines Agency (DKMA) is of a different opinion, e.g. anti-obesity products;

f) it is not clarified if or when the pharmaceutical should be used as first line therapy, e.g. some new anti-rheumatic products;

g) there is a certain risk that the pharmaceutical may be abused, e.g. sleeping remedy;

h) the pharmaceutical is primarily used in hospital treatment, e.g. anti-cancer products; or

i) the pharmaceutical 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 pharmaceutical 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 (cf. 5.4).

General reimbursement limited to certain diseases

According to these criteria, the DKMA may limit the general reimbursement to the treatment of specific diseases ("general reimbursement limited to certain diseases"). 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.

Pharmaceuticals that have been granted general reimbursement and general limited reimbursement will be listed on the Positive List.[39]

Pharmaceuticals that do not meet the criteria for general reimbursement (or general reimbursement limited to certain diseases) will not be granted general reimbursement and will not be included in the Positive List. Pharmaceutical companies may appeal against unfavourable decisions to the Ministry of the Interior and Health (IM), but only regarding the procedure. As far

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

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. 4.2 and 4.2.2).

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 pharmaceutical 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. pharmaceuticals 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 (cf. 4.4.1).

4.2.4 Reimbursement categories and reimbursement rates

The current needs-based reimbursement system 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 pharmaceutical – regardless of its eligibility for general reimbursement, limited general reimbursement or according to an individual reimbursement granted for a specific pharmaceutical – the reimbursement rates are the same. The rates are based on the patient's pharmaceutical consumption, or rather the patient's out-of-pocket payment (OPP) for pharmaceuticals within a 12-month period. This period starts for each patient individually the first time a reimbursed product is dispensed.

The reimbursement rates are 0, 50, 75 and 85% – the larger the pharmaceutical expenditure (PE), the bigger the rate will be (cf. 4.4 and Table 4.2 for details).

Until 2000 all pharmaceuticals 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 (cf. 4.2.1). 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 pharmaceutical might have two reimbursable indications of differing severity.

Table 4.1: Denmark - Reimbursement of pharmaceuticals

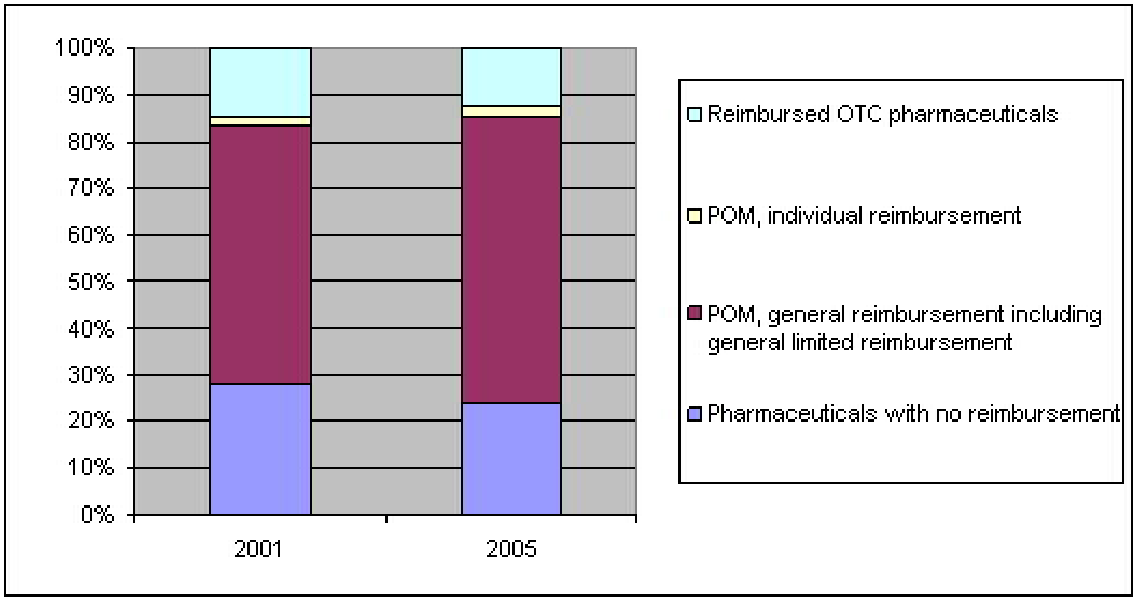
Reimbursement category	Reimbursement rate	Characteristic of category
General reimbursement POM	0, 50, 75, 85 (100) % of reimbursement price	The pharmaceuticals meet the criteria in 4.2.1
General reimbursement POM, limited	0, 50, 75, 85 (100) % of reimbursement price	Limited to specific diseases. Do not in all cases meet the criteria in 4.2.1
General reimbursement OTC, limited	0, 50, 75, 85 (100) % of reimbursement price	Limited to specific diseases or to pensioners
Supplementary: Individual reimbursement for a specific product. 0, 50, 75, 85 (100) % of the reimbursement price. Potentially all pharmaceuticals which are not eligible for general reimbursement.		

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

Source: DKMA 2007

Most pharmaceuticals eligible for general reimbursement are in principle included in the reference price system (cf. 4.3 for information on the principles of this system). Only for completely new pharmaceuticals (new active substances or new different types/pharmaceutical forms of already existing active substances and before marketing of potential parallel imported pharmaceuticals) is the pharmacy retail price (PRP) identical to the reimbursement price. For all other pharmaceuticals the reported pharmacy retail price (PRP) may or may not be identical to the reimbursement price.

Figure 4.1: Denmark - Development of pharmaceuticals in reimbursement categories by percentage (volume)



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

Source: DKMA 2007a (data for 2000 are not available)

4.2.5 Reimbursement lists

In Denmark there is a positive list containing details of all pharmaceuticals (name and pharmaceutical form) eligible for reimbursement, arranged according to the Anatomic Therapeutic Chemical (ATC) classification system.[40] 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 pharmaceuticals and OTC pharmaceuticals.

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

The Reimbursement Committee (MTN) meets once a month and recommends whether pharmaceuticals 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 pharmaceuticals are granted general reimbursement without application if their prices do not exceed the prices of the original (reimbursable) products. The companies can market new pharmaceuticals every two weeks (hence the bi-weekly updates).[41] Pharmaceuticals 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.

4.3 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 pharmaceuticals the reimbursement groups are identical to the substitution groups. This section should therefore be read together with 5.5.1 on generic substitution.

The core characteristic of the system is that similar (so-called interchangeable) pharmaceuticals are clustered in substitution groups. “Similar” is defined as pharmaceuticals 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 sold in similar or nearly similar pack sizes (cf. 5.5.1 for details). The number of pharmaceuticals in a substitution group (including the number of packs) may vary from 2 to about 15.

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

[41] 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.

The reference price system includes all pharmaceuticals, defined as above, including parallel imported pharmaceuticals. For those pharmaceuticals that are eligible for reimbursement the reference price groups are identical to the substitution groups. The system is based on the grouping of synonymous pharmaceuticals (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.

The reference price groups are updated whenever new pharmaceuticals, 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 pharmaceuticals 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 (cf. 3.1). In 2007 the reference price system included approximately 2,400 marketed pharmaceuticals (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 pharmaceuticals) containing the same active substance in the same strength. The actual reimbursement rate is calculated as 0, 50, 75, 85 (or 100) % of the reimbursement price (cf. Table 4.1).

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 pharmaceutical and the one prescribed, on top of the regular co-payment (cf. Table 4.2). This also applies to situations where the patient opts for a more expensive product than the cheapest one at her/his own will (cf. 5.5.1).

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 Danish Medicines Agency (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.

4.4 Private pharmaceutical expenditure

The main principles of out-of-pocket payments (OPP) by patients for pharmaceuticals 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 (cf. Table 4.2 for actual figures).

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 pharmaceutical expenditure (PE) in recent years.

Much information is available to patients on the Danish Medicines Agency (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 pharmaceuticals. On the Institute for Rational Pharmacotherapy (IRF) web site (www.irf.dk) there is a list of recommendations for individual Anatomic Therapeutic Chemical (ATC) groups, e.g. for lipid-lowering pharmaceuticals, beta-blocking agents, etc.

As patients always have to pay a variable percentage co-payment for pharmaceuticals (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).

4.4.1 Direct payments

Some groups of pharmaceuticals have not been granted general reimbursement as they do not meet the criteria for general reimbursement (cf. 4.2.1). Examples include products that are likely to be abused, antismoking pharmaceuticals 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 pharmaceuticals.

The patient pays the full price for these pharmaceuticals. However, for all pharmaceuticals which are not eligible for general reimbursement the doctor can apply to the Danish Medicines Agency (DKMA) for individual reimbursement to the patient (cf. 4.2.1). This includes non-reimbursable OTC pharmaceuticals, if prescribed by a doctor. In some cases the social laws may cover (part of) the direct payment for pharmaceuticals (cf. 4.4.2.4 for exceptions).

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

4.4.2 Out-of-pocket payments

4.4.2.1 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 pharmaceutical.

4.4.2.2 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 out-of-pocket payments (OPP) by the end of the personal

reimbursement period. Every patient has a personal reimbursement period beginning on the date when s/he bought reimbursable pharmaceuticals 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 pharmaceuticals for the first time after the previous period has expired.

Table 4.2 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 4.2: Denmark - Reimbursement rates and patient co-payment rates, 2006

Annual expenditure for patients in terms of reimbursement price in DKK / €[1]	**Co-payment rate in %**	**Reimbursement rate in %**
Adults		
DKK 0-480 / € 0-64.41	100%	0%
DKK 480-1,165 / € 64.41-156.34	50%	50%
DKK 1,165-2,730 / € 156.34-366.35	25%	75%
> DKK 2,730 / € 366.36	15%	85%
Children up to 18 years		
DKK 0 - 1,165 / € 156.34	50%	50%
DKK 1,125-2,730 / € 156.34-366.35	25%	75%
> DKK 2,730 / € 366.36	15%	85%
Chronically ill [2]		
DKK 0-18.105 (adults) or 19,705 (< 18 yrs) / € 0-2,625.8 (adults) or 2,858.4 (< 18 yrs)	Co-payment rates and reimbursement rates as stated above	
> DKK 18,105 or 19,705 / € 2,625.8 or 2,858.4	0%	100%
Terminally ill [3]		
DKK 0 / € 0	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 pharmaceuticals and therefore similarly large costs.

[3] Includes all consumed pharmaceuticals (also non-reimbursable pharmaceuticals) prescribed by a doctor.

Source: The Danish Health Act, No. 546 of 24 June 2005, as amended.

In 2006, there was an annual out-of-pocket payment (OPP) maximum of DKK 3,520 / € 472.37 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 was slightly lowered in 2007.

4.4.2.3 Deductibles

No deductibles are used in the predominant reimbursement scheme in Denmark. For disabled people or parents providing for a disabled child in their own home (cf. 4.2.2), an initial deductible of maximum DKK 500 / € 67.12 must be paid.

4.4.2.4 Exceptions for vulnerable population 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 50% 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 4.2) 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 pharmaceuticals free of charge upon application by the doctor.
- Certain over-the-counter (OTC) pharmaceuticals are reimbursable for pensioners.

According to the social laws (cf. 4.2.2) in Denmark, pensioners, people with low income, disabled people and others may be granted additional reimbursement. 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.

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.

4.5 Reimbursement in the hospital sector

In Denmark all hospital treatment, including pharmaceuticals, is free of charge to the patient. This is fundamentally different from the primary care sector. In both sectors, pharmaceutical treatment is financed 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.

In every region there is one or more Drug and Therapeutics Committee that makes the relevant decisions regarding the formulary lists. The choice of pharmaceuticals is not in any way related to the eligibility criteria in the primary care sector (cf. 4.2.1). For more information, cf. also 2.1.3.4.

4.6 Reimbursement-related cost-containment measures

Two important cost-containment measures applied in Denmark are generic substitution (cf. 5.5.1) and the reference price system (cf. 4.3).

On 15 December 2006 the Pharmaceutical Industry Association Lif and the Ministry of the Interior and Health (IM) signed an agreement on pricing stating that the prices of reimbursable prescription-only medicine(s) (POM) cannot exceed the prices valid by 30 August 2006. The agreement will be valid for the next two years and will only apply to companies that are members of the Danish Association of the Pharmaceutical Industry (Lif) (cf. 3.6.3). For the next two years the Ministry of the Interior and Health (IM) must not – without prior negotiation with the Lif – implement major changes of the terms of the pharmaceutical market, e.g. regarding price control, mandatory generic prescribing and any basic changes in the scope of products included in the reference price and substitution systems. Similar agreements have already been in place over the years, albeit to a limited extent.

4.6.1 Major changes in reimbursement lists

For many years there have been no fundamental or major changes to the Positive List. On a smaller scale there have been changes concerning specific pharmaceuticals or groups of pharmaceuticals, e.g. lipid-lowering pharmaceuticals and Cox-2 inhibitors.

Until 1998 lipid-lowering pharmaceuticals 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. also 4.6.5).

4.6.2 Introduction / review of reference price system

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, as defined in 4.3.

In 2000 a new reference price based on European prices was introduced.[42] The reimbursement was to be calculated from an average of the pharmacy purchasing prices (PPP) 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 pharmaceuticals 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

[42] 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.

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.[43, 44] 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.[45]

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

The major change in 2000 of the reimbursement system – the introduction of the needs-dependent system and the fundamentally different out-of-pocket payment (OPP) element – is described in 4.2 and 4.2.2.

4.6.4 Claw-backs

Claw-backs are not used in Denmark.

4.6.5 Reimbursement reviews

The Danish Medicines Agency (DKMA) has started reassessing the reimbursement status of all pharmaceuticals. This reassessment will take place over a 5-year period. All products will be reviewed to ensure that pharmaceuticals that have been granted general reimbursement continue to meet the eligibility criteria (cf. 4.2.1) and, conversely, that pharmaceuticals which have not been granted general reimbursement still do not meet these criteria.

In 2004, the Danish Parliament decided to carry out a reassessment based on a recommendation in Committee report No. 1444 of May 2004 “Reimbursement and rational use of medicinal products”. Among other things the recommendation states that “…such decisions on reimbursement status shall not be permanent, as the conditions which were essential to the decision may change over time”. The Danish Medicines Agency (DKMA) has drawn up guidelines on the procedures, evaluation, etc., of the reassessments.[46]

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[43] 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 were excluded from the previous country basket.

[44] 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.

[45] 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.

[46] Guidelines of 8 June 2005 on the procedure for reassessment of reimbursement status (including an outline of the reassessment procedure) and in the Guidelines of 4 July 2006 for evaluation and comparison of medicinal products in the reassessment of reimbursement status

The first reassessment of reimbursement status (in which the target pharmaceuticals were lipid-lowering pharmaceuticals) led to a change in reimbursement status in April 2007. The rest of the Anatomic Therapeutic Chemical (ATC) group C and the groups A and J will follow. All information on the reassessment process is constantly published on the Danish Medicines Agency (DKMA) web site, including a rough plan for which Anatomic Therapeutic Chemical (ATC) groups will be reassessed at what time, the status of ongoing reassessments, formal consultations of companies and scientific societies, final decisions, etc.[47]

Besides the formal reassessment of the reimbursement status, decisions on reimbursement may be reviewed on an ad hoc basis. Pharmaceutical companies may appeal against a “negative” decision or simply reapply for general reimbursement. New scientific documentation can mean that it is necessary to review a reimbursement decision, e.g. new and better documentation of a clinical effect, new documentation of previously unknown side-effects (e.g. Cox-2 inhibitors), documentation of incorrect use, etc.

[47] http://www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=6301

5 Rational use of pharmaceuticals

5.1 Impact of 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 pharmaceuticals 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 (cf. 4). 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 (cf. 2.1.3.5).

All general practitioners (GP) regularly receive an evaluation of their prescribing habits in the form of lists enumerating the amount and costs of prescribed pharmaceuticals. 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.

All hospital wards manage their own budget for purchasing pharmaceuticals. The aim is for the doctors only to prescribe those pharmaceuticals which have been recommended by the Drugs and Therapeutics Committees or the pharmaceuticals that are on the standard list of pharmaceuticals regularly used in the ward. The pharmaceuticals have been included in the pharmaceutical 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 pharmaceuticals. 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 (cf. 2.1.3.4). In case where the ward orders a pharmaceutical 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 pharmaceutical. In spite of this procedure it is still possible for the ward to order an expensive pharmaceutical, as long as the total consumption of the ward is with the budgetary limits.

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

5.2 Prescription guidelines

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 moni-

tored 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 (cf. 5.6 for more information).

Doctors have ample opportunity to receive detailed and valuable information on pharmaceuticals. 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 pharmaceuticals and new studies of interest are reported. INFOMATUM Ltd. is a subsidiary company of Danish Drug Information Ltd. (Dansk Lægemiddel Information A/S, DLI).[48]

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 Pharmacotherapy (IRF) issues lists of recommendations on therapeutic areas (Den Nationale Rekommandationsliste, the National List of Recommendations) recommending which pharmaceuticals to choose and in which strengths.[49] 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 general practitioners (GP) 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.

5.3 Information to patients / doctors

Advertising of pharmaceuticals to the general public and health professionals is regulated by the Danish Medicines Act,[50] the Executive Order on Advertising, etc., of Pharmaceuticals[51] and the

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

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

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

Executive Order on Distribution of Free Samples of Medicinal Products,[52] 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.

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) prescription-only medicine(s) (POM) to a patient).

Over-the-counter (OTC) advertising is allowed in all media. Advertising of pharmaceuticals 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, pharmacoeconomists or students within one of those fields) and entrance to the site is controlled by user identification and password. Advertising on the Internet for prescription-only medicine(s) (POM) is not allowed unless it is on a special site for health professionals. Advertising of a pharmaceutical 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.[53] These are the basic rules on advertising of pharmaceuticals. There are supplementary rules on advertising to the general public and to health professionals in the Executive Order on Advertising, etc., of Pharmaceuticals.

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

The market authorisation holder is obliged to keep a copy or other documentation of all advertising of a pharmaceutical for two years. The Danish Medicines Agency (DKMA) may order disclosure of all necessary information with a view to monitoring compliance with the regulations on advertising. The Danish Medicines Agency (DKMA) responds to complaints and carries out spot checks in order to monitor compliance.

Pharmaceuticals 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 pharmaceuticals they present. Pharmaceuticals 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 pharmaceutical presented, together with information on prices and reimbursement provisions. Any documentation sent or supplied for promotional purposes to health professionals concerning a pharmaceutical 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,

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

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

[53] The Medicines Act, section 63.

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 pharmaceutical 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 od a fine.

There are several restrictions on sending **pharmaceutical 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 pharmaceuticals are to be distributed under the conditions listed here.

- Samples of pharmaceuticals shall be distributed only to physicians, dentists and veterinarians, and only in so far as the people concerned are qualified to prescribe the pharmaceutical and are permitted to use the product in their respective professions.
- Only one sample of each pharmaceutical shall be distributed each year to each physician, dentist or veterinarian. Where the pharmaceutical 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 pharmaceuticals shall be distributed only in response to a written, signed and dated request from the recipient.
- Samples of pharmaceuticals 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 pharmaceuticals listed in the Euphoriant Substances Act must be distributed.

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

Patients are mostly informed by packaging inserts, by their doctors and by pharmacists. Regarding specific pharmaceuticals, 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 pharmaceuticals approved by the Danish Medicines Agency (DKMA). “Medicinhåndbogen” was first published in 1985 and

is now also available online.[54] It is sold from pharmacies. Danish Drug Information Ltd. (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,[55] providing a large amount of information on rational use of pharmaceuticals. In a wider sense, the Danish Medicines Agency (DKMA) provides much web-based information to patients, e.g. on side-effects, safety, prices, reimbursement, generic substitution, counterfeit pharmaceuticals, etc.[56] A National Drug Interactions Database was launched in April 2007.[57]

As far as the hospitalised patient is concerned (and her/his relatives), s/he has a right to relevant and objective information on their pharmaceutical treatment. The patient should preferably be informed prior to the treatment and give her/his acceptance on an informed basis. Many hospitals use written information based on the Handbook of Pharmaceuticals mentioned earlier.

5.4 Pharmacoeconomics

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 pharmaceuticals 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 survival 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 pharmaceutical and includes no economic aspects. As pharmaceuticals are freely priced in Denmark (cf. 3.2.3) 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 pharmaceutical. 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 pharmaceuticals 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 pharmaceuticals are granted reimbursement if the originator has been granted reimbursement,

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

[55] www.medicinmedfornuft.dk

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

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

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").[58] 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" ("Retninglinier for samfundsøkonomiske analyser af lægemidler") were issued, and in 2004 the "Standardised reporting structure for health-economic analyses in applications for general reimbursement" ("Standardiseret rapporteringsstruktur for sundhedsøkonomiske analyser i ansøgninger om generelt tilskud til lægemidler") was issued specifying how to structure and report a health-economic analysis.[59]

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 pharmaceuticals, 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.

[58] Act No. 224 of 25 March 1997 on Temporary Price Stop on Pharmaceuticals, etc.

[59] Cf. http://www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=6450#health

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 Danish Medicines Agency (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 Danish Medicines Agency (DKMA). Supplementary to the guidelines and the reporting structure, the Danish Medicines Agency (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 pharmaceutical. In fact, practically all analyses have been cost-effectiveness analyses and did not include quality-adjusted life year (QALY) considerations.

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 pharmaceuticals) 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 pharmaceutical falls under one or more of the eligible criteria (cf. 4.2.3, bullet points a-i), 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. 4.2.3, subsection g).

The above-mentioned guidelines relate to the out-patient sector alone. For the in-patient sector the same guidelines are applied as they are generally accepted as best practice for performing health-economic analyses.

5.5 Generics

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 (cf. 5.5.1 and 4.3). Table 5.1 shows the share of generics.

Table 5.1: Denmark - Development of the generics market in the out-patient sector 2000-2005

Generics market share	2000	2001	2002	2003	2004	2005
Volume (no. of prescriptions per year)[1]	n.a.	280	332	418	643	813
Value (Mio. €)	n.a.	100.5	126.0	144.5	192.1	211.1

[1] Number of prescriptions is not available. The volume is in Mio. defined daily dose (DDD).

Source: DKMA 2007b

5.5.1 Generic substitution

Please note that this section should be read together with 4.3 on the reference price system, as the two systems are very much interlinked. For reimbursable pharmaceuticals the reimbursement groups are identical to the substitution groups, and the reference price system is based on the generic substitution system. However, non-reimbursable pharmaceuticals are also included in the generic substitution scheme.

Voluntary generic substitution of pharmaceuticals 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 pharmaceutical qualifies for substitution. The pharmaceuticals are grouped into substitution/reimbursement groups according to their Anatomic Therapeutic Chemical (ATC) classification code (whereby only Anatomic Therapeutic Chemical (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).

Regarding the initial qualitative decision, the Danish Medicines Agency (DKMA) considers for most active substances that market authorisation for a generic may be granted if the usual acceptance limits for bio-equivalence (80-125%) are observed. For some “narrow therapeutic index” pharmaceuticals, market authorisation can be obtained if bio-equivalence within the 80-125% limits has been demonstrated, but the pharmaceutical will only be submitted for automatic generic substitution if narrow limits (90-111%) for bio-equivalence are met. For a limited number of pharmaceuticals (e.g. immunosupressants) the bio-equivalence limits have been narrowed (90-111%) in order to eliminate any therapeutic problems in relation to generic substitution.[60]

[60] Cf. the DKMA web site: http://www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=6437

Substitution of a certain pack size by another pack size is only possible if it is within a range of 10-25% divergence in the pack size from the smallest pack to the largest pack in the group, depending on the type of pharmaceuticals (e.g. narcotics only 10%).[61]

Although generic substitution is mandatory, 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.

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) (cf. 4.4.2) – 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 (cf. Table 4.2). 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 (cf. 2.2.2) may have no or little incentive to accept substitution, as their co-payment may be partly or totally covered by this insurance.

If the patient cannot tolerate a cheaper (generic) product, the doctor can apply to the Danish Medicines Agency (DKMA) for increased reimbursement for the more expensive (often brand name) pharmaceutical (cf. 4.3).

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 (cf. 5.1). 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 pharmaceutical and the cheaper alternative is minor. If the difference between the prescribed pharmaceutical 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 pharmaceutical. This “triviality limit” was introduced in 1996.

In order to assist the pharmacies in dispensing the correct pharmaceutical 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 pharma-

[61] DKMA 2007c

cies' duty to substitute and inform on cheaper combinations of similar smaller packs, No. 45 of 29 May 2006.

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. Pharmacies in Denmark are not allowed to substitute therapeutically.

5.5.2 Generic prescription

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

Due to a recommendation[62] 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 Danish Medicines Agency (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.

5.5.3 Generic promotion

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.

5.6 Consumption

All pharmaceuticals with valid market authorisation may be, but are not necessarily, marketed in Denmark. All marketed pharmaceuticals are available all over the country, but occasional cases of delivery failure may occur. However, this is mainly a problem with the cheapest generic of a substitution group and does not imply that there is a problem with availability of specific active substances. The Danish Medicines Agency (DKMA) has not observed any problems so far with new pharmaceuticals not being marketed in Denmark.

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

The reimbursement system is designed to favour patients with extensive consumption of prescribed pharmaceuticals (including reimbursable over-the-counter (OTC) pharmaceuticals), thereby making it possible for all patients to buy the necessary pharmaceuticals. The reimbursement criteria are designed to support rational pharmacotherapy, i.e. that the right patients receive the right pharmaceuticals.

Individual consumption data are monitored via a database containing information on all sales taking place in pharmacies, administered by the Danish Medicines Agency (DKMA). For each attendance it is recorded which pharmaceutical 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 Danish Medicines Agency (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) send in electronically this information on their sales.

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

In 2006 the volume of pharmaceuticals sold in the primary care sector was 1.287 defined daily doses (DDD) per 1,000 inhabitants per day. In the hospital sector the volume was 50 DDD per 1,000 inhabitants per day. In total the consumption was 1,337 DDD per 1,000 inhabitants per year. For many pharmaceuticals used in the hospital sector no defined daily dose (DDD) value is assigned, so this volume used is underestimated.

6 Current challenges and future developments

6.1 Current challenges

The Danish Medicines Agency (DKMA) is aware of several challenges related to the pharmaceutical system, as is undoubtedly the case in many other countries. 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 pharmaceuticals, combined with more intensive medical treatment including a rising number of different substances.
- The introduction of new innovative pharmaceuticals at the optimum time, i.e. neither too early nor too late.
- A lack of relevant head-to-head clinical trials of new pharmaceuticals against existing treatment.
- The so-called lifestyle pharmaceuticals 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 pharmaceuticals 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 pharmaceuticals, e.g., the use of new vaccines, etc.

6.2 Future developments

A long-term pharmaceutical policy that has already been decided upon in Denmark is the reassessment of reimbursement status, set in motion by the Parliament in 2004 (cf. 4.6.5). No major changes are planned.

7 Appendixes

7.1 References

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7.2 Further reading

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

Danish Association of the Pharmaceutical Industry (Lif): Tal og data (2007) (Facts and figures): http://www.talogdata.dk

Ordiprax: www.ordiprax.dk (in Danish only).

7.3 Web links

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

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

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

National Causes of Death Register:
http://www.sst.dk/Informatik_og_sundhedsdata/Registre_og_sundhedsstatistik/Beskrivelse_af_registre/Doedsaarsagsregister.aspx?lang=da

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

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

Danish Consumer Council: http://www.forbrugerraadet.dk

Danish Patients: http://www.danskepatienter.dk

Danmark: http://www.sygeforsikring.dk

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7.4.2 Country editors

The first version of the Danish Pharmaceutical Pricing and Reimbursement Information (PPRI) Pharma Profile was reviewed in March/April 2007 by Health Economist Ms. Claudia Habl of the

Austrian Health Institute (GÖG/ÖBIG) and Technical Officer Ms. Trine Lyager Thomsen of WHO Regional Office for Europe, who also acted as editor-in-chief.

The layout and content of the second draft was edited by Ms. Habl in June 2007 and then copy-edited by Ms. Nicole Satterly of WHO.

The final editing process was completed in December 2007 together by Ms. Habl (GÖG/ÖBIG) and Ms. Thomsen (DKMA).