International Generic and Biosimilar Medicines Association (IGBA)

Perspective on International Harmonization

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ABOUT IGBA

• Founded in March 1997 as the International Generic Pharmaceutical Alliance
• Renamed International Generic and Biosimilar Medicines Association (IGBA) in September 2015
• Legally incorporated in Geneva, Switzerland
• Maintains constant dialogue with the WHO, WTO, WIPO, ICH and other national, regional and international bodies
MEMBERS

- IGBA is committed to promoting generic and biosimilar medicines worldwide, and consists of the following associations:
  - Canadian Generic Pharmaceutical Association (CGPA-Canada)
  - Association for Accessible Medications (AAM-United States)
  - Japan Generic Medicines Association (JGA-Japan)
  - Jordanian Association of Pharmaceutical Manufacturers (JAPM-Jordan)
  - Medicines for Europe (Europe)
  - Generic and Biosimilar Medicines of Southern Africa (GBM)
  - Taiwan Generic Pharmaceutical Association (TGPA-Taiwan)

The generic and biosimilar medicines associations of Australia, Brazil, Malaysia and Mexico are Associate Members.

- In addition, IGBA includes:
  - Biosimilars Canada
  - Biosimilars Council (AAM Division)
  - Biosimilar Medicines Group (Medicines for Europe Sector Group)
IGBA Goals

• Promote regulatory cooperation and convergence for approval of generic and biosimilar medicines
• Promote the widest possible access of medicines globally with high quality, safety and efficacy
• Promote intellectual property regimes which foster innovation and allow timely launch of generic and biosimilar medicines, while supporting fair competition and preventing risks of IP abuses globally
• Support and co-operate with international bodies and initiatives including the WHO, WTO, WIPO, ICH, IGDRP, IPRF, etc.
• Support parties in international and regional agreement negotiations to remove barriers and facilitate the registration and supply of generic and biosimilar medicines
• Foster sustainability of medicine manufacturers in the interests of healthcare systems and patients
• Advance better access to generic and biosimilar medicines globally by organizing international conferences for the industry, stakeholders and regulators
IGBA and ICH

- Generic Industry Scientific experts have served on ICH Expert Working Groups since inception of IGPA in 1997 as Interested Parties
- IGBA was accepted as an Industry Member of the ICH Assembly in June 2016 following the ICH Reorganization in 2015
- IGBA is represented by Experts on 8 current ICH Expert Working Groups
- IGBA hopes to increase the number of new topic areas with areas of most relevance to the generic and biosimilar industries
Current ICH Association Members

• **Regulatory Members**
  – FDA, US
  – EC, Europe
  – PDMA/MHLW (Japan)
  – ANVISA, Brazil
  – Health Canada
  – Swissmedic, Switzerland
  – CFDA, China
  – MFDS, Korea

• **Industry Members**
  – PhRMA
  – EFPIA
  – JPMA
  – IGBA
  – WSMI
  – BIO

• In addition there are currently 23 Observer organizations in ICH

• Full information on ICH may be found at the website: www.ich.org
IGBA Experts on Current ICH Topics

- Q3D(R1) EWG - Revised PDEs for the cutaneous and transdermal Route of Administration
- Q12 EWG - Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management
- M9 EWG - Biopharmaceutics Classification System-based Biowaivers
- M10 EWG - Bioanalytical Method Validation
- E8(R1) Informal WG - GENERAL CONSIDERATIONS FOR CLINICAL TRIALS
- E19 EWG - Optimisation of Safety Data Collection
- M4Q(R1) IWG — M4Q (CTD Q) Questions and Answers
- M2 EWG - Electronic Standards for the Transfer of Regulatory Information

IGBA Experts are from diverse companies from around the world.
IGBA Companies – Our Position in the Pharmaceutical Industry

• IGBA Member Companies are staffed with the best scientific talent and brightest minds in the global generic pharmaceutical and biosimilar industries.

• IGBA Member Companies develop, register, manufacture, and distribute medicines in virtually every country in the world.

• IGBA Member Companies are ready, willing, and able to deploy the most advanced scientific methods for development of their products.

• IGBA Member Companies would like to partner with the Drug Regulatory Authorities from around the world to establish harmonized regulatory standards and pathways for generic and biosimilar medicines using state-of-the-art scientific methodologies that result in the widest access to affordable quality medicines.