International Generic Pharmaceutical Alliance (IGPA) History, Impact and Relevance to ICH

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IGPA
INTERNATIONAL GENERIC PHARMACEUTICAL ALLIANCE

Overview

- **IGPA-ICH representation**
- **Overview of IGPA**
  - Who we represent
  - Global reach
  - Impact of generic industry on public health
- **Transition of the generic/biosimilar medicines industries and ICH**
- **Impact of ICH**
- **History of IGPA's Engagement with ICH**
- **IGPA Represents a Critical Stakeholder for the ICH Mission**

IGPA-ICH Representation

- IGPA members produce the majority of medicines in represented regions
- Most ICH guidelines, and all Quality guidelines, impact the generic and the biosimilar industries
- Global prominence and contribution to public health via generic and biosimilar medicines
- Benefits ICH by expanded representation reflecting global generic and biosimilar industries and full product life-cycles
- *IGPA respectfully requests equal industry representation within ICH governance and membership*

Overview of IGPA

Overview of IGPA

- **Sole organization representing the global generic industry in highly regulated regions**
- **Founded in 1997 to promote high standards for generic medicines**
  - Safety, efficacy, quality, bioequivalence and relevant “Good Practices” (GMP, GDP, GCP, etc.)
  - Principles consistent with ICH's mission “to achieve greater harmonization to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner.”

IGPA Tenets

- Promote Access to affordable quality medicines
- Ensure timely and increased access for patients and promote competition and thereby affordability
- Support for Global harmonization of regulatory approaches for medicines
- Work with national governments and international organizations to promote product quality
- Prevent counterfeit and falsified medicines

IGPA Members

- Canadian Generic Pharmaceutical Association (CGPA)
- European Generic Medicines Association (EGA)
- Generic Pharmaceutical Association (GPhA) – U.S.
- Jordanian Association of Pharmaceutical Manufacturers (JAPM)
- Japan Generic Medicines Association (JGA)
- National Association of Pharmaceutical Manufacturers (NAPM) – South Africa
- Brazilian Generic Medicine Drugmakers Association (Progenericos)
- Taiwan Generic Pharmaceutical Association (TGPA)
- Mexican Association of Generic Medicines (AMEGI)
- Generic Medicines Industry Association (GMIA) – Australia


CGPA
EGA
JGA
Japan Generic Medicines Association
GPhA
Generic Pharmaceutical Association
JAPM
The Jordanian Association of Pharmaceutical Manufacturers
TGPA
TAIWAN
GENERIC
PHARMACEUTICAL
ASSOCIATION
AMEGI
ASOCIACIÓN MEXICANA DE GENÉRICOS
PróGenéricos
ASSOCIAÇÃO BRASILEIRA DAS INDÚSTRIAS DE MEDICAMENTOS GENÉRICOS
NAPM
National Association of
Pharmaceutical Manufacturers
GMiA
Making medicines affordable

Global Presence

- **Many member companies manufacture and market globally**
  - E.g., Teva, Actavis, Sandoz, Mylan, Fresenius-Kabi, Apotex…
- **Dramatic global growth over past decade, which continues today**
- **Generic medicines account for over 50% of the global prescriptions**
  - Examples of Generic medicines utilization in some of the regions we represent (in volume)
    - 86% U.S.
    - 67% Canada
    - 66% South Africa
    - 54% EU
    - 47% Japan
- **Dynamic increase of biosimilar medicines use and contribution to public health**
- **It is essential for the generic and biosimilar medicines industry to partner with ICH in global harmonization and quality efforts impacting public health**

IGPA Core Global Activities

- **Global Involvement**
  - Consistent dialogue with global organizations
    - WHO
    - WTO
    - WIPO
  - Input on regional/national issues related to quality, IP, harmonization, trade, etc.
    - TPP
    - TTIP
    - CETA

Evolution of the Generic Industry and ICH

Generic Industry Evolution

- **Extraordinary growth of the global generic industry over the past 20 years**
- **Generic manufacturers have largely transitioned from domestic to global businesses**
  - Most large generic firms operate as multinational organizations
  - IGPA members are dedicated to quality manufacturing
- **Many generic manufacturers are developing and marketing biosimilar medicines**

Generic Industry Evolution[2]

- IGPA has strengthened its organization, direction and representation substantially over the last decade by engaging more members and regional and world health authorities
- ICH guidelines are being broadly and increasingly applied to generic and biosimilar industries by regulators[1]
- With one set of standards, it is imperative that all key industry sectors have an equal voice
- As stated earlier generic medicines now represent over 50% of medicines dispensed globally

[1] "Same quality standards for all drugs;" Lawrence Yu, U.S. FDA, GPhA Fall Technical Conference, Oct. 28, 2014

ICH/IGPA “Interested Party” Engagement

Quality Guidelines Applicable to Generic Drugs by Regulators

- Q1A-Q1F: Stability
- Q1A(R2): Stability Testing of New Drug Substances and Products
- Q1B: Stability Testing - Photostability Testing of New Drug Substances and Products
- Q1C: Stability Testing for New Dosage Forms
- Q1D: Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products
- Q1E: Evaluation of Stability Data
- Q1F: Stability Data Package for Registration Applications in Climatic Zones III and IV
- Q2: Analytical Validation
- Q3-Q3A : Impurities
- Q4-Q4B: Pharmacopoeias
- Q5A-Q5E: Quality of Biotechnological Products
- Q6A-Q6B: Specifications
- Q7: Good Manufacturing Practice
- Q8: Pharmaceutical Development
- Q9: Quality Risk Management Q9
- Q10: Pharmaceutical Quality System
- Q11: Development and Manufacture of Drug Substances

Multidisciplinary Guidelines Applicable to Generic Drugs by Regulators (examples)

- Electronic Standards M2
- Nonclinical Safety Studies M3
- Common Technical Document M4
- M4(R3): Organization
- M4Q(R1): Quality
- M4S(R2): Safety
- M4E(R1): Efficacy
- M7: Genotoxic Impurities

Safety & Efficacy Guidelines Applicable to Generic Drugs by Regulators (examples)

- **Safety**
  - Carcinogenicity Studies S1A-S1C
  - Genotoxicity Studies S2
  - Toxicity Testing S4
  - Reproductive Toxicology S5
  - Biotechnological Products S6
  - Photosafety Testing S10
- **Efficacy**
  - Pharmacovigilance E2A-E2F
  - Good Clinical Practice E6

IGPA Experts/Participation for ICH Working Groups

- Q1A(R) Stability– Nicholas Cappuccino
- Q1D-Q1F Stability – Nicholas Cappuccino
- Q3A(R),Q3B(R) Drug Substance and Product Impurities – N. Cappuccino
- Q3C Impurities – Residual Solvents – Tony Amman
- Q3D Elemental Impurities – Melissa Figgins
- Q4B Pharmacopoeial Interchangeability – Costin Camarasu, Biovail,
- Q4B Annexes – N. Cappuccino
- Q6 Specifications – Ron Nedich (1997)
- Q7 GMP – Paolo Romagnoli
- Q7 IWG Q&A - Martin Schiestl, Sandoz

IGPA Experts/Participation for ICH Working Groups

- Q8 Pharmaceutical Development – Mike Teiler, Taro
  - Geoff Ansell (Niche Generics, Unichem-alternate)
- Q8(R) Pharmaceutical Development, N. Cappuccino
- Q9 Quality Risk Management – Christine Mundkur, Barr Labs
- Q10 Quality Systems – Jan Moors, Pharmachemie NV (Teva) / Gordon Munro, Watson
- QIWG Training Course and Points to Consider, N. Cappuccino
- Q11 Development and Manufacture of Drug Substances - Martin Schiestl, Sandoz, Rajannamar Thennati, Sun Pharma
- Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management - Keith Webber, Perrigo (2014)

IGPA Experts/Participation for ICH Working Groups

- M2 – John Hems
- M8 eCTD – John Hems
- M3(R2) Nonclinical Safety Studies – Sandy Eisen
- M4Q CTD – Ron Nedich, Alice Till, N. Cappuccino
- M7 Genotoxic Impurities, Jack Lipman, Tamotsu Fujino
- E2C, E2F Pharmacovigilance – Jacqueline Conant, Apotex
- S10 Photosafety Testing – Sandy Eisen
- Reprotoxicity Workshop, Tallinn 2010 – N. Cappuccino
- Safety Brainstorming Workshop, St. Louis 2009 – Jack Lipman
- Drug Safety Informal WG - Keith Earle Duramed, Barr
- Biotech Informal WG - Suzanne Sensabaugh, Teva

IGPA Participation and Concerns

- **Involvement as an ICH Steering Committee Party is essential so that generics have an equal voice in the structure/administrative policies and procedures of ICH – selection of topics for harmonization, and sign-off at steps not reserved to regulators**
- **Interested parties have been excluded from those important discussions, as well as outnumbered on expert working groups – many times viewed as optional attendees to the working group meetings.**
- **Interested parties are also excluded from being a Rapporteur, Topic Leader, and Deputy Topic Leader.**
- **Some but not all WG encouraged substantial IGPA involvement**
  - Opportunity for equal input has been limited in some cases resulting in no or restricted generic perspectives
  - Restricted involvement impacted member's consistency of support
  - Number of IGPA experts in each EWG has been limited to one (with a few exceptions) versus two for other industry associations
  - In spite of limitations, IGPA has a consistent history of contributions

Moving Forward: ICH and the Global Environment

ICH Successes

- ICH has accomplished unparalleled harmonization over the past 20 years
- ICH serves as a key change agent for regulators/industry
- ICH promotes quality, safety, efficacy
- Great efficiencies have been and continue to be realized for both industry and regulators in Preparation and Review of Dossiers
- Develop Common Technical Documents which provide global firms with a single platform for sponsors

Time for Change

- **ICH is assessing reforms**
- **No other forum exists to promote deliberative industry-regulator dialogue for the pharmaceutical industry**
  - Regulators moving towards converged global standards
  - Excluding a **major** stakeholder from administrative processes, results in a lack of transparency and representation for a key global stakeholder
- **Generic and biosimilar stakeholders have sought equal standing for over a decade**
  - IGPA members have had ongoing discussions with regional regulators
  - Time to create a space for generic and biosimilar producers' inclusion in dialog with regulators at the global level

Time for Change[2]

- There has been dramatic changes in the generic industry, driven by growth, globalization and sophistication, since the inception of ICH
- Generic and biosimilar medicines are a critical component of the global public health
- Global vision of ICH aligns with all sectors of the pharmaceutical industry
- IGPA is the global voice of the generic and biosimilars industry

Time for Change[3]

- It is essential for the generic and biosimilar medicines industry to partner with ICH in global harmonization and quality efforts impacting global public health
- Equitable representation for the generic and biosimilar medicines industry at ICH is consistent with the realities of the global pharmaceutical market

Summary

- This is a pivotal moment in the history of drug regulations.
- Regulators are collaborating and converging as never before.
- Regulations are becoming ever more globalized because the drug industry is more globalized.
- ICH has made a tremendous contribution to the harmonization of drug regulations over the last 24 years, and it deserves a great deal of credit for that.
- ICH also has a crucial role to play in the future. It can be a forum for setting converged standards that will apply around the world and to the entire industry.
- But, in order for that to happen, ICH must itself enter a new phase – when the rules that apply to all of industry are no longer made by the few.
- We believe this change is necessary in order to support ICH's future strength and credibility. ICH must be an equitable organization, and should be representative of the current industry realities.

IGPA Request

IGPA respectfully requests equal industry representation within ICH governance and membership. We are committed to standing with you.

Thank You