

July 23, 2024

CDER Small Business & Industry Assistance Webinar

INTRODUCTION TO FDA'S OFFICE OF TRADE AND GLOBAL PARTNERSHIPS

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Who are we?

Office of the Commissioner



What do we do?

- OTGP is the FDA lead on:
 - Issues related to international trade
 - Negotiating mutual recognition agreements
 - Entering into international arrangements
 - Addressing cross-cutting issues in multilateral organizations

What are our impacts?

- Strengthening partnerships and information-sharing
- Creating efficiencies and bolstering oversight
- Preventing unnecessary barriers and unintended consequences





**U.S. FOOD & DRUG
ADMINISTRATION**

Mutual Recognition Agreements (MRAs): Overview of MRAs between FDA and Foreign Drug Regulatory Authorities

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Office of Global Policy and Strategy, Office of
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What are Mutual Recognition Agreements (MRAs)?



- **Agreements between two or more countries to recognize a specific process or procedure of the other country's regulatory authority.**
- **FDA has the authority under the Food and Drug Administration Safety and Innovation Act, enacted in 2012.**

Benefits of Mutual Recognition Agreements

- Primary objectives:
 - Enhance regulatory efficiency
 - Avoid duplication of inspections
 - Enable reallocation of regulatory resources
- The COVID pandemic underscored the need for global partnerships
- FDA is better equipped to maintain and expand its oversight



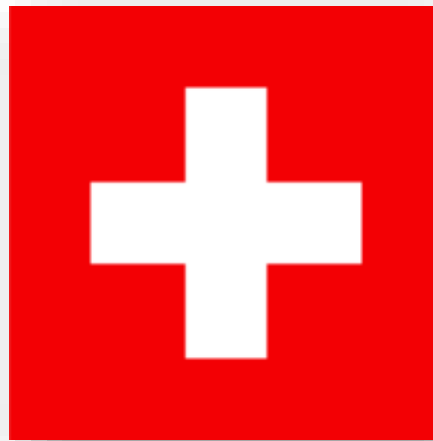
FDA's Mutual Recognition Agreements



Entered into force: November 1, 2017

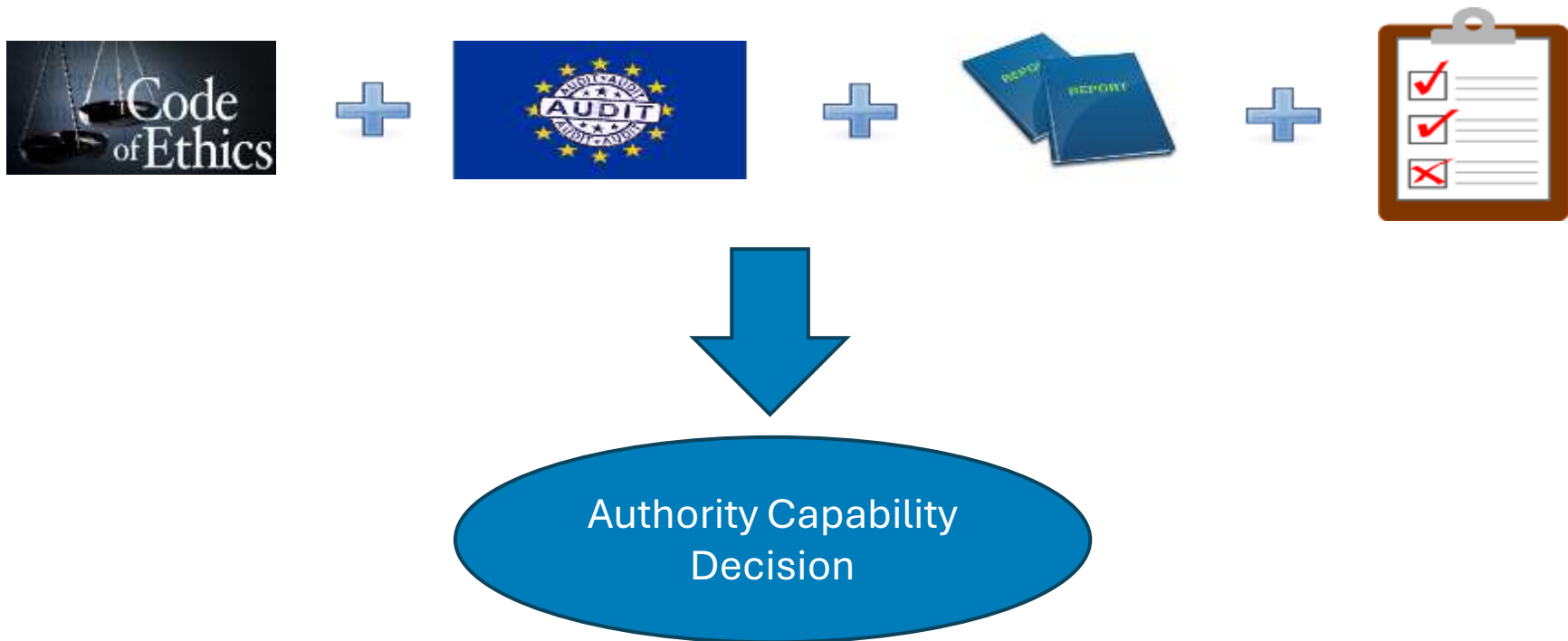


Entered into force: January 1, 2021



Entered into force: July 27, 2023

How is an Authority's Capability Defined?



More About FDA's MRAs

- MRA partners reserve the right to inspect at any time and in any country
- MRA partner's enforcement actions may differ
- Some products are excluded from the MRAs, such as:
 - Advanced Therapy Medicinal Products (ATMPs)
 - Human blood
 - Human plasma
 - Human tissues and organs
 - Veterinary immunologicals

OTGP's Role in MRAs

- Serving as the primary point of contact with U.S. interagency counterparts and foreign government entities
- Ensuring information exchange arrangements are in place
- Leading liaison activities and communications with foreign regulatory authority
- Leading a collaborative effort with other FDA Centers and Offices
- Establishing and maintaining procedures

Resources

[FDA Mutual Recognition Website](#)

[U.S.-EU Mutual Recognition Agreement](#)

[U.S.-UK Mutual Recognition Agreement](#)

[U.S.- Switzerland Mutual Recognition Agreement](#)



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Impact of FDA's International Arrangements on Pharmaceutical Products

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International work and FDA's relationships with counterpart agencies around the world is an integral and routine part of FDA's work

- Imports account for many pharmaceuticals used by U.S. consumers.
- Regulatory oversight of product manufacturing, distribution and storage and handling is increasingly difficult amid complex transnational supply chains.
- FDA works with foreign government counterparts and international organizations to foster and ensure the development, safety, and availability of pharmaceuticals



FDA interactions with foreign regulatory counterparts enhance public health promotion and protection in the U.S. and globally

- Tools to set up and memorialize partnerships include:
 - Cooperative arrangements
 - Written understanding that FDA can establish with foreign government counterparts or international organizations
 - Describes the willingness and good-faith intentions of FDA and its counterpart(s) to engage in cooperative and regulatory activities
-
- Confidentiality commitments
 - Permits the FDA to exchange non-public information with foreign government counterparts or international organizations
 - Must be in place for FDA to share non-public information



Benefits of international arrangements

Cooperative Arrangements

- An important tool for establishing or strengthening international relations.
- Facilitates cooperative interactions between FDA and foreign counterpart.
- Helps in maintaining continuity of the outlined collaboration in the face of a change in Administration, or other operational changes.

Confidentiality Commitments

- Advances FDA's public health mission.
- Improves FDA's oversight.
- Increases FDA's understanding of complex global supply chains and their effects on the safety and quality of products we regulate.
- Strengthens FDA's capacity to detect and remove violative products.
- Mitigates public health risks through regulatory actions.
- Offers better regulatory guidance in its review activities.

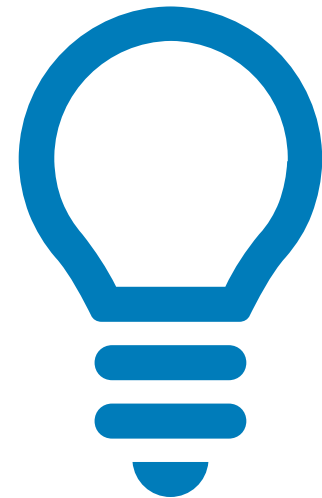
Confidentiality commitments support many of FDA's collaborative work activities with foreign counterparts

- Examples include:
 - Information exchange with our counterparts in the Americas, Europe, Africa, Asia and Australia, and with certain international organizations, including the World Health Organization
 - Scientific and technical clusters
 - Project Orbis
 - U.S.- EU Mutual Recognition Agreement (also referred to as an MRA)
 - Strengthening supply chains



OTGP role with respect to international arrangements

- Oversee the development, clearance, and conclusion of international arrangements in consultation with FDA centers and offices
- Provide policy perspective on proposed language in negotiations to ensure consistency with FDA law and policy
- Help FDA centers and offices implement active international arrangements



Resources

www.fda.gov/international-programs/international-arrangements

Overview of FDA's Engagement in Trade Policy

Kristan Callahan

Office of Trade and Global Partnerships

Technical Barriers to Trade

- Avoid unnecessary trade barriers from:
 - Technical regulations
 - Standards-related measures
 - Conformity assessment procedures
- Interagency trade policy involves regulatory agencies

Trade Initiatives and Agreements

- Bilateral or multilateral between countries, economies, and entities
- Implications for drugs and medical products:
 - U.S.-Mexico-Canada Agreement sectoral annexes
 - Indo-Pacific Economic Framework for Prosperity
 - Supply Chain Resilience Agreement

Good Regulatory Practices

- Internationally-recognized processes foundational to rulemaking
- Why do GRPs matter?
 - Opportunities for stakeholders to comment
 - Transparent communication of regulatory information
 - Alignment with international standards

Trade Enforcement

- Monitor actions that may impact drug products, such as:
 - Tariffs
 - Unfair import investigations



International Instrument on Plastic Pollution

Matthew Scherer

Office of Trade and Global Partnerships

Background

- UNEP Resolution 5/14: End plastic pollution: Towards an international legally binding instrument adopted March 2, 2022
 - Binding and voluntary approaches
 - Full life cycle of plastic (production to waste)
- Intergovernmental Negotiating Committee (INC) process
 - Every 6 months with possibility for intersessional work
 - Next: IS work Aug 2024 and INC5 (of 5) Nov 2024

USG Engagement

- Broad USG participation, led by State
- Seeks ambitious; broadly inclusive; implemented through Executive Action



FDA equities, engagement

- Plastic is incorporated into many FDA-regulated products – packaging and core components
- Avoid consumer confidence or supply chain issues
- OGPS/OTGP lead with multi-Center/Office SME participation

Pharma engagement

- Limited until INC-4 (Ottawa, April 2024)
- IFPMA position paper
 - Support an ambitious instrument that creates globally harmonized plastic regulations.
 - Commitment to innovative approaches
 - Potential need for extended compliance periods or exceptions

Avoid disruptions to patient access to medical and medicinal products due to bans or lack of availability of necessary plastic materials and components.

Instrument provisions

Life-cycle stage	Example types of provisions
Upstream	<ul style="list-style-type: none">• Phase out/down of plastic production, virgin polymers, additives “of concern”• Measures covering pollution from plastic production
Product	<ul style="list-style-type: none">• Minimum recycled content levels• Reduction/elimination of problematic, single-use plastics• Encouraging use of alternative materials, innovation
Downstream	<ul style="list-style-type: none">• Circular economy measures (e.g., recycling infrastructure, re-use programs)• Waste management infrastructure and practices• Remediation of existing pollution
Other issues	Just transition for workers in informal economy (wastepickers), environmental justice, research (health, transit), trade, financing for implementation, tech assistance, and more...

State of play

- INC1 (Nov 2022): initial sharing of views
- INC2 (June 2023): requested zero-draft text
- INC3 (Nov 2023): ~~text negotiations~~ DELAYED
- INC4 (April 2024): text-based negotiations
[intersessional meetings (August 2024)]
- INC5 (Nov 2024): ongoing and final(?) negotiations



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