The Pharma Legal Handbook

Belgium

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

PHARMA BOARDROOM

Belgium

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

Prepared in association with ALTIUS, one of the largest Belgiam Independent law firms, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

*** THIS REPORT WAS ORIGINALLY PUBLISHED IN DECEMBER 2019 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.**

ALTIUS advocaten avocats lawyers

ALTIUS is one of the largest Belgian independent law firms, consisting of approximately 65 lawyers. Established in Brussels, we advise Belgian and international companies on the legal aspects of transactions, projects and disputes.

We help our clients navigate through often-complex legislation and regulatory environments and provide clear solutions to a wide range of legal issues. In addition to our specialist legal knowledge, we focus on thinking creatively with our clients to offer tailor-made solutions. Our aim is to turn, through careful listening and awareness, strategic questions into clear, straightforward answers.

For tax-related issues, ALTIUS works closely with Tiberghien, a leading independent Belgian firm that specialises in tax law.

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CONTENTS

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?

The Federal Agency for Medicines and Health Products ('FAMHP') is the competent authority for drugs, biologicals and medical devices in Belgium. In particular, the FAMHP is in charge of controlling the quality, safety and efficacy of those products.

The Federal Public Service of Economy ('FPS Economy') sets the prices of those products.

The National Institute for Health and Disability Insurance ('NIHDI') sets the conditions for reimbursement of those products.

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

For drugs and biologicals, the **general** framework, including in relation to the authorisation, of drugs, biologicals and medical devices can be found in the following laws and regulations:

- Law of 25 March 1964 on medicines;
- Royal Decree of 14 December 2006 on medicines for human and veterinary use;
- Law of 15 December 2013 on medical devices;
- Royal Decree of 15 July 1997 on active implantable medical devices;
- Royal Decree of 18 March 1999 on medical devices;
- Royal Decree of 14 November 2001 on in vitro diagnostic medical devices.

Specific provisions relating the **pricing** of medical products and certain medical devices are found in:

- Royal Decree of 10 April 2014 (Royal Decree laying down the conditions of admissibility, time limits and practical arrangements for price fixing requests, price increase requests, price notifications and (price) communications of medicines, objects, apparatus and substances similar to medicines, and raw materials).

Finally, the **reimbursement** of the medical products is governed by :

- Law of 14 July 1994 on compulsory health insurance and compensation;
- Royal Decree of 1 February 2018 laying down the procedures, time limits and conditions for the intervention of compulsory health care insurance and compensation in the costs of pharmaceutical specialties;
- Royal Decree of 24 June 2014 laying down the procedures, time limits and conditions for the intervention of compulsory health care insurance and compensation in the costs of implants and invasive medical devices.

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

The authorisation for medicines can be obtained via the following steps:

1) Pre-clinical trials;
2) Clinical trials;
3) Marketing authorisation ('MA').

The MA can be requested by introducing a national procedure, a centralised procedure, a mutual recognition procedure or a decentralised procedure (see also **Chapter III, Question 22**).

The procedure to obtain an authorisation for medical devices is quite different. To put a medical device on the market, it needs to bear the CE marking. Depending on the class of the medical device, the marking must either be submitted to a notified body for approval and/or be notified to the FAMHP (for more details, please refer to **Chapter III, Question 30**).

4. What are the approximate fees for each authorization?

The fees for the **MA** of the medicines are the following, depending on the type of procedure chosen by the applicant:

Type of procedure			Fees*
National procedure	Full Ma		31.855,39 €
	Generic MA		27.725,57 €
Centralised procedure			From 291.800,00 €
Decentralised procedure and mutual recognition procedure	If Belgium = CMS	Full MA Generic MA	10.838,86 € 9.324,08 €
	If Belgium = RMS	Full MA Generic MA	51.153,47 € 42.960,36 €

* Fees for 2019 and for each file submitted.

The fees for **medical devices** are as follows:

Type of medical device	Fees*
Notification of clinical research for active implantable medical devices	10.436,42 €
Notification of clinical research for medical devices in vitro diagnostic medical devices	10.436,42 €
Notification of clinical research for in vitro diagnostic medical devices	393,85€

* Fees applicable as from 31 May 2019.

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

MAs are valid for five years. An application for renewal of a national MA must be submitted through the national procedure or the mutual recognition procedure at least nine months prior to the expiring date of its validity. After the first renewal, MAs are valid for an indefinite time.

Since 1 January 2016, the use of the electronic form for the submission of a MA renewal application has become mandatory.

The fees that have to be paid for renewal are the following:

Procedure		Fees*
National procedure		5.905,59 €
Centralised procedure		14.400,00 €
Decentralised procedure and mutual recognition procedure	If Belgium = CMS	1.070,58 €
	If Belgium = RMS	12.035,33 €

* Fees for 2019.

In the event of duly justified reasons related to pharmacovigilance (please refer to **Chapter III, Question 26**), the FAMHP may require an additional five years renewal at the same conditions than the first one.

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

Generic products can be authorized through a so-called abbreviated procedure, meaning that the applicant is not required to submit a complete file to receive a MA and can rely on the documents already submitted for the brand-name product.

The presentation of pre-clinical and clinical trials is not required if the applicant can demonstrate that the medicine for human use is a generic of a reference medicine for human use which is or has been authorised for at least eight years in Belgium or in another Member State (i.e. so-called data protection). Once this period of data exclusivity has expired, the MA application can be submitted, as well as the pricing and reimbursement application. However, an additional two (or in some cases three) year period is required before the generic drug can be marketed (i.e. so-called market protection).

The same rules apply equally to local and foreign manufacturers.

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

There is no specific regulation for combined products. The combination of medical devices and/or medicines requires that both products have individually obtained the respective authorisations.

However, it is important to emphasize that even if biologic products are classified as medicines, they are subject to different rules than the medicines in general.

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

The FAMHP is responsible for monitoring the correct application of the laws and decrees in force in the field of medicines. To this end, the FAMHP is legally authorised to carry out inspections, searches, analyses, interrogations, seizures, etc. within companies operating in the medical field.

The regulatory regime is based on the EU directives on medicines and medical devices and is in line with the European Medicines Agency expectations and requirements.