The Pharma Legal Handbook

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

PHARMA BOARDROOM

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 Denmark's largest law firms. We employ approx. 530 people of which more than 300 are lawyers, and we provide advice within all areas of business law. As a firm, we emphasize the importance of quality, ethics, value creation, vision and team spirit. To go the extra mile has been one of our slogans for many years, and at Gorrissen Federspiel it applies to both clients and colleagues - we want to be "In a league of our own".

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01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

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") and the Danish Pharmacies Act (Consolidated Act no. 801 of 12 June 2018).

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

Further, as an EU member state Denmark is required to follow the union rules governing authorization of medicinal products. The provisions set out in the EU directives are transposed into Danish acts, and the applicable EU regulations, e.g. the Regulation (EC) no. 726/2004 on procedures for the authorisation and supervision of medicinal products for human and veterinary use, are directly applicable.

Biologicals

The Danish Medicines Act and secondary legislation issued under the Medicines Act also apply to 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 is supplemented by a number of executive orders issued by the DKMA, e.g. the two main executive orders on i) medical devices and products without a medical purpose, and ii) in vitro diagnostics medical devices.

As an EU member state Denmark is required to follow the union rules governing authorization of medicinal products and medical devices, e.g. Regulation (EU) 2017/745 of 5 April 2017 on medical devices and Regulation (EU) 2017/746 of 5 April 2017 on in vitro diagnostic medical devices.

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

Medicinal products

Development and testing

In order to initiate and conduct a clinical trial with medicinal products, the person or entity in charge of the initiation, monitoring and financing of the trial (the sponsor) must apply for an authorisation from the DKMA. Furthermore, clinical trials involving humans must be approved by a competent state medical committees. Non-interventional trials may as a starting point be implemented without the authorisation from the DKMA.

Following the entering into force of the Clinical Trials Regulation (Regulation EU No 536/2014), all applications for clinical trials initiated after 31 January 2022 (and amendments and other changes to ongiong clinical trials) must as a starting point be submitted through the new centralized EU portal - the Clinical Trials Information System (CTIS). This also applies in case of clinical trials that will only take place in Denmark.

Guidance on how to submit applications for clinical trials under the Clinical Trials Regulation and the CTIS can be found on the DKMA's website (https://laegemiddelstyrelsen.dk/en/licensing/clinical-trials/new-european-clinical-trial-regulation-from-the-31th-january-2022/#) and the EU Commission's website (https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-training-support).

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.

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 also register with the DKMA.

Marketing

As a starting point, only medicinal products that have been authorized by the DKMA or the European Commission may be marketed and/or dispensed in Denmark.

In order to obtain a marketing authorization for a medicinal product, the applicant must show that the benefits of the medicinal product outweigh the risks and side effects, that the medicinal product is safe and that it is of a sufficiently high and consistent quality.

When applying for a marketing authorization, the manufacturer may choose between four types of procedures:

i) The centralized procedure,
ii) The decentralized procedure,
iii) The national procedure, or
iv) The mutual recognition procedure.

While the European Medicines Agency ("EMA") is responsible for the centralized procedure, the DKMA is responsible for granting of marketing authorizations through the decentralized procedure, the national procedure and the mutual recognition procedure.

Pursuant to the centralized procedure, the holder of the marketing authorization is allowed to market the medicine throughout the EU. The application for a centralized marketing authorization is submitted to the EMA who is responsible for review of the application, and the European Commission oversees final authorization. The centralized procedure is mandatory for new biological medicines, for medicines for orphan diseases, and medicines for certain defined indications (e.g. HIV, cancer and diabetes). In other circumstances, the centralized procedure can be chosen, e.g. in case of a new active ingredient.

Under the decentralized procedure, the applicant may submit identical applications in a number of chosen EU/EEA countries – the concerned member states. The applicant must request a reference member state to be responsible for the first assessment of the application, prepare a draft assessment report, a draft summary of product characteristics and a draft of the labelling and package leaflet. Once the reference member state has drafted an assessment report, etc., the concerned member states must as a starting point approve the assessment report, etc. If the any of the concerned member states are not able to do – on the grounds of potential serious risk to public health - then the matter of disagreement must be referred to settlement through a special coordination group procedure (the article 29 procedure).

The mutual recognition procedure follows the same procedure as the decentralized procedure with the main difference being that medicinal product in question has already received a marketing authorization at the time of application. The concerned member states are as a starting point obliged to recognize