



INTERNATIONAL GENERIC AND  
BIOSIMILAR MEDICINES ASSOCIATION

# International Generic and Biosimilar Medicines Association (IGBA) Generic Industry Voice for Regulatory Convergence and Harmonization

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FDA Public Workshop  
October 2, 2017

# 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



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# 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



- 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 7 current ICH Expert Working Groups
- IGBA hopes to be elected to serve on the Management Committee of ICH in the near future



# IGBA Companies – Our Position

- IGBA Member Companies are staffed with the best scientific talent and brightest minds in the global generic pharmaceutical industry.
- 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.

