ABOUT IGBA

• The International Generic Pharmaceutical Alliance (IGPA) was founded in March 1997

• The organization was renamed the International Generic and Biosimilar Medicines Association (IGBA) in September 2015

• In an era when increasing demands are being made on the world’s healthcare services, generic and biosimilar medicines provide a major benefit to society by ensuring patient access to quality, safe and effective medicines while reducing the cost of pharmaceutical care

• Through its constituent member associations, the IGBA maintains constant dialogue with the ICH, WHO, WTO, WIPO and other international bodies
IGBA MEMBERS

- IGBA is committed to promoting and providing access to quality generic and biosimilar medicines, and exchanging information worldwide, and consists of the following associations:
  
  - Canadian Generic Pharmaceutical Association (CGPA-Canada)
  - Medicines for Europe (formerly EGA)
  - Generic Pharmaceutical Association (GPhA-USA)
  - Japan Generic Medicines Association (JGA-Japan)
  - Jordanian Association of Pharmaceutical Manufacturers (JAPM-Jordan)
  - National Association of Pharmaceutical Manufacturers (NAPM-South Africa)
  - Taiwan Generic Pharmaceutical Association (TGPA-Taiwan)

- In addition, the generic and biosimilar medicines associations of Australia, Brazil, Malaysia, and Mexico are Associate Members.

IGBA PRINCIPLES ON REGULATORY COOPERATION

Benefits:

- ✓ Increase patient access to high quality medicines
- ✓ Share scientific knowledge with regulators
- ✓ Promote appropriate standards globally
- ✓ Lower development costs
- ✓ Reduce unnecessary & unethical duplication
- ✓ Promote global cooperation
Generic Medicines Industry Support

- Conceptually the development of a single generic drug dossier and subsequent simultaneous review and approval by multiple national drug authorities is extremely attractive to IGBA members.
- The goals of the IGDRP to promote collaboration and regulatory convergence are supported by the members of IGBA particularly those companies that operate on a global scale.
- Is There any Incentive for the Overall Generic Industry?

SINGLE DEVELOPMENT PROGRAMME FOR GENERIC MEDICINES

ADVANTAGES:

- Reduction of clinical development costs
- Opportunity to re-invest potential savings
- Reduction of unethical repetition of studies
- Increased patient access to quality, safe and effective generic medicines in many regions simultaneously
- Sustainability of healthcare systems
- Promote high standards globally
- Increased Patient Confidence
- Reliability of supply through use of common bulk product for multiple markets
A single development programme is particularly important for complex generics:

- Examples: patches, injectables, respiratory products, complex APIs, etc.
- Reduce unnecessary/unethical duplicative clinical studies
- Reduce development costs by up to €35 million per product
- Increases access in smaller markets to innovative dosage forms

Bio Waivers and Bioequivalence

Key Issues:

- Science-Based Regulation - BCS
- Common Reference Product
- Ethical Considerations
- Economics
- Convergence Required Urgently for all Classes of Products, Promised expansion to other BE topics is eagerly awaited
ASMF and DMFs

- Major suppliers of APIs internationally are generic companies
- Compendial standards are uniquely important to the generic industry, therefore regulatory convergence if not harmonization of compendia is especially important.
- ICH Q11 is still a work in progress

MUTUAL RELIANCE OF GMP INSPECTIONS

- Joint Good Manufacturing Practice (GMP) inspections are on-going
- Opportunity: More efficient use of resources for both industry and regulators
- Clear, consistent, appropriate GMP requirements
- Inspections may be coordinated with Dossier Assessments
- Inspection of clinical research organizations can benefit by the same harmonization approaches.
**Experience to date with IGDRP**

**Work Sharing:**

- There have been communication issues among agencies
- Answers to some technical questions are still asked by only a single regulator
- Communication issues back to sponsor
- Greatest need perceived by industry is for increased regulatory convergence on some fundamental aspects of technical requirements
- However, experience has been overall positive
- The industry would strongly like to see the scope of the project expanded to more complex dosage forms.

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**Regulatory Convergence**

There is a huge need for regulatory convergence on technical requirements for generic drug registration

Examples:

- Common scoring configuration
- Acceptability of different sterilization methods
- Post-Approval Changes
- Definition of Active Substance
- In-Process control specifications
- Common Reference Product
Needs

- Increased Regulatory Harmonization (not just Convergence)
- National Governments’ Involvement/Commitment
- Increased Involvement and Communication between IGDRP and Industry on Current Projects
- Engagement with Industry in Selection and Design of Future Projects to ensure relevance and participation

Communication

- As new work areas are considered for the agenda of IGDRP it may be helpful to the process to get input from IGBA regarding priorities.
- Communication among Drug Regulatory Authorities is critical
- Awareness of IGDRP must be raised
- Living agreement: other countries may join later
Expectations

• Confidentiality
• Consistency
• Timely Assessments
• Communication
• Transparency

THANK-YOU!

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