



INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

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IGBA Welcomes update to ICH M7 on Assessment and Control of Nitrosamine Impurities

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The [International Generic and Biosimilar Medicines Association \(IGBA\)](#) commends the [General Assembly of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use \(ICH\)](#) for its decision to develop an Addendum to the ICH M7 Guideline on Assessment and Control of DNA Reactive (mutagenic) impurities, to incorporate the latest scientific advancements supporting the safety assessment and control of nitrosamine impurities into internationally harmonized guidance.

This significant development, which took place at the recent ICH meeting in Fukuoka, Japan, represents the culmination of considerable efforts by IGBA members, stakeholders, and regulators to share emerging data and collaborate to support the development of internationally aligned, scientifically based guidance on nitrosamines.

The International Generic and Biosimilar medicines Association (IGBA) recognizes that quality, safety, and efficacy of generic and biosimilar medicines is of the utmost importance for global public health and supports increasing access to high-quality, cost-effective medicines worldwide. IGBA members are committed to ensuring the medicines they develop, manufacture and market are safe, effective and do not contain potentially mutagenic nitrosamines in harmful amounts.

While the current ICH M7 provides guidance to establish acceptable intakes for mutagenic impurities, it does not provide a general framework for mutagenic impurities within the 'cohort of concern' in the guidance, such as nitrosamines. The new addendum will build off the existing methodology of M7 and adapt recent significant advances to establish a more scientifically based framework to setting more consistent, practical and empirically established safety limits for novel nitrosamines that takes into account the benefit of access to new cost-effective treatment options and the ongoing access to cost-effective medicines that patients around the world rely on everyday to maintain and improve their health.

IGBA has been consistently advocating to elevate the regionally developed aligned nitrosamine guidance to the ICH process to establish a globally harmonized approach to resolve remaining inconsistencies and prevent the introduction of future divergence to support our collective progress to investigate and mitigate the potential presence of nitrosamines in the global medicine supply. A globally aligned approach will ensure resources can be effectively prioritized and deployed to ensure continued access to affordable medicines and mitigate gaps in supply for patients. "We commend the ICH Assembly for their commitment to advancing scientific research and global harmonisation in the field of nitrosamines," commented [Dr. Nicholas Cappuccino](#), ICH Assembly and Management Committee member representing IGBA. "The ICH is the ideal forum for regulators and industry to work



together to establish a globally harmonized approach to developing technical guidance on nitrosamine risk assessment and controls, through an Addendum to M7," Cappuccino continued.

IGBA looks forward to actively participating in the development of this new M7 Addendum alongside regulatory authorities and other stakeholders. IGBA and its members remain steadfast in their mission to foster a globally aligned regulatory environment, which is critical to ensuring that safe and affordable medicines are available to patients around the world.

About IGBA: The International Generic and Biosimilar medicines Association (IGBA) strengthens cooperation between associations representing manufacturers of generic and biosimilar medicines from around the world. Adopting a patient centric approach, IGBA works to improve patients' access to quality assured, safe and cost-effective medicines, by promoting competition and enabling innovation in the pharmaceutical sector and sustainable economic contributions for all stakeholders. For more details, regarding IGBA and its member associations, see the IGBA website at: www.igbamedicines.org