GPhA
Generic Pharmaceutical Association

OPPORTUNITIES OF INTERNATIONAL REGULATORY COOPERATION

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About GPhA

GPhA represents the manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. Our members manufacture more than 90% of all generic pharmaceuticals dispensed in the U.S., and their products are used in more than three billion prescriptions every year. Generics represent greater than 89% of all prescriptions dispensed in the U.S. but only 27% of the expenditures of prescription drugs.

GPhA Members

- 3M Drug Delivery Systems
- Accord Healthcare Inc.
- Alvogen Inc.
- Amneal Pharmaceuticals LLC
- ANI Pharmaceuticals
- Apotex Corporation
- Aurobindo Pharma USA Inc.
- Baxter Healthcare Corporation
- Cipla USA
- Dr. Reddy's Laboratories, Inc.
- Fresenius Kabi USA LLC
- G & W Laboratories, Inc.
- Glenmark Generics Inc., USA
- Impax Laboratories, Inc.
- Kremers-Urban Pharmaceuticals Inc.
- Lupin Pharmaceuticals Inc.
- Mallinckrodt Pharmaceuticals
- Mayne Pharma
- Momenta Pharmaceuticals Inc.
- Mylan N.V.
- Par Pharmaceutical Companies, Inc.
- Perrigo PLC
- Sagent Pharmaceuticals, Inc.
- Sandoz Inc.
- Strides Shasun Limited
- Sun Pharmaceutical Industries, Inc.
- Teva Pharmaceuticals USA
- Therapeutic Proteins International, LLC
- West-Ward Pharmaceuticals
- Wockhardt USA Inc.
- Zydus Pharmaceuticals USA

Global Regulatory Cooperation

- The pharmaceutical industry is global
- Industry and many global regulators are evaluating efficient use of available resources to increase patient access to quality, safe and effective medicines.
- This is of utmost importance in the current context of the increasing pressures global healthcare system are experiencing on spending and the increased regulatory and administrative burdens.
- Global regulatory convergence is a key opportunity to improve efficiency in the regulatory system.

Generic Medicines Industry Vision

Patients	→ Increase access to complex medicines
Quality	→ Promotes high global standards
Value	→ Increase efficient use of limited resources
Sustanaibility	→ Lowers development & review/approval costs
Partnership	→ Improve regulatory science globally

Generic Medicines Industry Vision

…with Regulatory Cooperation

- Ongoing progress on mutual recognition of cGMP inspections
- Single development of complex generic medicines

A positive example of regulatory cooperation

Mutual Recognition of cGMP Inspections

- Single recognized inspection protocol
- Convergence of categorizing inspection findings
- Confidential sharing of inspection findings
- Legal hurdles to sharing of data/information

Progress on Mutual Recognition of cGMP Inspections Between the EU and U.S.

- Joint inspections are currently being conducted
- Scientific knowledge is being shared
- Reduction of duplications is being evaluated
- Efficient use of resources is being measured
- The current focus is on EU/U.S. recognition and once complete, the U.S. FDA intends to expand the scope to other countries
- Thus far, the U.S. FDA has observed 14 joint audits performed by EU member countries and received 6 completed audit reports – more to follow

Single Development Pathway of Generic Medicines

- Reduce unnecessary/unethical duplicative clinical studies
- Reduce product development costs
- Invest potential savings into innovation and new medicines
- Sustainability of EU/U.S. healthcare systems
- Promote high global standards

Progress on Single Development Pathway Between the EU and U.S.

- Legal concerns
  - Alignment of laws, statutes, guidelines/guidances, etc.
- Alignment of regulatory standards/specifications
  - CMC, BE, Clinical, etc.
- Convergence on the use of a “foreign” reference product (EU in the U.S. or U.S. in the EU)

Summary

- In a global marketplace, regulators must cooperate to create a more efficient harmonized regulatory approach for product development and approval, including the cGMP inspection components.
- Medicines for Europe and GPhA call on the EU EMA and the U.S. FDA to support a mutual recognition regulatory framework for;
  - the use of a single reference product
  - a single development, review and approval pathway
  - a single recognized cGMP inspection protocol