



INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

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IGBA Joins ICH Management Committee and Welcomes the Positive Vote of the General Assembly

Kyoto, Japan (June 7, 2018) The International Generic and Biosimilar Medicines Association (IGBA) very much welcomes today's decision of the ICH General Assembly to elect the IGBA as a Management Committee Member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH).

After joining the ICH as a full member of the General Assembly in June 2016, the membership in the Management Committee (MC) is an important next step in the IGBA-ICH relationship. As of June 2018, the IGBA will be represented in the ICH Management Committee by Nick Cappuccino and Beata Stepniewska, current IGBA representatives to the ICH General Assembly.

"To be elected to the ICH Management Committee is a historical moment for our industry, and a great next milestone for the generic & biosimilar industries' engagement in the international harmonization process", commented Nick Cappuccino, the Chair of the IGBA Science Committee. We strongly believe, having contributed to the ICH work as an interested party during the last 20 years, that we can now open a new chapter of engaging even more fully in the ICH activities of developing the international standards applied to the pharmaceutical industry, including generic and biosimilar manufacturers".

"The IGBA is very much looking forward to taking a leadership role in the ICH, and continuing our active engagement in various Experts Working groups through the representation of our members across the five continents", said Beata Stepniewska, the IGBA representative to the ICH General Assembly. The positive decision of the ICH to elect the IGBA as a Management Committee Member reflects the recognition of values and expertise which the generic and biosimilar pharmaceutical industries can continue to bring to the scientific discussion at the ICH. "

As generic and biosimilar medicines industries are global industries, IGBA is well positioned to continue contributing to the harmonization of the scientific and regulatory standards led by the ICH. Deeper integration and involvement of the IGBA in the ICH Management body will clearly contribute to development and promotion of the ICH regulatory standards among the IGBA membership. This will indeed benefit patients worldwide, providing access to high quality, safe and efficacious generic and biosimilar medicines.



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