The Pharma Legal Handbook

Portugal

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

Portugal

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

Prepared in association with Cuatrecasas, a leading portuguese 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 SEPTEMBER 2018 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.**
****LAST UPDATE: APRIL 2019**

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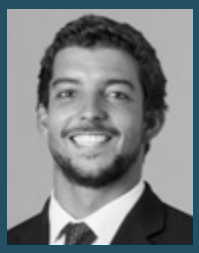
LANGUAGES
- Portuguese
- English
- Spanish



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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?

Jurisdiction over drugs, biologicals and medical devices is centralized in Infarmed, the Portuguese Medicine Regulatory Authority (*Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.*), hereinafter referred to as "Infarmed".

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

The authorization, pricing, and reimbursement of drugs, biologicals, and medical devices is governed by the following laws and regulations:

(i) Decree Law 176/2006, 30 August 2006 (Medicinal Products Act);
(ii) Decree 145/2009, 17 June 2009 (Medical Devices);
(iii) Decree-Law 97/2015, 1 June 2015, Ordinance 195-A/2015, 30 June 2015, and Ordinance 195-C/2015, 30 June 2015 (Pricing and Reimbursement of medicinal products and medical devices).

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

In order to develop and test medicinal products in Portugal, it is necessary to obtain an authorization for the manufacturing of medicinal products and to comply with the requirements established in the Medicinal Products Act for the manufacturing of medicinal products.

In addition, a medicinal product to be marketed in Portugal must hold a marketing authorization obtained via one of the following methods: **(i)** National Procedure; **(ii)** Mutual Recognition Procedure; **(iii)** Decentralized Procedure; and **(iv)** Centralized Procedure at the European Medicines Agency.

4. What are the approximate fees for each authorization?

The fee for the manufacturing authorization is approximately EUR 575.
The fees for the Marketing Authorization approval of the medicinal products are the following, depending on the type of procedure to be adopted (please refer to **Chapter 1, Question 4.)**:

National Procedure	EUR 2.850
National Procedure for Generics	EUR 1.720
Mutual-Recognition Procedure	EUR 5.000
Decentralized Procedure	EUR 3.000

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

Marketing authorizations are valid for 5 (five) years. Renewals shall be applied for no later than nine months prior to the expiration date. After the first renewal, marketing authorizations are valid for an indefinite term. In the event of duly justified reasons related to pharmacovigilance, Infarmed may require an additional 5 (five) year renewal.

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

According to the Medicinal Products Act, marketing authorization for generic products is subject to the same legal process as brand-name products.

However, for generic products the process may be shorter since the presentation of pre-clinical and clinical trials is not required, i.e., provided that (i) bioequivalence is demonstrated on the basis of bioavailability studies; or (ii) therapeutic equivalence is demonstrated by means of appropriate clinical pharmacology studies. This rule applies equally for both local and foreign-owned manufacturers.

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

There are no specific regulation for combined products. However, biologics are classified as medicinal products (drugs) and are subject to the same rules established in the Medicinal Products Act. Therefore, the combination of products of medical devices and medicinal products implies that both products, individually, should obtain the respective authorizations.

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?

Compliance with regulation is monitored and evaluated by Infarmed, which ensures the supervision and enforcement of the legal provisions through (i) periodical inspections and (ii) audit and reporting requirements, including of adverse reactions under pharmacovigilance rules.

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

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

The penalties consist of fines that may range between EUR 2,000 and 15% of the turnover, or EUR 180,000, whichever is lower, and other ancillary sanctions. The latter may be applicable in case of serious violations.

The ancillary sanctions may consist of: the suspension of the authorization or license granted to the entity that has committed the infraction up to a period of two years, loss in favor of the State of objects and equipment used by the defendant, and prohibition of participating in public tenders for a period of up to two years.

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

Portugal has a Social Security System with national healthcare coverage which is regulated by the Government through the Portuguese Ministry of Health (Ministério da Saúde). The National Health System (Serviço Nacional de

Saúde), better known as NHS, covers all Portuguese residents; it is universal, comprehensive and nearly free at the point of use. The National Health System is financed primarily by general taxes.

The NHS can be characterized by:

- providing universal coverage;
- providing global healthcare in an integrated way or else guaranteeing its provision;
- usually being free to its users, taking into account the social and financial position of citizens;
- guaranteeing equal access to its users, with a view to mitigating the effect that economic, geographic or other inequalities have on access to healthcare;
- regionalized organization and decentralized and participative management.

The following persons are entitled to NHS coverage:

- all Portuguese nationals;
- nationals of member states of the European Union, the European Economic Area and Switzerland in accordance with the EU regulations in place;
- foreign nationals residing in Portugal, subject to reciprocity;
- foreign nationals residing in Portugal within the framework of bilateral agreements;
- citizens requesting asylum and refugee status;
- stateless citizens residing in Portugal.

Planning and regulation take place largely at the central level in the Ministry of Health and its institutions. The management of the NHS takes place at the regional level. In each of the five regions, a health administration board that is accountable to the Ministry of Health is responsible for strategic management of population health, supervision and control of hospitals, management of primary care centers and implementation of national health policy objectives.

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

Hospitals belonging to the NHS are in the public sector, under the Ministry of Health's jurisdiction. Private sector hospitals, both profit-making and non-profit-making, have their own management arrangements.

The Ministry of Health and regional health administrations may contract with private hospitals to provide healthcare services to the users of the NHS whenever this is advantageous, especially considering the quality-cost binomial, and provided that the right of access is guaranteed.

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

Prices of drugs are regulated by the System of Assessment of Health Technologies (SiNATS). SiNATS was created by Decree-Law 97/2015, 1 June 2015, which established the provisions applicable to pricing, reimbursement and prior evaluation procedures.

Medicinal products subject to medical prescription are subject to a price approval procedure before Infarmed prior to launch on the Portuguese market.