An overview of Canadian and U.S. approaches to drug regulation and responses to postmarket adverse drug reactions.

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Source: J Diabetes Sci Technol. 2013;7(2):313-20

Date: 2013

Language: English

Publication Type: Article

Keywords: Canada
Diabetes Mellitus, Type 2 - drug therapy
Drug and Narcotic Control - legislation & jurisprudence - methods - organization & administration - trends
Humans
Hypoglycemic agents - therapeutic use
Patient Safety - legislation & jurisprudence
Product Surveillance, Postmarketing - methods - trends
Thiazolidinediones - therapeutic use
United States
United States Food and Drug Administration - legislation & jurisprudence - organization & administration

Abstract: Over the years, drug products, including those indicated for diabetes, have been withdrawn from the marketplace because of quality concerns and/or severe adverse drug reactions.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

Notes: Cites: N Engl J Med. 2007 Jun 14;356(24):2457-7117517853
Cites: J Am Board Fam Pract. 2001 Sep-Oct;14(5):362-711572541

PubMed ID: 23566987 View in PubMed