Health Canada Santé Canada

April 27, 2011

Notice

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Notice Regarding Interim Approach for Evaluating Cardiovascular Risk for New Antidiabetic Therapies to Treat Type 2 Diabetes Mellitus

Health Canada has received requests from the pharmaceutical industry regarding data requirements for cardiovascular risk assessment of new antidiabetic therapies. This Notice is being issued to ensure that relevant points related to assessing cardiovascular risk associated with these therapies are considered during the drug development process and filing strategies.

As an interim measure, Health Canada wishes to advise that the Food and Drug Administration (FDA) *Guidance for Industry: Diabetes Mellitus - Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes (December 2008)* represents an acceptable approach to filing New Drug Submissions to Health Canada for drugs in this therapeutic class. Discussions concerning the filing strategy are encouraged.

Please note that the endpoints used for cardiovascular risk assessments may vary depending on the pharmacodynamic and toxic effects of the antidiabetic therapy in question. Acceptability will be based on the thresholds specified in the guidance (for example, upper bounds of the two-sided 95% confidence interval) along with the point estimates, the reliability of the estimations, overall quality, and the benefit-risk assessment for each product.

For any comments or inquiries related to this notice, please contact:

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For emails pertaining to this issue, please include the statement **"Evaluating Cardiovascular Risk for New Antidiabetic Therapies"** in the subject line.

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