Health Canada Santé Canada

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Extension to timelines for submitting confirmation of completion of Step 1 - Risk Assessments for Nitrosamine Impurities as outlined in Health Canada's April 14th, 2021 letter

Please note that this communication is intended for Market Authorization Holders (MAHs) of human prescription and non-prescription pharmaceutical products with a Drug Identification Number (DIN) that contain chemically-synthesized active pharmaceutical ingredients (APIs). It is not intended for MAHs of biologics, radiopharmaceuticals, disinfectants, veterinary or natural health products.

Dear Market Authorization Holder (MAH):

As part of Health Canada's efforts to mitigate the risk of presence of nitrosamine impurities in all human pharmaceutical products containing chemically synthesized active pharmaceutical ingredients (APIs), including prescription and non-prescription (over the counter) drug products, Health Canada had requested that MAHs follow a three-step process for assessing and controlling the risk of nitrosamines. The deadline for completing the risk assessments (Step 1) was March 31, 2021. It should be noted that the timelines for completion of Steps 1, 2 and 3 remain unchanged.

On April 14th, 2021, Health Canada issued a follow up letter requesting affected MAHs to indicate their current status with respect to completion of Step 1 - Risk Assessments. The follow up letter included instructions for three parts:

- Annex 1: Risk Assessment Attestation letter - due May 14th, 2021.
- Annex 2: Summary of Completed Risk Assessments - due June 1st, 2021 and
- Annex 3: Details Regarding Incomplete Risk Assessments (for risk assessments that have not been completed by the March 31, 2021 deadline) - due May 14th, 2021

Health Canada is aware that, due to the continuing impact of the global COVID-19 pandemic, many MAHs are experiencing challenges to meet the deadlines for submitting information to

confirm the completion of Step 1 Risk Assessments as outlined in the April 14, 2021 letter and are working towards providing this information in the near future.

As a result, this communication is to inform you that the timelines for submitting information to Health Canada have been extended as follows:

- **Annex 1: Risk Assessment Attestation letter – extended to July 30, 2021,**
- **Annex 2: Summary of Completed Risk Assessments – extended to Sept. 1, 2021, and**
- **Annex 3: Details Regarding Incomplete Risk Assessments (if applicable) – extended to July 30, 2021.**

Despite this extension, MAHs are advised to submit completed Annexes to Health Canada as soon as possible. To facilitate completion of the Annexes, a Questions and Answers document has been developed and included along with this communication.

Health Canada expects this work to continue to be a high priority for MAHs in order to help ensure that risk is mitigated for Canadians.

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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