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Association for Accessible Medicines

Biosimilars Council
A Division of the Association for Accessible Medicines

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IGBA Perspectives on ICH

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Engineering the Future
of Generic + Biosimilar Medicines

International and Biosimilar Medicines Association (IGBA) Membership

IGBA is committed to promoting generic and biosimilar medicines worldwide, and consists of the following national or regional 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 (MfE-Europe)
- Generic and Biosimilar Medicines of Southern Africa (GBM-South Africa)
- Taiwan Generic Pharmaceutical Association (TGPA-Taiwan)
- India Pharmaceutical Alliance (IPA – India)

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IGBA Associate Members

IGBA has the following Associate Member Organizations:

- AMEGI – The Mexican Association of Generic Medicines
- GBMA – Generic and Biosimilar Medicines Association (Australia)
- MOPI – Malaysian Association of Pharmaceutical Industries
- Progenericos – Brazilian Generic Drug Makers Association
- National Committee for Pharmaceutical Industries (Saudi Arabia)

IGBA also includes: Biosimilars Canada, Biosimilars Council (AAM), Biosimilars Medicines Group (Medicines for Europe)

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IGBA and ICH

- Generic Industry scientific experts have served on ICH Expert Working Groups since the 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 was elected by the ICH Assembly to a 2 year term on the ICH Management Committee in June 2018
- IGBA is represented by Experts on 11 current ICH Expert Working Groups

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IGBA's Current ICH Topic Participation

- Q3D(R1) EWG - Revised PDEs for the cutaneous and transdermal Route of Administration
- Q3C(R7) EWG – Impurities : Guideline for Residual Solvents
- Q11 EWG – Development and Manufacture of Drug Substances
- 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) EWG -GENERAL CONSIDERATIONS FOR CLINICAL TRIALS
- E11A EWG – Pediatric Extrapolation
- E19 EWG - Optimisation of Safety Data Collection
- M4Q(R1) IWG – M4Q (CTD Q) Questions and Answers
- M2/M8 EWG - Electronic Standards for the Transfer of Regulatory Information

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IGBA Experts are drawn from diverse IGBA member companies from around the world

IGBA and ICH New Topics

- IGBA would like to see more ICH harmonization topics of significant relevance to the Global Generic and Biosimilar Industries in the future

- IGBA is part of an informal ICH group working with US FDA on their Paper:
  Reflection on Further Opportunities for Regulatory Harmonization of Standards for Generic Drugs

- IGBA will be represented on 3 new topics to begin at 2018 Charlotte meeting
  - Q13 Continuous Manufacturing
  - Q2(R2)/Q14 Analytical Method Validation/Analytical Method Development
  - M11 Clinical electronic Structured Harmonized Protocol

Challenges for ICH

- Increased Membership of ICH causes logistical issues at bi-annual meetings
- Size of EWGs must be limited to a workable number
- The number of topics active at one time will be limited by the availability of qualified experts for both Regulators and Industry
- Implementation of ICH Guidelines by Regulatory Members
- Conflict between traditional National Legal requirements and Modern concepts of Harmonization

Challenges for IGBA

- Diversity of IGBA Membership can make consensus difficult – e.g. Regional differences exist in regulatory priorities.
- Larger IGBA Member Associations have more resources to apply to the ICH initiatives and potentially can dominate the IGBA agenda and participation
- The generally leaner Generic Industry companies have less ability to allocate the time of experts to ICH activities and provide financial support
- There is a need to get more involvement and commitment of the actual member companies not just the associations
- Conflict between traditional national Legal requirements and Modern Concepts of Harmonization and Science

Future Topics of Interest to IGBA

- Global Reference Product
- Bioequivalence
- Scientific Considerations for Complex Drugs
- GMP for Finished Dosage Forms
- Biosimilars

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THANK YOU

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