Opportunities for International Regulatory Cooperation (IRC)

Dr. Jeremy Desai
CEO, Apotex

Agenda

• Drivers for IRC
• Current Initiatives for IRC
• IRC Focus- Industry Perspective
• IRC and Review Convergence
  – IRC and Dossier Review Convergence
  – IRC and Facility Review Convergence
• IRC Models in place for reviews
• IRC Future State- Industry Expectation
• Key Take Aways
Drivers for IRC

- IRC Drivers
- Avoid Duplication of Efforts
- Share Best RA practices and Policies
- Development of new Regulatory Science
- Enable capacity building for emerging regulators
- Exchange of Public and confidential safety data
- Supply Chain are Global

Current Initiatives for IRC

- ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals)
- PIC/S (Pharmaceutical Inspection Cooperation Scheme)
- United States Food and Drug Administration (USFDA), the European Commission and the European Medicines Agency (EMA) bilateral meeting
- International Medical Devices Regulators Forum
- International Generic Drug Regulators Pilot
- ACSS (Australia, Singapore, Switzerland, Canada) and Australia-Canada Regulatory Cooperation initiatives
IRC Focus - Industry Perspective

Review convergence and work-sharing

Sharing of GMP and GCP inspections and reports

Information sharing on GMP non-compliance, recalls, data integrity and risks of drug shortages.

Information exchange on Pharmacovigilance data, specifically on adverse reactions

Aligned regulatory interpretation

IRC & Review Convergence

Harmonize CQA/CPP Expectation

Align to ICH expectations

Why can we not consider one global Reference standard?

Harmonized regulator prevents duplication
IRC & Dossier Review Convergence

**How can we get the convergence for a Global Generic Drug Review?**

- Increase efficiency of review process - information exchange – coordination – responsiveness
- CMC review Strategy convergence can be accomplished by
  - Harmonizing global reviews to follow ICH expectations
  - Having a common approach to review by focusing drug product review on CQA, CMA and CPP’s
- Bioequivalence review- Common Reference Standard
- The sharing of information between the regulators and/or relying on each other’s review

*We envision that the decisions would still be made, based on these assessments, by individual regulators to maintain sovereignty of medicines approved for supply in each market.*

IRC & Facility Review Convergence

**How can we get the convergence for Facility review across all regulators?**

- Regulators to rely on each other’s inspection findings to avoiding duplication of efforts
- This will allow in enabling wider inspection coverage.
- Data integrity as a cornerstone to establishing and maintaining confidence in test results. There has to be a common understanding between on all regulators.
- Regulators could work on joint communication and training to help increase the awareness of manufacturers.

*Joint Inspection by regulators or reliance on global regulators inspection findings to determine the state of compliance is the only tangible solution to understand the risks in this complex global pharmaceutical supply chain.*
**IRC Models In Place For Reviews**

- EU/EEA
  - Validation
  - Assessment Step-1
  - Assessment Step-2
  - Market Authorization Granting

- Australia
  - Validation
  - Preliminary AR
  - Draft AR
  - Final AR
  - Market Authorization Granting (Registration)

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*International regulatory cooperation: more important than ever - John Skerritt, National Manager ARCS Scientific Congress 2014*

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**IRC Future State - Industry Expectation**

- One Global Quality Standard
- Enhanced Cooperation
- One Global Quality Standard

*INTEGRATED REGULATORY STANDARDS*

- Rapid exchange important safety updates
- Agreement on common Global Reference Standard
- Exchange of facility inspection
- One Quality Voice
- Rely on each other’s review findings
Key Takeaways

Increased harmonization of regulations through a wide variety of international regulatory cooperation (IRC) mechanisms. The world has never been more interconnected witnessed by:

- Ever increasing global trade
- Empowered regulators to cooperate and align
- Evolution in Regulatory partnerships between countries

Evidence shows growing IRC. However approaches to IRC remain ad hoc & the world of IRC is highly fragmented. Regulatory policy has a role to play but achieving greater regulatory coherence also requires more active approaches.

It’s About the Patient

[Diagram showing key stakeholders and an outline of international regulatory bodies]