Denmark
European Region

This document contains links to websites where you can find national legislation and health laws. We link to official government legal sources wherever possible. Where we link to unofficial sources this is noted and users should take this into account before relying on these materials. We recommend checking with the relevant national government if you have questions about the currency or validity of any unofficial source of law.

**Legal system**

Civil law

**National law database**

*Language:* Danish

*Link:* [www.retsinformation.dk](http://www.retsinformation.dk)

*Nature:* Official law database

*Organisation responsible for the website:* The department of civil affairs of Denmark

**Legal UHC start date**

1973


**The health system and policy monitor: regulation (PDF)**

As part of its Health Systems in Transition (HiT) series the European Observatory on Health Systems and Policies systematically describes the functioning of health systems in countries as well as reform and policy initiatives in progress or under development. The HiT health system reviews cover the countries of the WHO European Region as well as some additional OECD countries. This PDF includes information about the country’s regulation. To see the complete HiT report of this country go to: [http://www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits](http://www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits)
Search list of contents:

Regulation

Overview and publication details .................................................. 2
Regulation Denmark ..................................................................... 3
Regulation

Denmark


HSPM Members: Department of Public Health, University of Copenhagen - Centre of health economics research, University of Southern Denmark

Denmark: Regulation

2.8 Regulation

The central government sets the overall direction of health care and increasingly – but still only to a limited extent – defines specific targets for the health care sector. For some decades, it has tried to regulate the establishment of highly specialized departments and functions (such as heart transplants), and during recent years it has set targets for waiting times, introduced screening programmes, improved treatment for cancer patients, and so on. With the recent reform, the central authorities have been given the means to govern these activities more efficiently.

The Ministry of Finance negotiates the level of taxation with the municipalities, thus setting the financial framework of the activities. It also participates in negotiations between professional organizations and unions about salaries, working conditions, fees and the number of practitioners with regional contracts.

Removal of tax deduction for employers signing Voluntary Health Insurance for their employees

By Andreas Rudkjøbing, Terkel Christiansen, Allan Krasnik

The tax deduction for companies signing Voluntary Health Insurance (VHI) for their employees introduced by the previous centre-right government in 2002 was rolled back by the present centre-left government in 2011 with effect from January 1st 2012. This indirect state subsidy contributed to increased activity in the private sector, and was a highly contentious issue claimed to be unfair by favouring only groups who were active on the labour market.

Enacted as a part of budget negotiations for 2012.

Link to announcement (in Danish):

2.8.1 Regulation and governance of third-party payers

The main financing of the health care sector comes from municipal and state taxation. The state subsidizes the regions and municipalities and does not act as a purchaser or directly finance the providers. The municipalities contribute taxes, which make up 20% of the overall regional income. A counterbalancing system has been implemented to ensure equitable geographic distribution of capital between the municipalities. The redistribution is devised according to a formula that accounts for the following factors: age distribution, the number of children in single-parent families, the number of rented flats, the rate of unemployment, the number of people with a low level of education, the number of immigrants from non-EU countries, the number of people living in socially deprived areas and the proportion of older people living alone.

An increasing number of citizens take out VHI, which is organized by profit-making companies, in order to receive reimbursement for medical expenses, such as their utilization of private clinics. A rising number of companies offer VHI with variable coverage, and the market is not particularly transparent for the average consumer. The health insurance premiums are tax deductible for the companies, thus indirectly subsidized by the state. However, the newly elected government (see also Chapter 6) is planning to do away with this possibility. The private profit-making health insurance market is unregulated (see section 3.5).

2.8.2 Regulation and governance of providers

Organization

The role of the state is mainly to regulate and contain expenditure and to provide some general guidelines
for the health care sector. There is no national health plan for the development of the health sector. In terms of organization, the five regions are responsible for providing hospital, somatic and psychiatric care, and for financing private practitioners (such as GPs, practising specialists, dentists, physiotherapists, chiropractors, and so on) for their public sector work. Private practitioners are self-employed but reimbursed for their services by the regions. However, only those who have a prior agreement with the regions are reimbursed, based on a negotiated number of doctors per 1000 inhabitants. Very few doctors work without such an agreement. A few private profit-making clinics and small hospitals are also paid by the regions for attending to patients according to contracts or waiting time guarantees. Furthermore, municipalities employ health care providers, who mainly take care of children and the older people (see Chapter 5).

There is a licensing system for health care professionals but not for health care facilities. However, a number of quality standards in the Danish model for accreditation pertain to physical structure. Health care facilities are supervised and increasingly governed by the National Board of Health. The National Board of Health has a system of locally based medical officers who supervise health professionals. Medical doctors (physicians and surgeons) have been licensed since the 17th century, midwives since the early 18th century, and nurses since 1933. The National Board of Health grants the licences and, in case of malpractice or other undesirable behaviour, has the authority to withdraw them. There is no relicensing system. Further, through regulation of the capacity available for education, it is possible, to a certain degree, to control the number of authorized personnel within the different professional categories and specialties. During recent years, an increasing number of professional groups have obtained authorization/licensing by the National Board of Health. The groups that are able to obtain authorization/licensing currently are doctors, nurses, dentists and, most recently, also social and health care assistants, dental auxiliaries, clinical dental technicians, physiotherapists, chiropractors, midwives, prosthetists/orthotists, radiographers, opticians and contact lens optometrists, clinical dieticians, occupational therapists, medical laboratory technologists and chiropodists. According to the 2004 Law on a Profession Administrated Registration System for Alternative Practitioners, organizations of complementary and alternative medicine (CAM) providers may – provided they fulfill certain requirements – obtain permission from the Minister of Interior and Health to let their members describe themselves as registered CAM providers. Otherwise, the activities of CAM providers are regulated by the Law of Authorization of Health Professionals and of Health Care Activities, which forbids anyone other than authorized doctors to perform a number of activities.

Quality

A national model for quality assessment and improvement, the DDKM (see also section 6.1), was established in 2002. Its main objective was to monitor all publicly financed health care activities. In 2005, it was established as an independent institution. Its principal task is to provide ongoing feedback to individual health care institutions, including processed indicator data. The programme also promotes periodic accreditation, publication and benchmarking of assessments and indicators. National strategies for quality improvement have been published since 1993.

In 2004, an Act on Patient Safety came into effect. The Act aimed to promote patient safety by establishing a system in which all occurrences of adverse events must be reported, with the intention of preventing consequential events (Danish Society for Patient Safety, 2011). These reports do not allow the sanctioning of health care personnel or institutions. The National Board of Health registers and supervises qualified practitioners and other health care personnel. It is in charge of granting and, if necessary, removing authorization. The Board addresses questions regarding authorization revocation and activity reduction, according to the Law of Authorization of Health Professionals and of Health Care Activities passed by the central government. The Act states that authorization can be revoked or activity can be reduced if a qualified health care worker takes an unnecessary risk regarding a patient’s health or has shown serious or repeated unsafe professional activity. The final licence withdrawal occurs in court. This system of authorization helps to protect health care professions while at the same time reassuring the population and the responsible health authorities by ensuring minimum qualifications for health personnel.

A number of state agencies are responsible for securing the safety of citizens in health-related areas. The National Institute of Radiation Protection (Statens Institut for Strålebeskyttelse), an institute of radiation protection under the National Board of Health, is responsible for supervising utilization of X-ray machinery and radioactive substances. The Danish Working Environment Authority is responsible for supervising the
working environment and prevention of occupational hazards. The Danish Environmental Protection Agency is responsible for environmental safety. Finally, the Danish Veterinary and Food Administration is responsible for supervising food safety.

2.8.3 Registration and planning of human resources

The state has an element of control over the supply of health professionals, since the training of authorized health professionals (with a few exceptions) is public. This is the case when there are applicants for all places, which has not always been the case for nurses. The state can also influence health professionals’ qualifications by determining the content of their training. Training is regulated centrally by the Ministry of Science, Technology and Innovation, together with a number of councils, such as the Health Training Council and the Social and Health Training Council, which work in cooperation with the Ministry of Health, the National Board of Health and others. Further training in the health sector for specialists is the responsibility of the National Board of Health, and it is adjusted continually to meet the needs of the health sector with regard to subjects, content and capacity. Postgraduate training programmes for medical specialties, including general practice, are defined by the Ministry of Health based on advice from the National Board of Health and the National Council for Postgraduate Education of Physicians.

The state decides which professions are to be reimbursed by the regions. There are certain quotas, for example for physiotherapists, and in order to buy a general practice, authorization as a GP is required from the National Board of Health plus a license from the regions. Dentists, however, can establish a practice wherever they choose and still be reimbursed by the regions. The regions limit the number of GPs entitled to receive reimbursement as a means of controlling costs. The number of GPs, measured per 1000 population, is negotiated by each region and representatives of the GPs working in the region.

Denmark has implemented EU Directive 2005/36/EC, which provides for the mutual recognition of professional qualifications in EU Member States, with the aim of facilitating the provision of cross-border services in the EU, including in the health sector. The National Board of Health is responsible for considering applications for authorization from medical personnel who hold authorizations from other countries. A special agreement between the Nordic countries, the “Arjeplog-aftale”, also exists (BKI no. 81 1994).

2.8.4 Regulation and governance of pharmaceuticals

Direct-to-consumer advertising of prescription drugs is permitted under strict legislation. In an ethical agreement between the Danish Medical Association, the Association of Danish Pharmacies (Danmarks Apotekerskabel) and the Danish Association of the Pharmaceutical Industry in 2003, it was stressed, among a long list of restrictions, that advertising of drugs should not give the impression that it is not necessary to consult a GP, that side-effects don’t exist, that the product is better than another drug, that it is recommended by scientists, that it mainly or solely addresses children, that it contains references to examinations, or that a person’s well-being depends on their use of the drug. These advertising restrictions do not include advertising for vaccination campaigns, which are approved by the Danish Medicines Agency. However, the agreement was suspended in April 2011 and a new Ethical Committee of the Pharmaceutical Sector (Etisk Nævn for Lægemiddelindustrien (ENLi)) has been established (Ethical Committee of the Pharmaceutical Sector, 2011; Danish Medicines Agency, 2011).

In 1999, the National Institute for Rational Pharmacotherapy (a part of the Danish Medicines Agency) was founded to guide doctors in rational prescribing. It also has the function of elaborating treatment guidelines with respect to costs. Each region employs local groups of pharmacists and GPs to monitor prescription patterns and advise GPs on rational prescribing. The Institute for Rational Pharmacotherapy coordinates educational activities for groups at the local level too. It also established a national formulary for medical doctors to support rational choice of treatments in 2003. Practice guidelines are produced by the medical colleges for various specialties and by the Danish College of General Practice. The Institute for Rational Pharmacotherapy aims to provide objective information and guidelines on the rational use of pharmaceuticals, in both pharmacological and economic terms. However, marketing authorization is based on chemical, pharmaceutical, clinical and safety criteria, without any assessment of need or cost-effectiveness; this means that there is no essential drugs list in the Danish pharmaceutical sector. Instead, consumption is partly regulated through the reimbursement system.
The Council for Adverse Drug Reactions offers general guidance to the Danish Medicines Agency and proposes recommendations and solutions to the Agency for improving the prevention and monitoring of adverse reactions. The main task of the Council is to monitor and assess the reporting of adverse reactions in practice. Further, it proposes recommendations and supports the Danish Medicines Agency’s information and communication tasks with regard to adverse reactions for consumers, patients and healthcare professionals. The most important source of information on adverse drug reactions is spontaneous reports. The Agency recommends that all patients who experience adverse drug reactions not mentioned on the package leaflet should contact their GP. GPs are then required to report all presumably serious or unexpected adverse drug reactions or reactions to medical products to the Danish Medicines Agency. Moreover, GPs are obligated to report any known and non-serious adverse drug reactions within the first two years that a medicinal product is on the market. It is also possible for the patient or the patient’s relatives to report adverse drug reactions directly to the Agency.

The pricing of medicinal products is not directly controlled but is governed by negotiations. Generic substitution is one of the tools used to contain the growth of pharmaceutical expenses. Pharmacists are required to substitute the least expensive, or close to the least expensive, generic medicine for the medicine prescribed by the physician when the prescriber does not clearly state to the contrary or the patient refuses substitution. Generic substitution slows down the increasing drug costs in two ways: by the actual change to a less expensive generic drug and by stimulating price competition among interchangeable medicines. Generic substitution is possible among products containing the same quantity of the same active substance, if their biological equivalence has been proven and marketing authorizations granted. During recent years, some important medicines (including citalopram, simvastatin, omeprazol and felodipine) have lost their patent protection. This, along with generic substitution, has led to heavily decreased prices and a relatively small increase in pharmaceutical expenditure. Another approach to controlling pharmaceutical expenditure is through parallel imports of pharmaceuticals, which has been practised since the beginning of the 1990s.

Denmark has a high proportion of generic and parallel import products on the market. Parallel importing of pharmaceuticals has been permitted since 1990. Generic products make up about 59% of the Danish usage of prescribed pharmaceuticals measured as defined daily doses. As the generic products are typically cheaper, the costs ascribed to generic pharmaceuticals only make up around 17% of the total pharmaceutical market costs (Association of Danish Pharmacies, 2010). The use of generic and parallel-imported products was promoted from 1993 through a reference pricing system for reimbursement. Under this system, reimbursement was based on the average price of the two least expensive versions of a specific product. In 2005, the basis for reimbursement was changed to the lowest price paid in the EU.

Reimbursement for pharmaceuticals

Reimbursement for an individual medicine is based on its main indication; however, other secondary indications also warrant reimbursement. Some pharmaceutical products are only reimbursed for certain diseases. The medicine’s therapeutic effect, value added, and side-effects are factors considered when deciding on reimbursement. Price comparisons and economic evaluations also form part of the decision-making process.

The Danish Medicines Agency decides on the reimbursement status of each pharmaceutical product. The Danish Medicines Agency is a parallel board to the National Board of Health under the Ministry of Health. It is responsible for legislation concerning pharmaceuticals and medical devices, the approval of new products, clinical trials, deciding which drugs should be reimbursed and licensing companies that produce and distribute pharmaceuticals. The Reimbursement Committee advises the Danish Medicines Agency before they make any decision on whether or not to reimburse a particular drug. In general, reimbursement is granted for drugs that have a definite and valuable therapeutic effect and when they are used for a well-defined indication.

Usually, only pharmaceuticals subject to prescription are eligible for reimbursement. Drugs available without a prescription may be included in the list of reimbursable pharmaceuticals, but in such cases reimbursement is only granted to pensioners and patients suffering from a chronic illness that requires continuous treatment with the drug. A prescription would also have to be issued for the pharmaceutical in question. Even if a drug meets the criteria for reimbursement, certain characteristics of the pharmaceutical, its specific use or the way in which it is prescribed may lead to a non-reimbursement
There are no fixed percentages for the reimbursement of medicines, but reimbursement relates to the patient's annual pharmaceutical expenses. From April 2005, reimbursement is calculated according to the least expensive generic product. Patients with high pharmaceutical expenses are reimbursed for a higher percentage of their expenses. As of 2011, percentage groups were 0%, 60%, 75% and 85%, depending on the amount spent within the year. Expenses below DKK 865 per year are not reimbursed. Complementary VHI covering the cost of medication is quite common in Denmark: approximately 2.1 million Danish citizens are members of the non-profit-making mutual insurance company Health Insurance "danmark" (Health Insurance "danmark", 2011).

The total trade of medicinal products in the primary sector assigned reimbursement in 2009 equalled DKK 10.1 billion (Danish Medicines Agency, 2011). For pharmaceutical products without general reimbursement, an individually based subsidy may be obtainable by submitting an application, through a patient’s own physician, to the Danish Medicines Agency. The cost of public reimbursement for medicines in the primary health sector has increased steadily over the years.

Mapping experiences on purchase and regulation of pharmaceuticals across Nordic countries

By Terkel Christansen
Additional Credits: Andreas Rudkjøbing

At a meeting within the Nordic Council of Ministers in September 2015, the Danish Minister of Health proposed a mapping of experiences on purchase and regulation of pharmaceuticals as a first step to increase collaboration between the five Nordic countries on this area. This initiative would allow strengthening the exchange of information across Nordic countries which, similarly to Denmark, have experienced an increase in the cost of hospital medicine, in particular in recent years. A committee of ministerial officials with representatives from each country was asked to deliver a presentation on how the country experiences in this area could be mapped and on possible collaboration in the future. This initiative follows the recommendation of increasing Nordic health care collaboration as suggested by a recent report from the Nordic Council of Ministers.

More information (in Danish):

New legislation regulating cooperation between pharma and medtech industries and doctors

By Andreas Rudkjøbing

This autumn, the minister for health will propose new legislation for regulation of cooperation between doctors and the pharmaceutical and medical-devices industries. A report from a ministerial committee with members of relevant interest groups, including the Danish Medical Association, the Danish Pharmaceutical Manufacturers Association and Medical Devices Industry, has been published. The report recommends harmonizing regulation of the pharmaceutical and medical-devices industries' cooperation with doctors, a ban on holding pharma and devices shares for doctors who advice authorities on medicines and medical devices and a shareholding cap of 200,000 DKK (€ 27,000) for all doctors.

More information (in Danish):
A priority setting institute under debate

By Terkel Christiansen, Andreas Rudkjæbing

As a general rule in Denmark, pricing of pharmaceuticals for use either in the primary health sector or in the hospital is unregulated, although various mechanisms of setting guidelines for use exist.

Public pharmaceutical expenditure, in particular for those administrated within the hospital setting (from now on, hospital medicines), has been rapidly increasing as the application of new pharmaceuticals often starts in hospitals and new ones are often expensive. In Denmark, expenditure on hospital medicines increased from 4 to 7.1 billion DKK between 2007 and 2014 (Andersen, 2015a), and planned savings on prescribed medicines will not take place in 2015 due to steadily increases in expenditures on hospital medicines. Suggestions have come up to explicitly implement a prioritization process, for example, by establishing a public institute for priority setting in health care, in line with neighboring countries such as the UK, Norway and Germany.

At the General Assembly of Danish Regions (Danske Regioner, an association of the Danish regions) in April 2015, it was decided by a majority to start pushing for public priority setting for expensive hospital medicines, although some politicians rejected the idea with reference to the public opinion (Ritzau, 2015a) and arguing that there will be a risk of dividing patients into two groups: those who can afford a private insurance, enabling them to buy a medicine which has not been prioritized and consequently is not reimbursed by the regions, and those who cannot. It has been argued that a consequence of not controlling pharmaceutical expenditures would be to reduce hospital manpower. The idea of creating an institute has been supported by the Danish Medical Association and the Organization of Danish Medical Societies (Nielsen and Rasmussen, 2011). The former Minister of Health and his party (Social Democrats) and the association of Danish Patient Organizations, among others, have rejected the idea (Hemmingsen, 2014; Andersen, 2015b; Ritzau, 2015b). The former Minister of Health has argued that the existing system ensures that new medicines can be used earlier than in other countries (Kjaergaard, 2015). The new Minister of Health from Venstre, the Liberal Party of Denmark, has declared that there should be allocated budgets to cover increasing costs of expensive hospital medicines (Christensen, 2015).

The debate has touched upon strengthening the negotiations with the industry through a European priority-setting institute or letting the European Medicines Agency (EMA) negotiate prices with the industry along with marketing permissions of new medicines (Hildebrandt, 2015).

References


Andersen PK (2015b). Overlæger: Vi ender med piller til 200.000 kroner, men ingen omsorg [Chief physicians: We end up with pills to 200,000 crowns, but no care]. Danmarks Radio, Nyheder [http://www.dr.dk/Nyheder/indland/2015/02/141517.htm; accessed 23 July 2015]


Kjaergaard, MB (2015). Haakkerup vil ikke have nationalt prioriteringsinstitut [Haakkerup will not have a national priority institute]. Medwatch [http://medwatch.dk/Medicinal Biotek/article6700896.ece; accessed 23 July 2015]


2.8.5 Regulation of medical devices and aids

Because of the relatively decentralized health system, there is very limited national information available from hospitals and primary care facilities on existing medical equipment and its use in the Danish health system. According to the 2010 OECD report *Health at a glance*, Denmark had 15.1 magnetic resonance imaging (MRI) units per one million inhabitants and conducted 37.8 examinations per 1000 inhabitants in 2008. Similarly, the number of computer tomography (CT) scanners in 2008 was 21.5 per one million inhabitants and 83.3 examinations per 1000 inhabitants were conducted (OECD, 2010).

2.8.6 Regulation of capital investment

The regional and local authorities are responsible for conducting estate condition surveys. There is no central assessment of overall estate conditions. In the primary health care sector, GPs and practising specialists own or rent their practice as independent contractors. No central or regional estate condition surveys are conducted at this level. The task of ensuring functional sustainability and appropriate space utilization of existing buildings is the responsibility of the decentralized levels and the state is rarely involved. Supervision over fire and safety compliance in hospitals lies with the local authorities.

Regional capital investments are funded through general revenue with the exception of occasional grants, which are provided as direct transfers from the central government to earmarked investments in health areas with special political focus, such as medical equipment to improve cancer care services.

The financing of large-scale buildings is accomplished through a combination of general revenue, savings and loans. However, the central administration sets limitations on the economic activities of the regions regarding the level of expenditure and borrowing. These limitations vary over time and they are generally based on political considerations. From 2007, the Ministry of Health must approve investments above a certain level. A redistribution of funds between municipalities has been implemented to ensure equitable geographic distribution of resources. The influence of the private health care sector is marginal and its size is not regulated.