

**Market Access
& Health
Technology
Assessment**

Denmark

Denmark

The Market Access & Health Technology Assessments answers essential questions about this environment for pharmaceuticals in Denmark.

It is a must have for any company operating in the country or looking to enter the market.

Prepared in association with Gorrissen Federspiel, a leading corporate law firm in Denmark.

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01

HEALTHCARE SYSTEM

1. Please make a general introduction to the public health sector in your country and its organization

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THE DANISH HEALTHCARE SYSTEM

The Danish public healthcare system is universal – all registered Danish residents are automatically enrolled in the publicly financed system – and it is based on the principles of free and equal access to healthcare.

The public healthcare system operates across three overall levels: the national level (the state), the regional level (the five Danish regions), and the local level (the 98 municipalities).

The Danish public healthcare system is decentralized; while the government sets the regulatory framework, is responsible for licensing of healthcare professionals, monitoring and allocates funding, the healthcare services are provided by the regions and the municipalities.

In 2017, Denmark spent 10.1% of its GDP on health. The largest category of spending is outpatient care (appointments with general practitioners and ambulatory care). Inpatient care (mainly care provided in hospitals) accounted for one fourth of health spending¹. In 2018, the total expenditures on medicine was DKK 14.523 million².

In Denmark, the majority of healthcare and social services are financed by general taxes and are supported by a system of central government block grants, reimbursements and equalization schemes.

Approximately 84% of healthcare expenditure in Denmark is publicly financed, with the remaining spending mostly paid out-of-pocket by households (mainly for medicines and dental care³).

Services covered by the publicly financed healthcare system include:

- Primary care
- Preventive care
- Hospital care
- Medicines prescribed in connection with inpatient hospital care
- Mental health care
- Dental services for children under the age of 18

Certain services (such as maternity care, consultation for preschool children, and home care) are funded by the local municipalities.

Other services and products, such as prescription drugs within the primary healthcare sector and adult dental care, are partially covered through subsidies.

COSTS OF MEDICINES

There are two main markets for medicines in Denmark: the primary healthcare sector (prescription medicines) and the secondary sector (hospitals).

Approximately 60% of the total public expenditure on medicines in Denmark is consumed by hospital medicines⁴.

1 <https://eurohealthobservatory.who.int/publications/m/denmark-country-health-profile-2019>

2 Ehlers, L. H. (2019). Introduction to medical market access in Denmark. Djøf Forlag, page 52

3 <https://eurohealthobservatory.who.int/publications/m/denmark-country-health-profile-2019>

4 Ehlers, L. H. (2019). Introduction to medical market access in Denmark. Djøf Forlag, page 61

Hospital medicine is free-of-charge for patients. Within the primary sector, patients have to pay part of the bill for prescription medicines at local pharmacies.

The companies placing the medicinal products on the Danish market are in principle free to set the prices for the medicinal products both within the primary sector and the secondary sector.

However, the unrestricted pricing is to a certain extent influenced by pricecap agreements negotiated every four years by the Ministry of Health, the Danish Regions, and the Danish Association of the Pharmaceutical Industry (Danish: *Lægemiddelindustriforeningen* or Lif). For more information on the price-cap agreements please see **Chapter 3** below.

02 HEALTHCARE ACTORS AND PAYERS

1. Which are the administrations, bodies and institutions in charge of public health in your country and what are their respective responsibilities?

2. Which are the administrations, bodies and institutions in charge of drug approvals in your country and what are their respective responsibilities?

3. Which are the administrations, bodies and institutions that qualify as “payers” in your country and what are their respective responsibilities?

4. Which are the administrations, bodies and institutions in charge of pricing decisions in your country and what are their respective responsibilities?

5. Which are the administrations, bodies and institutions in charge of reimbursement decisions in your countries and what are their respective responsibilities?

6. Which are the administrations, bodies and institutions in charge of Health Technology Assessment in your countries and what are their respective responsibilities?

7. Which are the administrations, bodies and institutions in charge of public procurement and tendering in your country and what are their respective responsibilities?

8. What are the other actors of significance with regards to market access in your country and what are their respective responsibilities?

1. Which are the administrations, bodies and institutions in charge of public health in your country and what are their respective responsibilities?

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NATIONAL LEVEL

At the national level, the healthcare system is regulated and monitored by the Parliament, the Ministry of Health and a number of governmental agencies, including:

- The Danish Health Authority (which is responsible for advising and support the general population, the Ministry of Health, the regions and the municipalities on health issues, and for ensuring the best possible quality of healthcare and elderly care across the country)
- The Danish Medicines Agency (which is responsible for authorisation and monitoring of pharmaceutical companies, licensing of medicinal products in the Danish market, monitoring adverse reactions from medicinal products, authorisation of clinical trials, deciding on matters concerning reimbursement with respect to medicinal products, monitoring medical devices, and appointing and supervising proprietary pharmacists)
- The Danish Patient Safety Authority (which authorises healthcare professionals and health organisations, and handles the central administration of the reporting system for adverse events in healthcare services)
- The Danish Agency for Patient Complaints (which handles patient complaints and compensation cases)
- The Danish Health Data Authority (which is responsible for developing and running national health registers, digital health solutions and for coordinating efforts to ensure cyber and information security within the Danish healthcare sector)

REGIONAL LEVEL

The five regions

Denmark is divided into five regions: the Capital Region of Denmark, the Central Denmark Region, the North Denmark Region, the Region of Zealand, and the Region of Southern Denmark. Each region is governed by democratically elected Regional Councils.

The regions are, i.e., responsible for treatment provided under the Danish healthcare system and operate the Danish public hospitals. The regions are also responsible for the functioning of the medical practice sector, they are funding the majority of the services provided by private general practitioners, and they plan and deliver specialized healthcare services.