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Information to Market Authorization Holders (MAHs) of Human Pharmaceutical Products Regarding Nitrosamine Impurities

Extension to Timelines for Completing Risk Assessments and Subsequent Actions as Outlined in Health Canada's October 2nd, 2019 Letter

(Please note that this communication is intended for MAHs of human pharmaceutical products and over the counter medications. It is not intended for MAHs of biologics, radiopharmaceuticals, disinfectants, veterinary or natural health products.)

Background

As part of Health Canada's efforts to mitigate the risk of nitrosamine contamination for all active pharmaceutical ingredients (APIs) and drug products, Health Canada requested in its letter of October 2, 2019, that MAHs follow a three- step process for conducting risk assessments of their drug products containing chemically synthesized APIs. It was recognized that the volume of products to which this applies might be significant for some MAHs. Therefore, Health Canada requested that the risk assessments (Step 1) be conducted within 6 months of the issuance of the Health Canada October 2nd letter (i.e., by April 2, 2020).

Further, Health Canada requested that subsequent actions for confirmatory testing (Step 2) and any changes to the marketing authorizations (Step 3), as required, be completed within two years of the issuance of the Health Canada October 2nd letter (i.e., by October 1, 2021).

However, Health Canada is aware that due to the impact of the global outbreak of COVID-19 many MAHs are encountering significant challenges in completing the required nitrosamine impurities risk assessments and any necessary subsequent actions within the previously requested timeframes.

Extensions to the Deadlines - Conduct of the Risk Assessments and Subsequent Actions

As a result of the challenges related to the current COVID-19 situation, Health Canada is granting an extension as follows:

Step 1 – Risk Assessments:

- to be completed by October 1, 2020

Step 2 – Confirmatory Testing and Step 3 – Changes to the Market Authorization (as required):

- to be completed by October 1, 2022

Any additional questions relating to the original October 2, 2019 letter or this communication should be directed to hc.bps.enquiries.sc@canada.ca.

Sincerely,

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