Health Canada Santé Canada

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August 1, 2000

To: Associations

Re: Medical Dictionary for Regulatory Activities (MedDRA) terminology document
MedDRA Term Selection: Points to Consider

MedDRA, an International Conference on Harmonization (ICH) initiative, is an internationally accepted, clinically validated medical terminology meant to standardize the terminology through which medical regulatory information is classified, stored, retrieved, presented and communicated. This terminology is intended to be used for regulatory activities related to both pre- and post-approval phases. It will facilitate the transmission of information using ICH E2B : Data Elements for Transmission of Individual Case Safety Reports and ICH E2C: Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs. Utilization of this standard terminology for all stages of the products life cycle will reduce the loss or distortion of information when communicated.

The aforementioned document was created to help pharmaceutical manufacturers, clinical investigators and other users achieve consistency in the manner in which they assign terms when using MedDRA. It is currently available for comment through the MedDRA Maintenance and Support Services Organization (MSSO) homepage http://www.meddramsso.org . This is also the location where you can find information on MedDRA such as costs, training and user group meetings. Please provide any comments on the document directly to the MSSO. Comments may be submitted until **September 15, 2000.**

Please note that the document is only available in English.

Should you have any questions please contact:

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