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Notice - Release of ICH Q3C(R7): Impurities: Guideline for Residual Solvents

13 December 2018 Our file number: 18-119594-275

Health Canada is pleased to announce the implementation of International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use (ICH) Guidance <u>Q3C(R7): Impurities: Guideline for Residual Solvents</u>

This guidance has been developed by the appropriate ICH Expert Working Group and has been subject to consultation by the regulatory parties, in accordance with the ICH Process. The ICH Assembly has endorsed the final draft and recommended its implementation by membership of ICH.

In implementing this ICH guidance, Health Canada endorses the principles and practices described therein. This document should be read in conjunction with this accompanying notice and with the relevant sections of other applicable Health Canada guidances. This and other Guidance documents are available on the <u>ICH Website</u>. Please note that the ICH website is only available in English. If you would like to request a copy of the French version of the document, please contact the <u>HPFB ICH inbox</u>.

It is recognized that the scope and subject matter of current Health Canada guidances may not be entirely consistent with those of the ICH guidances that are being introduced as part of our commitment to international harmonization and the ICH Process. In such circumstances, Health Canada-implemented ICH guidances take precedence.

Health Canada is committed to eliminating such discrepancies through the implementation of a phased-in work plan that will examine the impact associated with the implementation of ICH guidances. This will result in the amendment or, depending on the extent of revisions required, withdrawal of some Health Canada guidances.

Should you have any questions or comments regarding the content of the guidance, please contact:

Health Canada - ICH Coordinator E-mail: <u>hc.ICH.sc@canada.ca</u>

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