OPPORTUNITIES OF INTERNATIONAL REGULATORY COOPERATION

David R. Gaugh, R.Ph.
Senior Vice President,
Science, Regulatory and International Affairs

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 88% of all prescriptions dispensed in the U.S. but only 28% of the expenditures of prescription drugs.
The pharmaceutical industry has become global.

Industry and many global regulators are currently evaluating more 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** → Better access to complex medicines

**Quality** → Promotes global high standards

**Value** → Efficient use of limited resources

**Sustainability** → Lowers development & review/approval costs

**Partnership** → Improves regulatory science across borders

---

...and Regulatory Cooperation

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

A positive example of regulatory cooperation in the TTIP
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 E.U. 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 E.U./U.S. recognition and once complete the U.S. FDA intends to expand the scope to other countries
- The U.S. FDA has signed “letter of intent” with 4 of the 28 E.U. countries – more to follow
Single Development Pathway of Generic Medicines

- Reduce unnecessary/unethical duplicative clinical studies
- Reduce product development costs
- Invest potential savings into new medicines
- Sustainability of E.U./U.S. healthcare systems
- Promote the highest standards globally

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

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

• In a global marketplace, regulators need to cooperate and create a more harmonized regulatory approach for product development and approval, including the cGMP inspection components.
• Medicines for Europe and GPhA call on the E.U. and the U.S. 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