# The Pharma Legal Handbook

# Norway

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labelling 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

# Norway

**The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in Norway.**
**It is a must have for any company operating in the country or looking to enter the market.**

**Prepared in association with DLA Piper, an international law firm, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.**



*** THIS REPORT WAS ORIGINALLY PUBLISHED IN MAY 2020 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.**
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DLA Piper's life sciences team comprises lawyers with legal, scientific and medical knowledge who understand the complexity of the business and regulatory environments in which our clients operate. Our life sciences sector team is one of the largest and most active of any law firm. Operating as one team across more than 30 jurisdictions, we combine subject matter experience with considerable knowledge of the sector, including the scientific, medical, regulatory, commercial and enforcement environments facing our biopharmaceutical, medical device, research and diagnostics clients.

DLA Piper's life science practice includes litigation, compliance and investigations, IP strategy and enforcement, M&A, licensing and distribution, clinical trial advice. We also support clients across all other areas needed to address risk, including competition law, public procurement, government affairs and contracts, environmental law, import/export, tax, real estate and employment law.

In Norway, DLA Piper comprise of 80 lawyers and a total of 115 employees, with a core life science team of 7.

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We are a full-service law firm providing top quality legal services to the corporate and public sectors. Our clients span private enterprises of all sizes as well as public authorities at local, regional, and national levels and publicly owned enterprises.

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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 Ministry of Health and Care Services (nw. Helse-og omsorgsdepartementet, "HOD") is the legislative authority. The Norwegian Medicines Agency (nw. Statens legemiddelverk – "NoMA"), a subordinate to HOD; is the national authority vested with jurisdiction over both medicinal products and the regulation and monitoring of medical devices. NoMA also is responsible for certain aspects regarding the regulation of non-prescription drugs, such as marketing authorization/approvals, promotion etc.

The Norwegian Health Economics Administration (nw. Helseøkonomiforvaltningen, "HELFO") decides on reimbursement for individual patients for where there is no general reimbursement or indication is not covered by general reimbursement.

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

### a) Authorization

The Medicines Act (LOV-1992-12-04-132) and associated regulations such as the Medicines Regulation (FOR-2009-12-18-1839) set forth the main regulatory framework for the authorization of medicines. The Medicines Act and associated regulations implement the corresponding EU legislation, including Directive 2001/83/EC and Regulation 726/2004.

The regulatory framework regarding authorization of medical devices can, as a starting point, be found in the Medical Devices Act (LOV-1995-01-12-6) and the Medical Devices Regulation (FOR-2005-12-15-1690), implementing the corresponding EU legislation, Directive 90/385/EC, Directive 93/42/EC and 98/79/EC.

However, as of 26 May 2021 a new Act on medical devices must be taken into account, the new Medical Devices Act (LOV-2020-05-07-37) and the new Medical Devices Regulation (FOR-2021-05-09-1476), implementing the EU regulation; Regulation (EU) 2017/745, which replaces Directives 90/385/EC, 93/42/EC.

The regulatory framework regarding authorization on in vitro diagnostic medical devices is still found in the Medical Devices Act (LOV-1995-01-12-6) and the Temporary Medical Devices Regulation (FOR-2005-12-15-1690). This because the EU Directive 98/79 will be will be replaced by Regulation (EU) 2017/746 as of 26 May 2022, cf. Regulation (EU) 2017/745 article 100. As of 22 May 2022 the Regulation (EU) 2017/746 regarding in vitro diagnostic medical devices will then be implemented through legislative acts into the new Medical Devices Act (LOV-2020-05-07-37) and the new Medical Devices Regulation (FOR-2021-05-09-1476),

### b) Pricing

All registered, prescription-only medicines for humans must have a maximum price, set by NoMA before they can be marketed in Norway, pursuant to chapter 12 of the Medicines Regulation. The market authorization-holder ("MAH") must apply for a maximum price. The maximum price consists of two elements; maximum pharmacy purchase price ("PPP") and maximum pharmacy retail price ("PRP"). The PPP is decided based on several factors:

- International price comparisons. Prices in other EEA countries save as the main basis for determining the PPP. The price in other EEA countries is set as the mean of the three lowest market prices of in a selection of relevant EEA countries. The current reference countries are: Sweden, Finland, Denmark, Germany, UK, Netherlands, Austria, Belgium and Ireland.
- Price of comparable medicines including biosimilars and generics
- Production costs can be taken into consideration in special cases

The MAH and NoMA can initiate a re-evaluation of the of the maximum prices. Adjustments should not occur more frequently than once per year.

PRP is decided by adding PPP and a maximal profit for the pharmacy. The maximum profit for prescription drugs are based on the following criteria:

- 2.0% add-on from the PPP
- NOK 29.00 add-on per package
- 0.5% add-on from the PPP if the prescription medicine requires cooling
- NOK 19.00 add-on per package for A/B-preparations. A and B preparations are medicines that are addictive, and thus requires specific prescriptions and personal ID prior to issuing. A preparations are the strongest, and includes morphine and other opiates. B preparations are addictive and includes e.g. Valium and sleeping pills.

In addition, after the patent protection and, if applicable, supplementary protection certificates has expired, medicines are subject to a so called "price step model" price reduction. The purpose is to reduce the cost of pharmaceuticals. The "price step model" entails that the price is reduced by a percentage of the original medicines maximal PPP. The PPP is reduced in two or three steps. The first step commence when there is generic competition on the market, while the second commence six months later. The third step commence at the earliest 12 months after commencement of the second step. The size of the price reduction depends on whether the original drug had an annual turnover of above 100 000 000 in a 12 month period within the two years prior to generic competition. The following table illustrates the "price step model":

| TURNOVER PRIOR TO GENERIC COMPETITION | FIRST STEP (IMMEDIATE AFTER GENERIC COMPETITION) | SECOND STEP (6 MONTHS AFTER GENERIC COMPETITION) | THIRD STEP (EARLIEST AFTER 18 MONTHS AFTER GENERIC COMPETITION) |
|---|---|---|---|
| BELOW 100 MNOK | 35% | 59% | TURNOVER > 15 MNOK. 69%<br>TURNOVER > 30 MNOK. 88% |
| ABOVE 100 MNOK | 35% | 81% | TURNOVER > 100 MNOK. 90% |