

# Pricing and Reimbursement in Denmark



The Danish  
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# **Pricing and Reimbursement in Denmark**

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# Pricing and reimbursement in Denmark

## Introduction

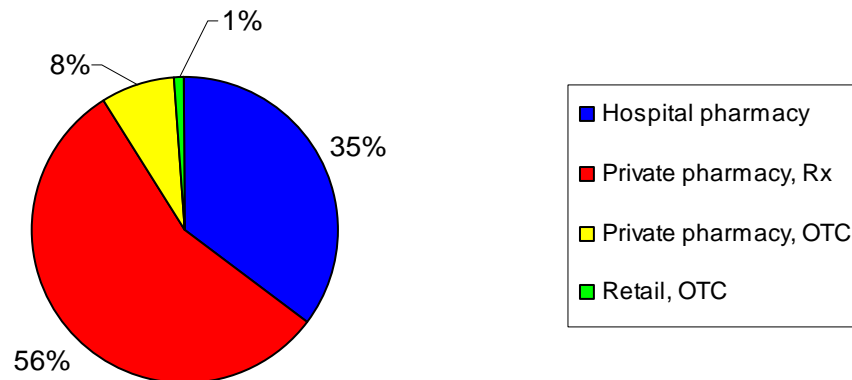
In this paper we describe the current Danish pricing and reimbursement regime within the pharmaceutical areas. We also touch on current cost containment measures and sporadically we mention some previous initiatives to give the reader a historical understanding of background and trends.

The pharmaceutical area is heavily regulated in Denmark as in other countries. But while marketing authorization matters (effect, safety and quality issues) are regulated according to EU regulation and therefore almost identical regardless the country (in Europe), pricing and reimbursement issues are a matter of national competency. Not surprisingly, the regulation regarding pricing and reimbursement differs between countries.

In Denmark, as in most countries, cost containment in the pharmaceutical area has been on the political agenda for years. Within the field of cost containment measures Danish governments most definitely has not been among the “laggards”. On the contrary one might find that Danish governments – independently of their political affiliations – has been among the most “innovative” (or aggressive) within this field when it comes to the use of tools such as substitution schemes, reference pricing and prescription monitoring. Temporary price caps by law and price agreements with the pharmaceutical industry have also been among the tools employed.

An ever growing demand for healthcare services combined with the continuing introduction of new therapies/products leading to relatively high growth rates in public expenditures for pharmaceuticals has been a key driver in this development. At the same time an inherited “cultural scepticism” towards the use of pharmaceuticals and to the pharmaceutical industry as such among the general public has made it politically “free of charge” to take even brutal measures within this area. Neither the professional societies nor the general public has loud and clearly been opposing to this development. Consequently Denmark has one of the lowest consumptions of medicines compared to other OECD countries – and is a laggard when it comes to introducing and diffusing new pharmaceuticals and other healthcare technologies in the Danish healthcare sector.

**Figure 1. Distribution of turnover in the Danish pharmaceutical market 2006**



Source: DLI, Dansk Lægemedelinformation.

Figure 1 gives an overview of the Danish pharmaceutical market in 2006. Almost 2/3 of the turnover is attributed to the private pharmacies but actually relatively large growth rates in the hospital sector in several years have decreased the “weight” of the private sector. In 2002 the hospital sector only constituted 25 % of total turnover compared to 35 % in 2006.

## 1. Pricing of pharmaceuticals

Having said that Denmark is tough concerning measures to curb cost it on the other hand should be acknowledged that Denmark to a high degree has been market oriented as regards the regulation of pricing.

But, that is not the same as saying that the price of pharmaceuticals is not an issue for Danish authorities and politicians, actually it is important to understand that the (more or less) free-pricing regime has led to the broadly shared perception that Danish pharmaceutical prices are very high compared to other relevant countries. This general opinion that Danish prices are (too) high has been one of the key drivers behind the political and public willingness to use cost containment tools. As shown in textbox 1 below it has also led to various restrictions in pricing throughout the years.

### 1.1 Pricing in the pharmaceutical industry

In Denmark pharmaceutical companies do not have to apply for permission to set their prices, i.e. there is no price control system. In fact there is no special regulation of the price setting of the industry's selling prices, and with no rules to comply with this means that pricing in *principle* is "free".

The marketing of a pharmaceutical in Denmark just requires that the company notifies the Danish Medicines Agency (Lægemiddelstyrelsen) of the pharmacy purchase price (PPP). This notified price is used when the authorities calculate the consumer price, and it is used in connection with the wholesalers' resale to the pharmacies. Companies can change prices fortnightly (every second Monday).

Nevertheless, pricing is an issue – and actually it is not as free as it seems. Since the middle of the 1990s a number of different temporary arrangements have in fact put restrictions on manufacturers' and importers' pricing of pharmaceuticals in Denmark c.f. textbox 1 below.

Currently the pricing of products from Lif's members are restricted by the "Agreement between the Danish Association of the Pharmaceutical Industry (Lif) and the Danish Ministry of the Interior and Health introducing a cap on medicine prices" of 15 December 2006. According to this agreement the price of prescription medicines in receipt of a general reimbursement (including general conditional reimbursement) cannot before 31 December 2008 be raised above the price applying to individual packages on 30 August 2006.

On top of this it shall be noted that price is an important issue in reimbursement cases, i.e. when the authorities decide on the companies' applications for reimbursement of their products, cf. section 2.3.

There are currently no restrictions on the pricing of OTC products, neither the pharmacy-only products nor the products which can be sold outside pharmacies. For the out-of-pharmacy OTC products companies are not even obliged to notify a price to the Danish Medicines Agency.

**Textbox 1. Temporary arrangements restricting the prices of pharmaceuticals**

A) January 1994 – April 1995 (Price Agreement): January 1994 the Minister for Health and the pharmaceutical industry associations MEDIF and MEFA (merging to Lif in 1997) entered into an agreement on pricing. According to the agreement prices should not be raised until April 1995.

B) March 1995 – April 1997 (Price Agreement): March 1995 a new agreement was entered between the authorities and the industry. According to this agreement the industry bound themselves to a general price reduction of 5% on prescription pharmaceuticals covered by the reimbursement scheme. The price of prescription pharmaceuticals not covered by the reimbursement scheme and the price of over-the-counter products (OTC-products) had to be cut by 2%. The price reductions entered into force on 10 April 1995. During the period until 1 April 1997 the industry was not allowed to raise the price of pharmaceuticals above the price in force on 10 April 1995.

C) April 1997 – March 1998 (Price Cap Act): In the beginning of 1997 the government called for further price reductions during the period 1997 - 1999. When an agreement on this could not be reached Act no. 224 of 25 March 1997 introduced a temporary price cap on pharmaceuticals. Pursuant to this Act companies could not, during the period until 1 March 1998, notify prices of pharmaceuticals already on the market that exceeded the pharmacy purchase prices in force on 24 March 1997. For pharmaceuticals which were marketed for the first time after 1 April 1997 a company could not, during the period until 1 March 1998, notify a pharmacy purchase price which exceeded the price that was notified when the product was first marketed.

Under special circumstances the Danish Medicines Agency could allow that a company exceeded the price that followed from the Act. E.g. if raw material prices were raised significantly or if the price in Denmark was significantly below the European average price of the product in question.

Beside the price cap rules the act introduced several other cost containment tools, some of which are mentioned in section 2 regarding reimbursement.

D) February 1998 – March 2000 (Price Agreement): In February 1998 the Price Cap Act was replaced by a new agreement between the Ministry of Health and Lif.

The aim of this agreement was “to secure a predictable and restrained growth in public health insurance expenditure for reimbursable pharmaceuticals under The National Health Insurance Service” (1.5 % in 1998 and 3.0 % in 1999 compared to 1998) and also “to ensure the possibility of introducing state-of-the-art pharmaceuticals”. It was the intention moreover “to improve consistency between the European and the Danish pharmaceutical price levels”.

The agreement contained a price cap, and in order to try to secure a predictable growth in reimbursement expenditure prices were to be lowered under certain circumstances. The prices of prescription pharmaceuticals and of OTC-products for which reimbursement could be obtained under the Health Security Act were not allowed to increase before 1 March 2000. The price of other OTC-products could not be increased in excess of 5%.

The agreement, which expired on 1 March 2000, led to price decreases, but did not curb reimbursement expenditures at the agreed levels.

D) March 2000 – November 2000 (Free Pricing): The 1998-2000 agreement was followed by a short period with no restrictions on the price setting. The government instead relied on new reimbursement rules introducing “European reference prices”, c.f. textbox 2. The government expected that the reimbursement rules would mean that the industry wouldn't set prices above the European reference prices and thereby secure patients from a higher co-payment share.

E) November 2000 – June 2001 (Price Cap Act): In the light of, what the government found to be, raising prices of pharmaceuticals and in view of some prices of pharmaceuticals well above the European average, Act no 1031 of 23 November 2000 introduced a new complex cost containment scheme containing two temporary price caps .

Pursuant to this Act, pharmacy purchase prices could not before 25 June 2001 exceed neither

- the pharmacy purchase prices in force as of 17 November 2000 (for pharmaceuticals that had not been marketed on 17 November 2000, the pharmacy purchase price could not exceed the price that was notified when the product was marketed the first time after 17 November 2000) nor
- the “average European price” (the average price of Austria, Belgium, Finland, France, Germany, Great Britain, Greece, the Netherlands, Ireland, Italy, Norway, Portugal, Spain and Sweden).

The pharmaceutical companies were under obligation to inform the Danish Medicines Agency of the pharmacy purchase prices for the individual product in the other EEC/EEA-countries (except Iceland, Liechtenstein and Luxembourg) every 6 months.

Under special circumstances the Danish Medicines Agency could allow that a company exceeded the price that followed from the Act if e.g. raw material prices were raised significantly.

During the period of the price cap the government and the key stakeholders within the pharmaceutical field carried out a committee work on the future regulation of prices and reimbursement.

F) June 2001 – April 2005 (Price Declaration): From June 2001 to April 2005 there was no compulsory price control or any price agreement between the Ministry of the Interior and Health and Lif, but from 25 June 2001 until 1 April 2005 Lif's member companies declared that the Danish prices of their products would not exceed the average European price of the products (package-to-package). The declaration came as the result of discussions in the committee mentioned above and the resulting reimbursement rules, especially the new definition of European reference prices, c.f. textbox 2.

April 2005 the linkage between European average prices and Danish prices was removed from the reimbursement rules. This was one of many results from a new committee report (Report 1444 of May 2004). As a consequence of the new reimbursement rules Lif members terminated the price declaration.

G) April 2005 – January 2007 (Free Pricing): The discontinuation of Lif's price declaration meant that pricing became free. According to the Minister for the Interior and Health the discontinuation of the price declaration and the following price development – some price raises were experienced – came as a surprise for the authorities and key governmental officials actually declared that Lif was breaking what they saw as a mutual understanding between the industry and the government.

Following the price development after 1 April 2005 the government and other stakeholders, most notably the Danish Regions, on several occasions declared that action was needed. Among other things the need for a price agreement was mentioned.

H) 1 January 2007 – 31 December 2008 (Price Agreement): Currently the pricing of products from Lif's members are restricted by the "Agreement between the Danish Association of the Pharmaceutical Industry (Lif) and the Danish Ministry of the Interior and Health introducing a cap on medicine prices" of 15 December 2006. According to this agreement the price of prescription medicines in receipt of a general reimbursement (including general conditional reimbursement) cannot before 31 December 2008 be raised above the price applying to individual packages on 30 August 2006.

During the term of the agreement, reimbursable prescription products with new active substances, new combination products, new pharmaceutical forms (not eligible for substitution) or pharmaceuticals, which in other ways are essentially different from already marketed products (e.g. considerable differences in strengths), marketed for the first time after the signature date of the agreement, may

not exceed the price which has been announced to the Danish Medicines Agency when applying for general reimbursement.

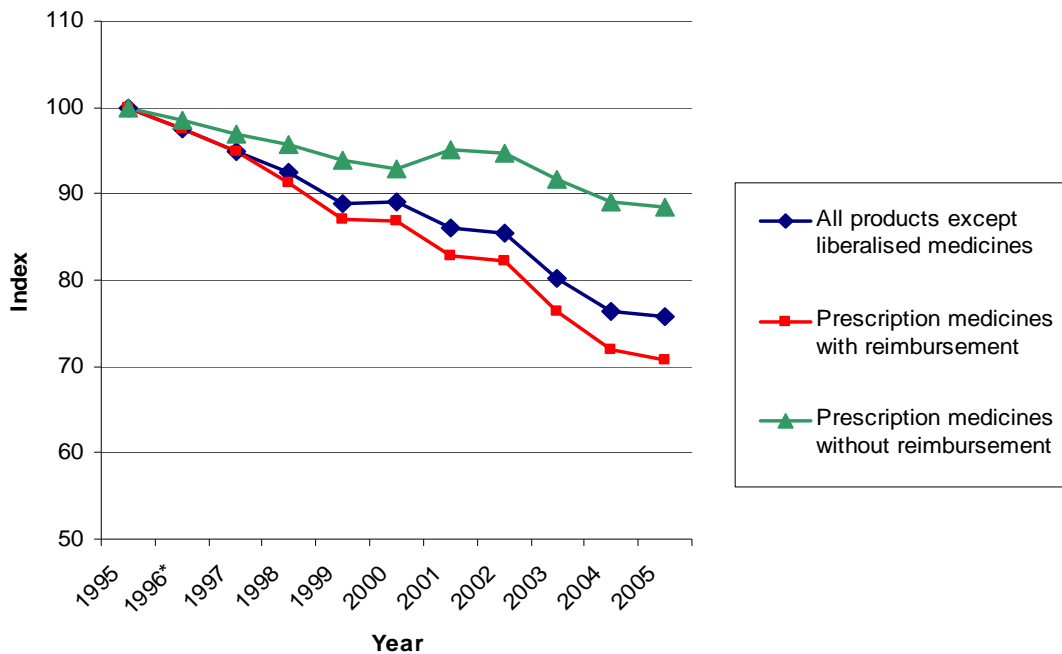
During the term of the agreement, new package sizes or strengths of products already on the market, marketed for the first time after the signature date of this agreement and not encompassed by the section above, may not exceed the price per unit which can be calculated proportionally on basis of the price cap for the nearest comparable package already marketed.

In exceptional cases, Lif's members may apply to the Ministry of the Interior and Health for authorisation to notify prices exceeding the price cap. The application must specify the particular reasons for the application.

Before the end of 2007, the agreement parties have agreed to carry out a halfway-discussion regarding the agreement. At the latest three months before the term of the agreement expires, the parties to the agreement will discuss the situation in connection with the termination of the agreement.

As shown in figure 2 the price trend in Denmark has not been unaffected by the initiatives mentioned in textbox 1.

**Figure 2. Danish PPP price index 1995-2005 (DDD based)**



Source: Danish Medicines Agency;

\* 1996 figures are constructed by extrapolation

## **1.2 Pricing and wholesalers**

The wholesale market for pharmaceuticals for humans in Denmark is dominated by 2(-3) full-line wholesalers distributing pharmaceuticals to the private pharmacies and the hospitals.

The wholesale profits are fixed through individual negotiations between each pharmaceutical company and the wholesaler and the profit level is determined by competition.

## **1.3 Pricing in private pharmacies**

The Danish pharmacy sector is highly regulated. The legislative frame is more than 450 years old, but the concrete legislation has not surprisingly been modernised in the course of time. The number of pharmacies – and to a great extent their location – is decided by the authorities. Every proprietor pharmacist (pharmacy owner) is appointed by the Minister for the Interior and Health. Only persons with a pharmacist degree can become owner of a pharmacy.

The consumer price for a certain pharmacy-only pharmaceutical has to be identical in all pharmacies throughout the country. In practice the pharmacies receive an official price lists from the Danish Medicines Agency (electronically) which the pharmacies has to comply with.

The total gross profit (i.e. the total turnover minus the cost of goods) of the entire Danish pharmacy sector is fixed according to agreement between the Ministry of the Interior and Health and the Danish Pharmaceutical Association every two years. For 2007 and 2008 the total gross profit of the approximately 255 private pharmacies was fixed at respectively DKK 2.3 billion and 2.34 billion exclusive VAT.<sup>1</sup> This agreement is linked to the pharmacy profit on the individual (pharmacy-only) pharmaceutical.

Pharmacy retail prices (consumer prices) are calculated on a scale set by the Ministry of the Interior and Health, c.f. below. The retail price consists of the pharmacy purchase price (the price for the wholesalers' resale set by the manufacturer) plus a fixed amount and a percentage profit (set by the Ministry). This system leads to uniform prices on pharmacy-only pharmaceuticals throughout the country.

A dispensing fee is added to the consumer price for prescription pharmaceuticals and OTC products sold on prescription (to obtain reimbursement). At present the fee is DKK 8.00 exclusive VAT per item prescribed (DKK 10 including VAT).

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<sup>1</sup> According to the agreement, the pharmacies have to pay the regions a (minor) turnover-dependent discount.

$$\text{Pharmacy retail price/consumer price} = \text{DKK } 10.00 + 1.25 \times (\text{PPP} + 0.088 \times \text{PPP} + 8.59)$$

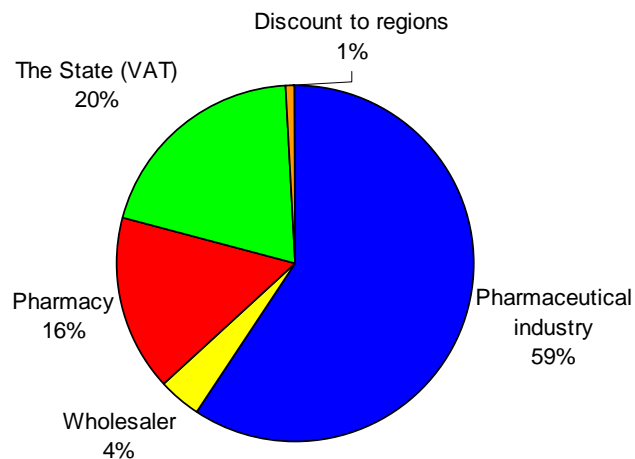
Including VAT

#### 1.4 VAT (State Taxation)

In Denmark, 25% VAT is added to the consumer price of pharmaceuticals, as well as to the consumer price of all other commodities. Compared to most other countries the Danish VAT on pharmaceuticals is very high.

Figure 3 illustrates the composition of the (average) consumer price when divided among the stakeholders mentioned above.

**Figure 3. The composition of the consumer price divided among stakeholders**



Source: The Danish Pharmacy Association; web site; March 2007

#### 1.5 Discounts to pharmacies

Under the European Union Directive on the advertising of pharmaceuticals pharmacies' suppliers are allowed to grant discounts to pharmacies. Discounts have to be linked to cost reductions, i.e. discount can only be granted to a pharmacy from the direct seller of the product (normally the wholesaler) and if the pharmacy has a cost effective way of purchasing products from the seller/wholesaler. The discounts do not affect the price of pharmaceuticals

*directly*, but prices are indirectly affected through the system of total gross profit agreements between the Ministry of the Interior and Health and the Danish Pharmaceutical Association.

### **1.6 Price lists**

Prices for all pharmaceuticals that are restricted to be sold in pharmacies are published by the Danish Medicines Agency on the website: [www.medicinpriser.dk](http://www.medicinpriser.dk).

### **1.7 Hospitals and prices of pharmaceuticals**

The public hospitals in Denmark can in principle either choose to buy pharmaceuticals through the private pharmacies or through a hospital pharmacy. In practice the sales through the private pharmacies is ceasing. Today more than 90 % of the pharmaceuticals used in public hospitals are bought through the hospital pharmacies and the rest through the private pharmacies. The hospital pharmacy percentage is expected to come close to 100 % as a consequence of the structural reform which came into force in January 2007.

In case of distribution of pharmaceuticals from private pharmacies to hospitals and other public institutions, the private pharmacy's retail price is dependent on the hospital's/institution's purchase of pharmaceuticals in the preceding year. The pharmacy profit margin is set by the Minister for the Interior and Health. The pharmacies are allowed to facilitate the granting of discount from pharmaceutical companies to the hospitals.

The regions/the hospital pharmacies have formed the wholesale society AMGROS I/S which invite international tenders for pharmaceutical contracts. As a consequence the hospital market for pharmaceuticals, and hence prices, is very different from the primary healthcare sector market.

## 2. Reimbursement system

### 2.1 Health insurance systems

The Danish healthcare services are primarily public but a growing private sector is emerging. The 5 regions run the hospital sector as well as the primary care sector, while the 98 municipalities have the responsibility regarding general prevention and health improvement policy as well as rehabilitation care outside hospitals.<sup>2</sup>

The public expenditures for healthcare are financed through taxes, primarily by a special national healthcare tax. According to the National Health Act (previously the Health Security Act) the regions offers totally or partially coverage of the expenditures for treatment by general practitioners, specialists, dentists, and physiotherapists etc., as well as reimbursement of pharmaceutical treatment. All inhabitants in Denmark are covered by the Healthcare Act's provisions.

Citizens are free to choose between two insurance groups:

- Group 1 members are attached to one general practitioner and need a reference from this GP in order to visit a specialist. Both visits to GP's and specialists are free of charge for the patients.
- Group 2 members are free to choose any GP and may visit a specialist without reference from a GP. The regions only cover part of the costs.

There is no difference between the two groups with regard to the reimbursement of pharmaceuticals.

98 % of the Danes are group 1 members. Citizens may of course take out insurance with private insurance companies and thus obtain further reimbursement of e.g. pharmaceutical expenditures. "Sygeforsikringen danmark" is the only major private (non-profit) health insurance company in Denmark (1.8 million members) but the private sector is rising especially due to collective arrangements within the labour market.

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<sup>2</sup> On January 1, 2007 the Structural Reform – or the Reform of the Administrative Structure – came into force. It was a far-reaching reform of the frameworks for the public tasks and the public services in Denmark. The reform implied that the (13 + 3) counties were dissolved and instead 5 new regions were established. The county tasks were split between the state, the regions and the municipalities. As a consequence of more and larger tasks the number of municipalities was at the same time reduced from 271 to 98.

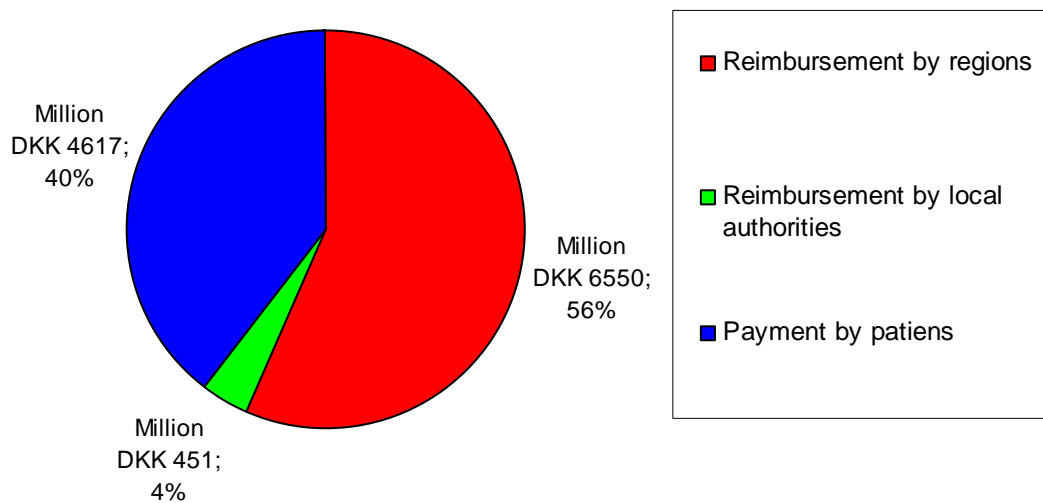
## 2.2 Reimbursement of pharmaceuticals

In accordance with the National Health Act the regions administrate reimbursement of the cost of pharmaceuticals. At the pharmacy the patient only pays his/her share according to the reimbursement status of the product, and the pharmacy gets the reimbursement amount from the region.

As part of the social security system some schemes exist according to which certain patients may be granted further aid from the municipalities, e.g. pensioners in particularly difficult economic circumstances, people in financial need, and disabled persons living in their own home.

Figure 4 shows the distribution between reimbursement sources and payment by patients of the sales of medicinal products in the primary healthcare sector.

**Figure 4. Sales in the pharmacy sector divided between reimbursement sources and co-payment**



Source: The Danish Medicines Agency

Treatment with pharmaceuticals as a part of public hospital treatment is free of charge for all citizens.

## 2.3 General and general conditional reimbursement for pharmaceuticals

According to S. 143 of the National Health Act, the regions are required to provide reimbursement for the purchase of medicinal products for which the Danish Medicines Agency has granted reimbursement.

Pursuant to S.144 (1), reimbursement is provided for the purchase of prescription drugs for which the Danish Medicines Agency has granted *general reimbursement*. Section 144 (2) states that reimbursement for prescription drugs in accordance with (1) may be made conditional on the medication being prescribed for the treatment of specific diseases, called general conditional/restricted reimbursement.

Table 1 shows the trends for turnover and usage of medicines in the primary healthcare sector, distributed by reimbursement status.

**Table 1. Distribution of medicinal product turnover compared to reimbursement status. (Pharmacy sector)**

	2001	2002	2003	2004	2005	2001-05
General and general conditional reimbursement <sup>1</sup>	6,830	7,633	7,861	7,811	7,926	16%
Individual reimbursement <sup>2</sup>	409	507	592	715	838	105%
No reimbursement <sup>3</sup>	917	927	892	902	933	2%
OTC with reimbursement	411	432	450	564	578	41%
OTC without reimbursement	1,110	1,125	1,166	1,226	1,275	15%
Dose dispensing	1	6	21	46	66	-
<b>Total</b>	<b>9,677</b>	<b>10,631</b>	<b>10,983</b>	<b>11,264</b>	<b>11,617</b>	<b>20%</b>
%						
General and general conditional reimbursement	70.6%	71.8%	71.6%	69.3%	68.2%	-
Individual reimbursement	4.2%	4.8%	5.4%	6.3%	7.2%	-
No reimbursement	9.5%	8.7%	8.1%	8.0%	8.0%	-
OTC with reimbursement	4.2%	4.1%	4.1%	5.0%	5.0%	-
OTC without reimbursement	11.5%	10.6%	10.6%	10.9%	11.0%	-
Dose dispensing	0.0%	0.1%	0.2%	0.4%	0.6%	-

Source: The Danish Medicines Agency

<sup>1</sup> It is not possible to split the turnover between products with general reimbursement and general conditional reimbursement from the Danish Medicines Agency's statistics. <sup>2</sup> Products, without general reimbursement, sold with individual reimbursement. <sup>3</sup> Products, without general reimbursement, sold without reimbursement. The sales of a product with conditional reimbursement status might, depending on the patient's disease, fall into either one of the three first categories in the table.

Section 155 of the Health Act provides that the Minister of the Interior and Health is required to set-up a Medicines Reimbursement Board to advise the Danish Medicines Agency in matters of reimbursement for medicinal products. Accordingly, it is the Danish Medicines Agency that makes the decisions in reimbursement cases. The Medicines Reimbursement Board (MTN) acts (in principle) solely in an advisory capacity.

The Danish Medicines Agency takes decisions concerning reimbursement status for each product after application from the company bringing the pharmaceutical on the market in Denmark. Table 2 summarises the Danish Medicines Agency's decisions on applications for general reimbursement for new products in the period 2001-2006. General reimbursement (and general conditional reimbursement) is granted for about 60% of company applications.

**Table 2. Reimbursement decisions**

	1999	2000	2001	2002	2003	2004	2005	2006
Number of applications for general reimbursement for new active agents <sup>1</sup>	15	21	26	18	13	12	16	20
Number of applications granted <sup>2</sup>	8	8	16	11	9	7	10	12
Number of rejections	7	13	10	7	4	5	6	8
Grant %	53%	38%	62%	61%	69%	58%	62%	60%

Source: The Danish Medicines Agency.

<sup>1</sup> Re-applications not included

<sup>2</sup> The number of accounts for both general and general conditional reimbursement. But in 2005 and 2006 none of the applications were granted conditional reimbursement.

As mentioned above price negotiations for pharmaceuticals do not exist in Denmark, i.e. there is no price approval procedure, so the pharmaceutical companies are in principle free to decide the prices themselves. However, in practice pricing is an issue and most directly in connection with reimbursement decisions.

Pursuant to the Executive order on reimbursement (Bekendtgørelse om medicintilskud) reimbursement is in general granted for pharmaceuticals:

- If the product have a certain and valuable therapeutic effect when used on a well-defined indication and
- if the price of the product is proportionate to the effect of the product.

However, the executive order also lists several cases where general reimbursement is (normally) *not* granted. This is the case:

- If treatment with the product requires special examination and diagnoses (e.g. Alzheimer's)
- if there is a risk of use outside the products approved indication (e.g. bisphosphonates)

- if there is a risk that the product will be used for purposes which cannot expect to be reimbursed by the authorities (e.g. antismoking products)
- if the effect of the product is not clinically documented (e.g. traditional herbal medicines)
- if there is a risk that the product will be used as a first choice though the Danish Medicines Agency does not find it desirable (e.g. products for obesity)
- if it is un-clarified whether the product should be used as a first choice (e.g. some new arthritis products)
- if there is a risk of abuse (e.g. tranquilisers)
- if the product is primarily used in hospitals (e.g. cancer products)
- if it is impossible for the patients to take the product themselves (e.g. products for injection).

Note: Products mentioned in (...) was listed in the comments to the government's proposal for the new reimbursement rules in 1998.

In 4 refusals out of a total of 6 applications for reimbursement in 2003 a too high price was mentioned as (part of) the reason for rejection. In 2006 it was 3 out of 8.

In order to justify a high price the applying company can submit a pharma-economic evaluation. It is not compulsory to submit such evaluations in Denmark.

As mentioned the Danish Medicines Agency may decide that reimbursement shall only be granted to patients with certain diseases (general conditional reimbursement), i.e. reimbursement is only granted when the product is prescribed for specific conditions. In case of conditional reimbursement the GP/physician has to mark the prescription with 'tilskud' (reimbursement) when issuing the prescription to a patient with the specific disease.

In 2006 3.7 % of turnover in the primary healthcare sector (pharmacy sector) and 10.3 % of total DDD usage were attributable to medicinal products with general conditional reimbursement (according to figures from DLI, Dansk Lægemedelinformation). The figures are primarily a function of usage of the lipid-reducing medications which accounts for 10 out of the total of 19 ATC groups covered by conditional reimbursement.<sup>3</sup>

When general – and general conditional – reimbursement is granted for a pharmaceutical, the Danish Medicines Agency includes the product on a positive list which is published on the website: [www.laegemiddelstyrelsen.dk](http://www.laegemiddelstyrelsen.dk).

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<sup>3</sup> It should be noted that on 23 April 2007 the reimbursement status of the lipid-lowering products was changed. Three types of statins (the cheapest) are now granted general reimbursement.

Companies who disagree with the decisions taken by the Danish Medicines Agency can file a complaint to the Ministry of the Interior and Health. The ministry will not, however, be able to assess the scientific evaluation made by the Danish Medicines Agency.

#### **2.4 Reassessment of reimbursement decisions**

By the end of 2004 the Danish Parliament decided that decisions on reimbursement shall be subject to periodic reassessment (every five years). The reassessment shall aim at assessing whether the assumptions underlying the original decision on granting or not granting reimbursement are still valid.

The process of periodic reassessment was initiated in the summer of 2005 but got a slow start due to lengthy (but necessarily) consultations regarding methodology, procedures and guidelines. The Danish Medicines Agency is currently reassessing the reimbursement status of all pharmaceuticals over a period of five years.

#### **2.5 Reimbursement for over-the-counter (OTC) medicines**

The rules for reimbursement for OTC products are laid down in S. 144 (3) of the Healthcare Act which states that reimbursement is conditional on the medication having been prescribed to treat specific diseases as determined by the Danish Medicines Agency (general conditional reimbursement), or to treat retirees in accordance with social pensions legislation or legislation on the highest, medium, enhanced standard or standard early-retirement pensions, etc. Pensioners receive reimbursement for eligible, prescribed, OTC medicines regardless of their illness.

It is possible to see which illnesses are eligible for reimbursement in the “List of eligible illnesses for OTC products subject to reimbursement” at [www.laegemiddelstyrelsen.dk](http://www.laegemiddelstyrelsen.dk).

#### **2.6 Individual reimbursement**

According to S. 145 of the National Health Act, the Danish Medicines Agency may in special circumstances decide to grant reimbursement for the purchase of a medicinal product prescribed for a specific patient, regardless that the product has not been granted general reimbursement (individual reimbursement). It is the patient's doctor that applies for individual reimbursement on behalf of the patient.

Grant of individual reimbursement means that usage of the pharmaceuticals concerned are included in the patient's medicines account in the needs-dependent reimbursement system in the same way as for products entitled to general reimbursement, as described below.

The possibility to grant individual reimbursement to a specific patient who meets the criteria is a classical “safety net” regulation aimed at helping the special cases, i.e. patients with special

needs. Logically this regulation means that any product not granted general reimbursement is referred to this “default category” of possible individual reimbursement.

For some of the products for which general reimbursement has not been granted, the Danish Medicines Agency has laid down guidelines for when individual reimbursement would typically be granted. There are no fixed criteria for when and how the Danish Medicines Agency sets guidelines for individual reimbursement, and actually the Danish Medicines Agency has only issued guidelines for a very small proportion of the products where it could in principle be relevant. The criteria are published on the website: [www.medicintilskud.dk](http://www.medicintilskud.dk).

In 2006 The Danish Medicines Agency received approx. 107,000 applications for individual reimbursement compared to approx. 64,000 in 1999, c.f. table 3. Overall, about 9% of all applications are rejected – but with wide variations in rejection rates for the various medicinal products.

**Table 3. Number of individual reimbursement applications**

	1999	2000	2001	2002	2003	2004	2005	2006
Individual reimbursement	63,700	53,822	58,702	77,513	84,519	96,594	111,218	106,753
Chronic ill reimbursement *	-	47,138	9,084	8,141	9,548	10,166	23,071	14,633
Terminal ill reimbursement *	-	8,072	8,430	8,568	8,564	8,883	9,023	9,252
Enhanced reimbursement *	-	134	63	69	55	102	2,766	2,713

Source: The Danish Medicines Agency

\* These types of reimbursement are described in the text below.

Note: The relatively large growth in numbers of applications for chronic reimbursement in 2005 was due to reapplications five years after the introduction of the needs-dependent reimbursement system. The growth in the number of applications for enhanced reimbursement is attributable to the amended reimbursement rules of April 2005 according to which reimbursement is determined in accordance with the lowest price within a given reimbursement group.

When the Danish Medicines Agency evaluates the applications for individual reimbursement the Agency, according to the Executive order on reimbursement, attaches importance to whether the medicinal product plays a special role in the patient's treatment,

- including whether the effect of the treatment has already been observed or the expected effect is very likely to occur, and
- other relevant methods of treatment have been found to be insufficient or inappropriate in the particular case.

It should be noted here that the Danish Medicines Agency grants individual reimbursement with different time limits, so the actual number of patients receiving individual reimbursement is considerably greater than indicated in the table. Some time limits are very short (e.g. 1 year),

but actually according to the Danish Medicines Agency most individual reimbursement licences are lifelong. This means that a very considerable number of patients currently get public subsidies for their medication via the individual reimbursement scheme. There are no official figures for this. But by way of illustration, reference may be made to the figures in the table that show that in 2006 there were approximately 107,000 applications for individual reimbursement and about 111,000 and 97,000 in 2005 and 2004 respectively. With a rejection rate of less than 10%, this means that there are a very large number of patients who in fact obtain a subsidy via the individual reimbursement scheme during a year.

In 2005 18 % of the turnover of prescription medicines in the primary healthcare sector was attributed to products not granted general or general conditional reimbursement.

The same year, the turnover of pharmaceuticals administered via the individual reimbursement scheme was DKK 838m (pharmacy retail prices), or 7.2 % of the total primary care market. This has almost doubled the amount in 2001.

In 2005 10.3 % of the total reimbursement funding went on medicinal products administered via the individual reimbursement scheme, whereas the comparable proportion in 2001 was 8 %.

## **2.7 Needs-dependent reimbursement system**

In March 2000 the reimbursement system was fundamentally changed. Until then reimbursable pharmaceuticals were reimbursed either 50 % or 75 % - and insulin was reimbursed 100 %. Now all reimbursable products have an equal status from the point of view of reimbursement rate.

Since 1 March 2000 the reimbursement rate for reimbursable pharmaceuticals depends on a given patient's prior consumption of pharmaceuticals within an individual "reimbursement period" of 12 months, i.e. the reimbursed amount depends on the total cost (calculated on the basis of "reimbursement prices" c.f. below) of reimbursable pharmaceuticals which the patient has purchased within a period of one year reckoned from the date of the patient's first purchase. A new period of one year commences the first time the patient purchases reimbursable pharmaceuticals after the expiration of the preceding period.

In table 4 the reimbursement shares and the co-payment shares are shown. Note that the rates differ depending on whether the person is older or younger than 18 years of age.

**Table 4. Reimbursement rates 2007**

Annual expense per person for re-imbursable pharmaceuticals before subtraction of reimbursement *	Reimbursement for patients older than 18	Patient charge for + 18 years	Reimbursement for patients younger than 18	Patient charge for 18 years and less
DKK 0 – 465	0%	100%	50%	50%
DKK 465 – 1,125	50%	50%	50%	50%
DKK 1,125 – 2,645	75%	25%	75%	25%
More than DKK 2,645	85%	15%	85%	15%

\* The amounts apply from 1 January 2007 and are adjusted on 1 January every year.

**An example to illustrate:** A patient (+ 18 years) who for the first time in a reimbursement period buys reimbursable products for DKK 1,500 will have to pay DKK 888.75 (100 % of DKK 465 + 50 % of DKK 660 + 25 % of DKK 375).

## 2.8 Reimbursement for chronically ill

The Danish Medicines Agency may decide that a patient is entitled to “reimbursement for the chronically ill”. That means that the patient will receive 100 % reimbursement for the part of total annual expenses on pharmaceuticals entitled to reimbursement that exceeds DKK 17.545 (DKK 19,095 for persons under 18). Patients who are granted reimbursement for chronically ill will at most pay DKK 3,410 annually for the consumption of reimbursable pharmaceuticals, provided they always buy the cheapest of generic pharmaceuticals c.f. the section regarding reimbursement prices below.

GP's/physicians can apply for reimbursement for chronically ill if the patient

- have a prolonged and medically well documented consumption of pharmaceuticals entitled to reimbursement and
- have total annual expenses on pharmaceuticals entitled to reimbursement – before reimbursement is subtracted – exceeding DKK 17,545 (DKK 19,095 for children under 18).

The amounts apply from 1 January 2007 and are adjusted on 1 January every year.

## 2.9 Reimbursement for terminally ill

On application from the treating GP's/physician the Danish Medicines Agency shall grant reimbursement of 100% of *all* pharmaceuticals prescribed by a physician for patients who are terminally ill and who, according to a physician's prognosis, will not live much longer and will not benefit from hospital treatment – i.e. terminally ill patients who wish to spend their last moments at home, or in a hospice, can get all expenses covered for pharmaceuticals that are

prescribed by a GP/physician (on a prescription) – whether the pharmaceutical is entitled to reimbursement or not.

## **2.10 Adjustments of amounts**

According to the National Health Act the Minister for the Interior and Health has to lay down regulations on the adjustment of the general cost limits in the needs-dependent reimbursement system and the cap on co-payment for the chronically ill. The cost limits and the price cap are changed once a year.

## **2.11 Reimbursement prices**

For all reimbursable products a “reimbursement price” is set. The reimbursement price is used when calculating reimbursement and co-payment.

The reimbursement price is either the price of the product in question or a “reference price”.

A reference price is set by the Danish Medicines Agency when several products contain the same active substance – i.e. generics or parallel imported products. It means that reimbursement is granted in the form of a fixed amount to all products in the “reimbursement group”.<sup>4</sup>

In Denmark reference pricing was introduced for the first time in 1993. Since then we have had a variety of reference price schemes. E.g. in the period from 25 June 2001 until 1 April 2005 the reimbursement price of the generic groups were either the price of the cheapest product in the group (if the group consisted of products only marketed in Denmark) or the lowest European price in the group (if a European price existed c.f. textbox 2 below).

Since 1 April 2005 the reference price (reimbursement price) has been the price of the cheapest product in the reimbursement groups. The Danish Medicines Agency lays down the reimbursement prices every second week, but is able to (and actually does) change reimbursement prices on a daily basis when needed due to lack of stock of the cheapest products.

To illustrate the working of the reference price system we give a simple example with 3 synonymous products (generics) and 3 different prices in table 5 below. For simplification we use a reimbursement rate of 50%.

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<sup>4</sup> Reimbursement groups – as well as substitution groups – contain products with the same active substance (generics) in the same amount. Different pharmaceutical formulas are grouped together if they are used in the same way and there are no therapeutic differences e.g. tablets and capsules.

**Table 5. Illustration of working of reference price system – reimbursement group with 3 products**

Product	Price of the product	Reimbursement price	Reimbursement (50%)	Patients price
A	DKK 200	DKK 200	DKK 100	DKK 100
B	DKK 300	DKK 200	DKK 100	DKK 200
C	DKK 600	DKK 200	DKK 100	DKK 500

**Textbox 2. Reimbursement prices and the use of European average prices**

A generic reference price system was introduced in 1993, and from June 1993 to June 2001 the reference price was calculated as the average of the two cheapest products in a group of generics.

During the years the reference price system was, in different variations, combined with the use of European average prices when calculating reimbursement.

From April 1997 to June 2000 the reimbursement rate for pharmaceuticals, which were marketed in Denmark for the first time after 1 April 1997, was calculated on the basis of an average of the pharmacy purchase prices at which the product was marketed for the first time in the other EU-countries – if the Danish price exceeded this average.

This rule was changed according to the Act No 469 of 31 May 2000.

The rules of the Act No 469 of 31 May 2000 implied that:

- It was not possible for any pharmaceutical to be eligible for reimbursement if its pharmacy purchase price in Denmark was higher than “the northern and central European average price”, i.e. the average price of Austria, Belgium, Finland, France, Germany, Great Britain, the Netherlands, Ireland, Norway and Sweden.
- If the pharmacy purchase price of a pharmaceutical in Denmark was higher than “the average European price”, i.e. the average price of Austria, Belgium, Finland, France, Germany, Great Britain, Greece, the Netherlands, Ireland, Italy, Norway, Portugal, Spain and Sweden, and below the average northern and central European price, reimbursement would be calculated on the basis of the European average price.

The second part of these rules was in force less than a month – and only partially in force (only for ATC-group N). The first part was never implemented. These rules on reimbursement and European

average prices were suspended during the period of the price cap from November 2000 until June 2001 – and in June 2001 followed by new rules.

In June 2001 the reference price system was replaced by the reimbursement price system. In fact the reimbursement price system is also a kind of reference price system but for several reasons it was decided to abolish the reference price term.

From 25 June 2001 until 1 April 2005 reimbursement was calculated on the basis of either the Danish price of the product or the “European price” of the product – if this was lower than the Danish price.

Under this regime the European price was the average of prices in the other EEC/EEA-countries except Spain, Portugal, Greece and Luxembourg. The pharmaceutical companies were under obligation to inform the Danish Medicines Agency of the pharmacy purchase prices for the individual product in the basket countries every 6 months.

Currently the reimbursement (reference) price system covers generics and parallel imports but the Minister for the Interior and Health has in principle the legal opportunity to extend the reimbursement price system to cover also analogous pharmaceuticals, i.e. pharmaceuticals that have similar therapeutic effects and similar levels and patterns of adverse effects but not necessarily the same active ingredients. This legal option has existed since 1997.

### **2.12 Enhanced reimbursement**

If a patient due to medical reasons – e.g. allergy caused by additives – are not able to use the cheapest product in a reimbursement group the GP/physician can apply to the Danish Medicines Agency for “enhanced reimbursement”.

Enhanced reimbursement means that reimbursement is calculated on basis of the actual price of the product prescribed instead of at the reimbursement price.

### **2.13 The substitution scheme**

The reimbursement price system is backed up by a substitution scheme. The substitution scheme uses the same grouping of products – generics and parallel imports – as the reimbursement price system.

The substitution scheme was introduced in November 1991. Back then it was included in the agreement between the Danish General Practitioners' Association (Praktiserende Lægers Organisation) and the Negotiating Committee of the National Health Insurance Service (Sygesikringens Forhandlingsudvalg).

Until 1997 the rule was that when prescribing a pharmaceutical covered by the substitution scheme the GP/physician could choose to print a "G" on the prescription, thereby leaving the choice of the actual product to the dispensing pharmacist.

This arrangement was fundamentally changed in June 1997, and slightly adjusted in 2001 and 2005. Now the pharmacy shall, as the principal rule, always dispense the cheapest of the pharmaceutical products covered by the scheme – unless the physician has marked explicitly on the prescription that the pharmacy shall dispense the product on the prescription. To counter substitution the physician has to print "Ej S" (No S(ubstitution)) on the prescription.

Triviality limits for substitution exists but does not rule out substitution.

Substitution is not mandatory within the following limits:

- Prices less than DKK 100: If the price difference is less than DKK 5
- Prices between DKK 100 – 400: If the price difference is less than 5%
- Prices higher than DKK 400: If the price difference is less than DKK 20

The patients may refuse substitution, but will then have to pay the difference. It is also the cheapest price (the reimbursement price) which will be added to the patient's personal "account" in the needs-dependent reimbursement system.

The Minister for the Interior and Health has the possibility to extend the substitution scheme to cover also analogous pharmaceuticals.

## **2.14 Databases**

The reimbursement system is administrated by each pharmacy using a nationwide database – The Central Reimbursement Register (Centrale Tilskudsregister, CTR) – set up by the Danish Medicines Agency. All pharmacies are connected to CTR. Patients are identified through their personal identification number (issued at birth).

The database ensures that patients receive the correct reimbursement when purchasing reimbursable products through calculating the amount the patient has paid for reimbursable products within the patient's current reimbursement period. The database contains no information about the type of pharmaceuticals purchased.

Patients can see their current account in CTR on their bill from the pharmacy. They can also see their account together with other information from the CTR on the Internet at the website: [www.sundhed.dk](http://www.sundhed.dk), where patients also have direct access to their "electronic medicine profile". Access requires a digital signature.

In addition to this system the pharmacies are obliged to report each sale of pharmaceuticals to another central database run by the Medicines Agency. For each sale the pharmacies are obliged to report the specific identification number of the product sold. For products sold on prescription the pharmacy must also report the number of the prescribing physician<sup>5</sup> and the ID number of the patient as well as the medical indication that the product has been prescribed for.

These data are used for monitoring the general pharmaceutical consumption in Denmark and the prescription practices of healthcare professionals for cost control and for the establishing of guidelines for the use of pharmaceuticals.

The database is also used to control the prescriptions issued by individual GP's/physicians. Information on the prescriptions of the individual physicians is passed on to the regions, which have the financial responsibility for reimbursement of pharmaceuticals as well as for the GP's. The information is also made available to the National Board of Health (Sundhedsstyrelsen). Individual patient data is considered confidential and must not leave the database.

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<sup>5</sup> In Denmark each pharmaceutical has its own identification number and GP's/physicians also have special identification numbers.