The Pharma Legal Handbook

Luxembourg

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

PHARMA BOARDROOM

Luxembourg

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

Prepared in association with Emmanuelle RAGOT, an independent firm anchored in Luxembourg, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

Many laws (11) have been published in Luxembourg in 2020, but 100% of them are in relation to the management of COVID 19.

*** THIS REPORT WAS ORIGINALLY PUBLISHED IN APRIL 2019 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.**
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Me Emmanuelle Ragot
Avocat à la Cour
42A rue Paul Binsfeld
L - 8119 Bridel
GD de Luxembourg

Contact:
+ 352 661 84 42 50
eragot@eragotlaw.lu
https://eragotlaw.lu

THE AUTHOR

EMMANUELLE RAGOT

Qualified as an Avocat à la Cour in Paris and Luxembourg for over 20 years, Emmanuelle launched her boutique law firm in 2021 and is ranked internationally as a leading lawyer for a top tier client service, focusing on advisory and litigation for international and local clients. Emmanuelle Ragot is a recognized expert by the industry in Pharma, Technologies, Intellectual Property, Data Protection, and more generally related regulatory work and understanding of the Pharma sector. She has been involved in litigation for Pharma companies and on various multi-jurisdictional pre-litigation patent cases.

Formerly equity partner in a major independent law firm and with substantial experience in magic circle law firms in London & Luxembourg and in Litigation in Paris, she is lauded for her insight, expertise and business-minded approach.

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EMMANUELLE RAGOT

Emmanuelle RAGOT
42 A rue Paul Binsfeld
L – 8119 BRIDEL
GDLUXEMBOURG
eragot@eragotlaw.lu
https://eragotlaw.lu

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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?

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?

01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

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

Within Luxembourg, the regulatory authority in charge of the matter of drugs, biologicals, and medical devices is the Ministry of Health ("Ministère de la Santé"), in particular the National Health Directorate ("Direction de la Santé"), composed of six departments among which:

- the Pharmacy and Medication Department ("Division de la Pharmacie et des Médicaments") is in charge of the regulatory framework concerning drugs and biologicals; and
- the Curative Care and Healthcare Quality Department ("Division de la Médecine curative et de la Qualité en santé") is in charge of the regulatory framework concerning medical devices.

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

For easier reading, drugs and biological will be referred hereafter as "medicinal products" except when otherwise mentioned.

I. MEDICINAL PRODUCTS

The main regulations governing the authorization of medicinal products, compiled in the Health Code ("Code de la Santé") are:

- the law of 4 August 1975 relating to manufacturing and import of medicinal products as amended;
- the law of 25 November 1975 relating to the delivery to the public of medicinal products, as amended;
- the law of 11 April 1983 on the regulation of the marketing authorization and advertising of medicinal products as amended;
- the law of 6 January 1995 relating to the wholesale distribution of medicinal products as amended;
- the Grand-Ducal regulation of 15 December 1992 relating to the marketing of medicinal products as amended; and
- the Grand-Ducal regulation of 19 November 2004 relating to the manufacturing, the distribution and the brokerage of medicinal products, as amended.

Regarding the pricing, and reimbursement of medicinal products, the Social Security Code ("Code de la Sécurité Sociale") and the statutes of the National Health Fund ("Caisse Nationale De Santé" or "CNS") would apply.

II. MEDICAL DEVICES

The regulatory framework for the authorization, pricing, and reimbursement of medical devices is:

- the law of 16 January 1990 on medical devices as amended, which constitutes the main regulation for medical devices and the Grand-Ducal regulations related thereto.
- the Social Security Code and the statutes of the CNS for pricing and reimbursement.

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

I. MEDICINAL PRODUCTS

Manufacturing authorization:

Pursuant to the law of 4 August 1975 relating to manufacturing and import of medicinal products as amended, in order to obtain authorization to develop and test new medicinal products, the manufacturer should apply and obtain a prior authorization of manufacturing from the Ministry of Health, except if there is specific exemptions in the law.

The application for the granting of the authorization is subject to investigations and a report established by the relevant authority ("Inspection des Pharmacies").

The decision taken by the Ministry is notified to the applicant and must contain the grounds of the decision.

As foreseen in the Grand-Ducal regulation of 19 November 2004 relating to the manufacturing, the distribution and the brokerage of medicinal products as amended, the application for a prior authorization of manufacturing must contain information such as the contact details of the applicant, the place where manufacturing operations are performed, list of medicinal products manufactured.

According to article 4 of the law of 4 August 1975 relating to manufacturing and import of medicinal products as amended, the manufacturing of the medicinal products is made under the supervision of a pharmacist duly agreed by the Ministry of Health.

Marketing authorization:

Before the launching of a new medicinal product on the market, the manufacturer must have obtained a marketing authorization.

- In case of a national marketing authorization, the manufacturer should apply for a prior authorization from the Ministry of Health. According to article 2 of the Grand-Ducal regulation of 15 December 1992 related to the marketing of medicinal products as amended, the complete application must be submitted to the Ministry of Health in electronic format in accordance with the requirements of the European file format.

  Details regarding the medicinal product and the applicant should be included in the application, including (without being exhaustive) the name or company name and the domicile or the registered office of the person responsible for the marketing and name of the medicinal products.
- In case of the filing of an application for an EU marketing authorization from the European Medicines Agency ("EMA"), several steps regulated at the EU level have to be duly followed.

In this case, there is no need for a marketing authorization within Luxembourg. However, prior to the sale of the medicinal product, a file has to be provided to the Ministry Health containing a copy of the European Commission's decision with all the annexes.

In addition, a request for the price to the public of the medicinal product has to be filed at the Ministry of Social Security.

Lastly, for the potential reimbursement of the medicinal product, if any, a request to the CNS has to be filed in order to be mentioned on a list called "liste positive", i.e. the list of the medicinal products for which a part of the price to the public will be reimbursed by the CNS, the rate of the reimbursement depending on the type of medicinal product.

II. MEDICAL DEVICES

Manufacturing authorization:

No prior authorization is required for the manufacturing of medical devices.

However, the manufacturer should fulfill the requirements related to the manufacturing provided for under the different Grand-Ducal regulations related to medical devices, among which there are requirements related to conception and production of the device.

Marketing authorization:

No prior authorization is required for the marketing of the medical devices.

However, the manufacturer should fulfil two conditions foreseen under the different Grand-Ducal regulations related to medical devices:

- the medical devices may only be marketed and/or put into service provided that they are duly supplied and are correctly installed, maintained and used according to their intended purpose; and
- the medical devices may only be marketed and/or put into service provided that the label EC is mentioned, this label indicating that their conformity with EC requirements has been validat

4. What are the approximate fees for each authorization?

I. MANUFACTURE AUTHORIZATION:

For a new medicinal product, the manufacture authorization fee is determined on a case by case basis depending on the scope of the investigations carried out by the Inspection des Pharmacies.

II. MARKETING AUTHORIZATION:

Pursuant to the Grand-Ducal regulation of 24 December 1993 fixing the fees due for the marketing authorization of medicinal products as amended, the marketing authorization fee amounts:

- to 600.€ (six hundred euros), when the medicinal product has already been granted with an authorization delivered in a Member State of the European Union, in accordance with the relevant directives;