

Regulatory Cooperation and Healthcare Products

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April 17, 2013



Questions Answered

- Why is regulatory cooperation important for traded healthcare products?
- What are the benefits of regulatory cooperation?
- What policy tools are available to governments to help implement regulatory cooperation?
- What international or regional regulatory cooperation exists to participate in or model?



Why is regulatory cooperation important for traded healthcare products?

- Provides regulators with a communication mechanism to exchange information on current practices
 - Understand how regulators are involved in the development of international standards, which may be included in regs.
 - Understand the timing of new proposed regulations and their implementation.
 - Exchange of practices prior to finalizing regulation.
- Provides an understanding of common practices and what might be unique about their system.
- Provides an opportunity for alignment of regulatory practices between close trading partners or partners in the same geographic proximity.

What are the Benefits of Regulatory Cooperation?

- Early exchange of information in new areas of regulation (ex. Innovative products)
- Leverage the experience the industry or other governments.
- Increase confidence among regulating peers.
- Use of common regulatory models and procedures can improve industry's ability to comply.
- Share information when participating in the development or adoption of international standards or conformity assessment procedures
- Technology Transfer

What policy tools are available to governments to help implement regulatory cooperation?

- WTO Agreement on Technical Barriers to Trade Agreement
 - Provides international obligations
 - Transparency mechanisms (notification of proposed technical regulations)
 - Opportunity for consultation with other Member governments
 - Use and acceptance of international standards
 - Use and acceptance of conformity assessment procedures
 - Use of accredited laboratories
 - Use of international standards for conformity assessment
 - Equivalence or mutual recognition of practices
- Discussion of Good Regulatory Practices

What policy tools are available to governments to help implement regulatory cooperation?

- The U.S. government has a new partnership with the WTO called the “Standards Alliance.”
- Developing countries are able to apply for the program, which can include proposals for
 - TBT Agreement Compliance
 - Discussion of Good Regulatory Practices
 - Regulatory Cooperation initiatives among WTO members.
- Future programming for regulatory cooperation concerning medical devices and pharmaceuticals could take advantage of this new program.



What policy tools are available to governments to help implement regulatory cooperation?

- APEC and OECD economies have acknowledged the role of implementing good regulatory practices as key to achieving open and competitive markets, and a key driver of economic efficiency and consumer welfare.
 - Phase 1 (2000-02) focused on the first results of regulatory reform and implementing regulatory reform in APEC and OECD economies.
 - Phase 2 (2002-05) enabled the development of the APEC-OECD Integrated Checklist for Regulatory Reform.
 - Phase 3 (2005-10) focused on how the Checklist on Regulatory Reform can be used by economies as a self-assessment policy tool, and more generally, how domestic and international co-operation on regulatory matters can be strengthened.
- OECD Integrated Checklist for Regulatory Reform – review of regulatory structure that optimizes opportunities to develop regulations which allows for risk analysis, review of the proposed measure, etc.

What international or regional regulatory cooperation exists to participate in or model?

- Product Specific Forum - Pharmaceuticals
 - The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (EU, US, Japan)
 - WHO/Pan American Health Organization (PAHO) – Pharmaceutical Policies
 - APEC Life Sciences Innovation Forum
 - Implementation of ICH
 - APEC Harmonization Center
 - Anti-counterfeiting



What international or regional regulatory cooperation exists to participate in or model?

- Product Specific Forum – Medical Devices
 - Global Harmonization Task Force (GHTF) now the International Medical Device Regulators Forum (IMDRF)
 - Members - EU, USA, Japan, AU, Canada
 - Participating and observing members status
 - Goal to standardize global medical device regulations
 - WHO/WHO/Pan American Health Organization (PAHO)
 - APEC Life Sciences Innovation Forum





Summary

- Regulatory Cooperation is important to the trade of medical device and pharmaceutical products.
- Both regulators and industry benefit from regulatory cooperation to facilitate new products into the market, ease non-tariff trade barriers and provide for common regulatory acceptance tools among trading partners.
- WTO trade agreements establish rules for information exchange and acceptance of each other's standards and regulatory practices.
- Other general policy tools, like the APEC/OECD Regulatory Reform Checklist may help the general structure of regulation in our countries.
- Government/industry cooperation in PAHO or ICH/IMDRF provide a forum for information exchange on best practices.



Questions and Contact

- Contact Information

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