Safety Alerts: An Observational Study in Portugal

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ABSTRACT

Purpose: The information that is available when marketing authorizations are approved is limited. Pharmacovigilance has an important role during the postauthorization period, and alerts published by national authorities allow health care professionals to be informed about new data on safety profiles. This study therefore sought to analyze all safety alerts published by the Portuguese National Authority of Medicines and Health Products I.P. (INFARMED).

Methods: We conducted an observational study of all alerts published on the INFARMED website from January 2002 through December 2014. From the data included in the alerts, the following information was abstracted: active substance name (and trade name), event that led to the alert, and the resulting safety measures. Active substances were classified according to the Anatomical Therapeutic Chemical (ATC) code.

Findings: A total of 562 alerts were published, and 304 were eligible for inclusion. The musculoskeletal system was the ATC code with more alerts (n = 53), followed by the nervous system (n = 42). Communication of the information and recommendations to the health care professionals and the public in general was the most frequent safety measure (n = 128), followed by changes in the Summary of the Product Characteristics and package information leaflet (n = 66). During the study period, 26 marketing authorizations were temporarily suspended and 10 were revoked.

Implications: The knowledge of the alerts published during the postmarketing period is very useful to the health care professionals for improving prescription and use of medicines and to the scientific community for the development of new researches. (*Clin Ther.* 2015;37:2122–2128)

Key words: pharmacovigilance, Portugal, safety alerts, National Regulatory Agency, adverse drug reactions, safety measures.

INTRODUCTION

The development process for new medicines includes preclinical and clinical studies whose objective is to evaluate their tolerability and efficacy.[1] However, the information that is available when marketing authorizations (MAs) are approved is limited. Among other limitations illustrated by the clinical trials is the fact that the population exposed to the pharmaceutical drug being studied is subject to strict inclusion and exclusion criteria, is homogenous, and does not always have similar (clinical, demographic, social, or other) characteristics to the real population.[2–7] This fact is at the root of the importance of continuously monitoring the safety profiles of medicine. Thus, triggered essentially by the thalidomide phenomenon in the 1960s,[8] pharmacovigilance systems were developed in various countries.[4,6,9] In

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