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Pharmacovigilance Regulations for the Pharmaceutical Industry: International Comparative Analysis †

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Abstract: Globalization of the pharmaceutical industry has prompted efforts towards harmonizing Pharmacovigilance practices worldwide to enable improved knowledge of medicine's benefit-risk profile and communication. The objective of this study was to compare Chilean legislation in the field of pharmacovigilance with those from Brazil, Canada, Denmark, New Zealand, India, and Japan. A cross-sectional descriptive study retrieving information from government websites and papers from scientific databases was developed. Legal documents regarding pharmacovigilance systems of each participating country were examined, and key information was extracted and organized in tables. Among the similar points, the corresponding deadlines to report adverse events to the authorities, the responsibility of having a pharmacovigilance manager in the country, and the obligation to carry out periodic safety update reports and constantly review the benefit-risk balance of the marketed medicines were found. Likewise, differences have been identified, such as the people who can report adverse events and the reasons for suspension/revocation of the sales license. Despite having only 10 years of pharmacovigilance legislation, Chile has normative harmonized with different countries. Meanwhile, the main discrepancy is related to the people notifying adverse events. In the future, standard operative procedures are needed to improve pharmacovigilance in the industry.

Keywords: pharmacovigilance regulation; adverse drug reactions; pharmaceutical industry; comparative analysis.

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Conflicts of Interest

The authors declare no conflict of interest.