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Over the years, drug products, including those indicated for diabetes, have been withdrawn from the marketplace because of quality concerns and/or severe adverse drug reactions.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.