Medicinal Product Regulation: Portugal's Framework

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ABSTRACT

Purpose: The pharmaceutical industry is one of the most tightly regulated sectors, and it is essential to know each country's legal framework to understand the regulation, approval, and marketing of medicinal products for human use. This article describes the main statutes and procedures governing medicinal products for human use in Portugal and the role of the country's National Medicines and Health Products Authority (*Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.*; INFARMED).

Methods: From the most recently available data, an update of requests and approvals concerning marketing authorizations, variations, pricing, and reimbursements is provided. Data were sourced from the INFARMED website, Infomed (database of medicinal products for human use), and periodic reports issued by national authorities. Organic laws, acts, and law decrees published in the government gazette (*Diário da República*) are cited and reproduced as required.

Findings: In 2015 Portugal ranked fifth in the European System of Medicines Evaluation in terms of the number of completed procedures as a reference member state. Approximately 80% of all approved drug applications in Portugal in 2015 were for generic drugs, mostly pertaining to the nervous system. In Portugal, INFARMED monitors drug quality, safety profile, and efficacy in all stages of the drug life cycle, ensuring patients' safety.

Implications: The Portuguese market for medicinal products for human use has been appreciably changed by the advent of generic drugs. There is an increased trend for new request applications for biological and biotechnological substances. (*Clin Ther.* 2016;38: 2118–2126) © 2016 Elsevier HS Journals, Inc. All rights reserved.

Key words: marketing authorization, medicinal products regulation, National Regulatory Agency, Portugal.

INTRODUCTION

The prescription, supply, and use of medicines should center on their rational use, to foster patients' interests and integrity and to promote public health and national economic sustainability. For a marketing authorization (MA) to be valid and a drug marketed in an intended member state (MS), its assessment is based on European Union (EU) standards. Furthermore, it is essential to know the legislative reality for drug approval, regulation, and market evolution in each country.

The pharmaceutical industry is one of the most tightly regulated sectors, with the European Medicines Agency tasked with overseeing such regulation in the EU. Even so, each MS undertakes its own regulation of pharmaceutical products, and in Portugal it is the National Medicines and Health Products Authority (*Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.*; INFARMED) that evaluates, authorizes,

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