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
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.

Norway

DLA Piper is an international law firm present in 66 countries, either directly or through relationship firms. Our expertise encompasses all areas of business law and experience in our clients’ sectors. With over 5,000 individuals, the firm provides top quality legal and fiscal assistance in every corner of the world. DLA Piper is constantly seeking sophisticated and innovative solutions to meet the needs of our clients.

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.
PARTNER, LOCATION HEAD IPT

Petter Bjerke, heads DLA Piper Norway’s Intellectual Property and Technology (IPT) department and regularly assists Norwegian and multinational companies in manufacturing, pharmaceutical, media and finance with issues related to data privacy (GDPR) and cyber security as well as intellectual property rights. He has served as Data Protection Officer for a global life science company. He also advises clients within the life science sector (service providers, manufactures of medical devices and pharmaceuticals) on sector specific regulatory issues in connection with various research programs, standard operation procedures, clinical trials, commercialization and distribution / procurement projects as well as obligations imposed through various codes of conduct applicable to the life science sector.

DLA Piper Norway
T: +47 906 07 708
E: petter.bjerke@dlapiper.com
A: Bryggegata 6, PO Box 1364, Vika, 0114 Oslo, Norway

PARTNER

Line Voldstad, heads DLA Piper Norway’s procurement team and specializes in public procurement, EEA/regulatory and competition law. She assists i.a. life science companies; both on a national and international basis in regulatory and competition law matters. Her experience include advising several pharmaceutical and/or life science companies in procurement processes, with i.a. regulatory and marketing issues, including regulatory framework in relation to collection and handling of health data, clinical studies, home treatment and possible set-up, and standard operating procedures to comply with Norwegian law and ethical rules; competition law issues, including accessibility of data and information sharing. She has significant experience from a vast range of cross border legal advice coordination and projects, including competition law analysis and advice relating to pharmaceutical patents and patent litigation as part of a cross border team before the Commission, General Court, and subsequently the European Court of Justice.

DLA Piper Norway
T: + 47 984 01 079
E: line.voldstad@dlapiper.com
A: Bryggegata 6, PO Box 1364, Vika, 0114 Oslo, Norway
Morten Gullhagen-Revling

**Lead Lawyer**

Morten Gullhagen-Revling focuses on Litigation and Regulatory matters. He has experience within the public sector and administration where he has had special focus on public procurement and public sector contracts.

In addition, Gullhagen-Revling has experience in other legal disciplines and questions within real estate and company law and regulations.

DLA Piper Norway
T: +47 24 13 15 00
E: morten.gullhagen-revling@dlapiper.com
A: Bryggegata 6, PO Box 1364, Vika, 0114 Oslo, Norway

Thea Åkermoen

**Associate**

Thea Åkermoen is associated with DLA Piper’s Litigation and Regulatory Group. She assists on the day-to-day legal matter handling and is primarily engaged in public procurement, competition law and other regulatory matters.

Thea has assisted clients in regulatory and competition law matters in various transactions and mergers.

DLA Piper Norway
T: +47 24 13 15 78
E: thea.akermoen@dlapiper.com
A: Bryggegata 6, PO Box 1364, Vika, 0114 Oslo, Norway

Oscar Lorentz Melaa

**Associate**

Oscar Lorentz Melaa practices in the area of IP and Technology law. His primary focus is on domestic and international issues relating to data protection, privacy and security. Within financial services, Oscar has experience with solving complex challenges related to data protection, privacy and security, and has also advised financial institutions regarding its marketing practices.

DLA Piper Norway
T: +47 24 13 15 74
E: oscar.lorentz.melaa@dlapiper.com
A: Bryggegata 6, PO Box 1364, Vika, 0114 Oslo, Norway
DLA Piper is the only global and truly pan-Nordic law firm in Norway. This enables us to provide consistent and efficient services locally and across borders.

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.

Our office is centrally located at Aker Brygge in Oslo and comprise of 80 lawyers and a total of over 115 staff members. Our vision is to be a leading global law firm by delivering quality and value to our clients to help them succeed.

7 Sectors
- Energy and Natural Resources
- Financial Services
- Insurance
- Real Estate
- Shipping, transport and logistic
- Technology
- Life Sciences

13 Practice areas
- Compliance and Risk Management
- Construction
- Corporate
- Employment
- Finance
- Intellectual Property and Technology
- Competition and antitrust
- Litigation, Arbitration and Investigation
- Public Procurement
- Real Estate
- Restructuring
- Tax
- White Collar Crime

+80 professionals IN OSLO
## CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW</td>
<td>7</td>
</tr>
<tr>
<td>02</td>
<td>PRECLINICAL AND CLINICAL TRIAL REQUIREMENTS</td>
<td>18</td>
</tr>
<tr>
<td>03</td>
<td>MARKETING, MANUFACTURING, PACKAGING AND LABELING, ADVERTISING</td>
<td>23</td>
</tr>
<tr>
<td>04</td>
<td>TRADITIONAL MEDICINES AND OVER-THE-COUNTER PRODUCTS</td>
<td>40</td>
</tr>
<tr>
<td>05</td>
<td>PRODUCT LIABILITY</td>
<td>52</td>
</tr>
<tr>
<td>06</td>
<td>PATENTS AND TRADEMARKS</td>
<td>57</td>
</tr>
<tr>
<td>07</td>
<td>REGULATORY REFORMS</td>
<td>65</td>
</tr>
<tr>
<td>08</td>
<td>CANNABINOID DRUGS, MEDICINAL CANNABIS AND OPIOID DRUGS</td>
<td>67</td>
</tr>
<tr>
<td>09</td>
<td>ORPHAN DRUGS AND RARE DISEASES</td>
<td>81</td>
</tr>
<tr>
<td>10</td>
<td>LOCALIZATION</td>
<td>86</td>
</tr>
<tr>
<td>11</td>
<td>BIOSIMILARS AND BIOLOGICS</td>
<td>90</td>
</tr>
</tbody>
</table>
1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

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

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

4. What are the approximate fees for each authorization?

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

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

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?

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

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

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

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

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

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

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?
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, Directive 93/42/EC and 98/79/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 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 serve 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 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”:

<table>
<thead>
<tr>
<th>TURNOVER PRIOR TO GENERIC COMPETITION</th>
<th>FIRST STEP (IMMEDIATE AFTER GENERIC COMPETITION)</th>
<th>SECOND STEP (6 MONTHS AFTER GENERIC COMPETITION)</th>
<th>THIRD STEP (EARLIEST AFTER 18 MONTHS AFTER GENERIC COMPETITION)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BELOW 100 MNOK</td>
<td>35%</td>
<td>59%</td>
<td>TURNOVER &gt; 15 MNOK. 69% TURNOVER &gt; 30 MNOK. 88%</td>
</tr>
<tr>
<td>ABOVE 100 MNOK</td>
<td>35%</td>
<td>81%</td>
<td>TURNOVER &gt; 100 MNOK. 90%</td>
</tr>
</tbody>
</table>