Health Canada | Santé Canada
Health Products and Food Branch | Direction générale des produits de santé et des aliments

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03-119151-206

Dockets Management Branch (HFA-305)
Department of Health and Human Services
Food and Drugs Administration
5630 Fishers Lane, rm 1061
Rockville, MD
20852

Dear Sir:

Re: Health Canada Comments on the FDA Proposed Rule (Safety Reporting Requirements for Human Drug and Biological Products)

Health Canada would like to take this opportunity to comment on the FDA's proposal to amend certain regulations governing the reporting of safety information by industry to the Agency for human drugs and biological products. In the new FDA proposed rule, Safety Reporting Requirements for Human Drug and Biological Products, the FDA is proposing to use MedDRA as the standard medical terminology for coding post-market safety reports. Health Canada agrees that MedDRA is the best choice because it was developed through an international harmonization effort with input from industry and regulatory authorities.

Over the last 5 years, the United States, Canada, Japan, Switzerland, and the European Union have worked towards the development and implementation of MedDRA as the standardized medical terminology for safety reporting purposes. MedDRA has been designed to support the classification, retrieval, analysis, and transmission of safety information. Communication between international regulatory authorities is therefore simplified with the use of MedDRA. With additional initiatives such as the CIOMS working group on the creation of Standardized MedDRA Queries (SMQs), analysis of safety data will be made more efficient and transparent. This should lead to faster detection of potential health risks.

The FDA and Health Canada have worked collaboratively over an approximate three year period towards the implementation of a Canadian adverse event database (AERS) as a mechanism for sharing post-market safety data between both countries. Sharing of international safety data is considered critical for timely detection of new and significant safety issues. The implementation of a Canadian AERS and the continued use of MedDRA for coding of post-market safety data by all parties would facilitate early signal detection.

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It this regard, we note that a number of companies have begun the implementation of MedDRA as their post-market safety report coding terminology in Canada and the United States. A single harmonized terminology is essential for companies to communicate cross-jurisdictionally as well as to simplify and facilitate electronic transmission of safety data to regulators.

In conclusion, Health Canada shares the FDA's view regarding the selection of MedDRA as the medical terminology for coding post-market safety reports, a decision that would help to promote international consistency of collection, analysis, and transmission of post-market safety data.

Original Signed By

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Director General
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