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SYMPOSIUM

An Overview of Canadian and U.S. Approaches to Drug Regulation and Responses to Postmarket Adverse Drug Reactions

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Abstract

Over the years, drug products, including those indicated for diabetes, have been withdrawn from the marketplace because of quality concerns and/or severe adverse drug reactions. While the drug regulatory process is designed to detect, among other things, adverse drug reactions before a drug receives marketing authorization, for various reasons, premarket detection of all potential adverse reactions associated with a drug may not be possible. As such, regulatory authorities must also react to and manage adverse reactions identified at the postmarket stage. In this article, we provide a general overview of drug regulation in Canada and the United States and consider an example of a drug indicated for the treatment of diabetes and how newly identified potential safety concerns were managed in the postmarket environment.

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Abbreviations: (DIN) drug identification number, (FDA) Food and Drug Administration, (FFDCA) Federal Food, Drug, and Cosmetic Act, (GSK) GlaxoSmithKline Inc., (IND) investigational new drug, (NDA) new drug application, (NOC) notice of compliance, (NOC/c) NOC with conditions, (NOC/c-QN) NOC with conditions qualifying notice, (PMC) postmarket commitment, (PMR) postmarketing requirement, (REMS) risk evaluation and mitigation strategy, (U.S.) United States

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