

# The Pharma Legal Handbook

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# Denmark

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms · Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs · Orphan Drugs and Rare Diseases · Localization · Biosimilars and Biologics

# Denmark

**The Pharma Legal Handbook 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, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.**

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## Gorrissen Federspiel

Gorrissen Federspiel is one of the leading corporate law firms in Denmark. The firm has strong international relations. More than half of Gorrissen Federspiel's approximately 450 employees are lawyers. The firm's offices are located centrally in Copenhagen and Aarhus.

Gorrissen Federspiel has a dedicated Life Sciences practice group that provides legal advice within all areas relating to medicinal products, biotechnology, medical devices, food and chemical products. The group also advises on all legal aspects within the pharmaceutical advertising sector, including in relation to the review and approval of product-specific marketing campaigns; the use of the internet, apps and social media for marketing activities; advice in relation to donations, sponsorships and grants; the interaction between pharmaceutical companies and healthcare professionals; pharmaceutical companies' interaction with patients and patient organisations; disease-awareness activities, gifts and medical samples; and regulatory law.

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# Towering ambitions

Gorrissen Federspiel is a leading Danish law firm with distinguished international relations. We cover all aspects of business law. Axel Towers and Prismet – our offices in Copenhagen and Aarhus – form the perfect platform for our towering ambitions. Our domestic and international clients have one thing in common. They all want the best

legal counselling from people they can trust. This is why we only employ ambitious professionals who understand that excellence is universally accepted as the key to becoming a trusted adviser.

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# 01

## **REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW**

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1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

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2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

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3. What are the steps to obtaining authorization to develop, test, and market a product?

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4. What are the approximate fees for each authorization?

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5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?

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6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?

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7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?

8. How is compliance with regulation monitored and evaluated? Is the regulatory regime comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations and requirements?

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9. What is the potential range of penalties for noncompliance?

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10. Is there a national healthcare system? If so, how is it administered and funded?

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11. How does the government (or public) healthcare system function with private sector healthcare?

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12. Are prices of drugs and devices regulated and, if so, how?

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13. How are drugs and devices used by patients paid for? What roles do public and private payers play?

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14. Who dispenses drugs and devices to patients and how are those dispensers compensated?

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15. What are the professional and legal responsibilities of those who dispense drugs and devices? What role do they play in providing patient care, information, and safety?

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# 01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

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## 1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

The Danish Ministry of Health is responsible for defining the overall framework for the national healthcare system. As a governmental body under the Ministry of Health, the Danish Medicines Agency (“DKMA”) is the Danish authority responsible for monitoring medicinal products for human and veterinary use, including biological medicinal products, and medical devices.

The DKMA is responsible for authorizing and inspecting pharmaceutical companies and other distributors, authorizing clinical trials, authorizing medicinal products, deciding whether medicinal products are eligible for reimbursement, overseeing adverse event reporting, and monitoring medical devices.

## 2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

### Medicinal products

The main Danish legislation on authorization, pricing, and reimbursement of medicinal products is the Danish Medicines Act (Consolidated Act no. 99 of 16 January 2018, “Medicines Act”).

The Medicines Act is supplemented by a large number of executive orders and guidelines issued by the DKMA.

### Pricing

In Denmark, pharmacies have the exclusive right to sell prescription-only medicinal products (and most over-the-counter medicinal products) to consumers.

At manufacturing level, the company placing the medicinal product on the market (or the importer of the medicinal product) is free to determine the prices for prescription medicinal products when selling to wholesalers, pharmacies and/or other authorised retail sellers. It should be noted, however, that the Danish Association of the Pharmaceutical Industry on behalf of its members have entered into agreements with the Danish Ministry of Health and the Danish Regions which introduce so-called “price ceilings” for medicinal products used in the hospital sector and for medicinal products eligible for reimbursement. The current agreements will remain in effect until April 2023.

The company placing the medicinal product on the market must report the so-called pharmacy purchase price (Danish: Apoteksindkøbspris) to the DKMA at least 14 days prior to launch of the product. All prices are published on the DKMA’s website [Medicinpriser.dk](https://www.medicinpriser.dk).

The pharmacies must charge the so-called pharmacy retail price (Danish: Forbrugerpris) when selling to consumers. The pharmacy retail price is calculated on the basis of the pharmacy purchase price and consist of the pharmacy purchase price, a retail margin and potentially different handling fees.

The prices for over-the-counter medicines that are not reserved for the exclusive sale in pharmacies are not specifically regulated, and the pharmacies and other authorised retailers are free to determine the prices.

### Reimbursement

In Denmark, the DKMA decides on the reimbursement status of each medicinal product.

The DKMA determines which medicinal products that are eligible for reimbursement based on an application from the company placing a medicinal product on the market. The DKMA may determine that reimbursement should be conditional, e.g. on it being prescribed to certain patient groups or specific diseases.

There are three types of general reimbursement **i)** reimbursement for prescription-only medicinal products, **ii)** conditional reimbursement for prescription-only medicinal products, and **iii)** conditional reimbursement for over-the-counter medicinal products.

In special cases, the DKMA may also grant individual reimbursement for specific, individual patients. Such reimbursements are granted on the basis of an application from the patient's doctor. The DKMA may also grant a reimbursement for the terminally ill.

The DKMA determines the annual reimbursement thresholds (i.e. the amount a person must spend on medicinal products within a 12 month period before being eligible for reimbursement), and the reimbursement price. The reimbursement thresholds and the reimbursement price is used when calculating the applicable reimbursement rate and the amount of co-payment of the patient.

As a starting point, the reimbursement price is the same as the pharmacy retail price. However, the DKMA may establish so-called substitution groups/reimbursement groups of medicinal products with the same indication and comparable treatment effects, for the purpose of calculating the same reimbursement price for all medicinal products within the same reimbursement group. For medicinal products within a reimbursement group, the applicable reimbursement price will be the cheapest medicinal products in the group. The purpose of the system is to encourage patients to purchase the most inexpensive medicinal product available.

### Biologicals

The Danish Medicines Act and secondary legislation issued under the Medicines Act also apply to biologicals and do not contain substantially different provisions on biologicals.

### Medical devices

The Danish Act on Medical Devices (Consolidated Act no. 139 of 15 February 2016, "Act on Medical Devices") constitutes the main regulatory framework for the authorization, pricing and reimbursement of medical devices. The Act

on Medical Devices implements the EU directives on medical devices, i.a., Directive 93/42/EEC of 14 June 1993.

The Act on Medical Devices is supplemented by a number of executive orders issued by the DKMA.

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### **3. What are the steps to obtaining authorization to develop, test, and market a product?**

#### **Medicinal products**

##### **Manufacturing**

The manufacture, import, export, storage, distribution, provision, dispensing, splitting and packaging of medicinal products and intermediate products intended for further processing into medicinal products are subject to authorization from the DKMA.

Applications for authorizations to manufacture medicinal products must be submitted to the DKMA by way of the agency's application form through the agency's extranet DKMANet or by way of e-mail to the DKMA.

The application form must contain information, i.a., on organization of the company, the site master file (in case of first application), the name and legally registered address of the manufacturer and address(es) of the manufacturing site(s), details of the manufacturing operations and of the products to be manufactured, information on quality control, any contract manufacturing sites and/or contract laboratories, qualified person(s), and details of the responsible management.

##### **Development and testing**

In order to initiate and conduct a clinical trial involving humans, the person or entity in charge of the initiation, monitoring and financing of the trial (the sponsor) must apply for an approval from the DKMA as well as from the competent Danish Research Ethics Committee.

The DKMA receives clinical trial applications electronically either via the DKMANet or Eudralink. The DKMA has published a guideline on applications for clinical trial authorizations on its website. The guideline includes information on the required contents of an application. Pursuant to the guideline, an application must include, i.a., a cover letter with information on the expected duration, the monitor of the trial (according to GCP), information on reference documents (e.g. the investigator's brochure, and summary of product characteristics), and invoicing details, the EudraCT application form, the trial protocol, Investigational Medicinal Product Dossier (if relevant), examples of labels, documentation that the manufacturer has been notified of the trial, and patient information.

A marketing authorization is not required for a medicinal product for clinical trials.

Please also note, that in order to manufacture, import and distribute active substances intended for use in the manufacture of medicinal products for human use that are covered by a marketing authorization, a company must register with the DKMA.