July 23, 2024

CDER Small Business & Industry Assistance Webinar

# INTRODUCTION TO FDA'S OFFICE OF TRADE AND GLOBAL PARTNERSHIPS

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Office of Trade and Global Partnerships (OTGP)
Office of Global Policy and Strategy (OGPS)
Office of the Commissioner (OC) | FDA

# 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


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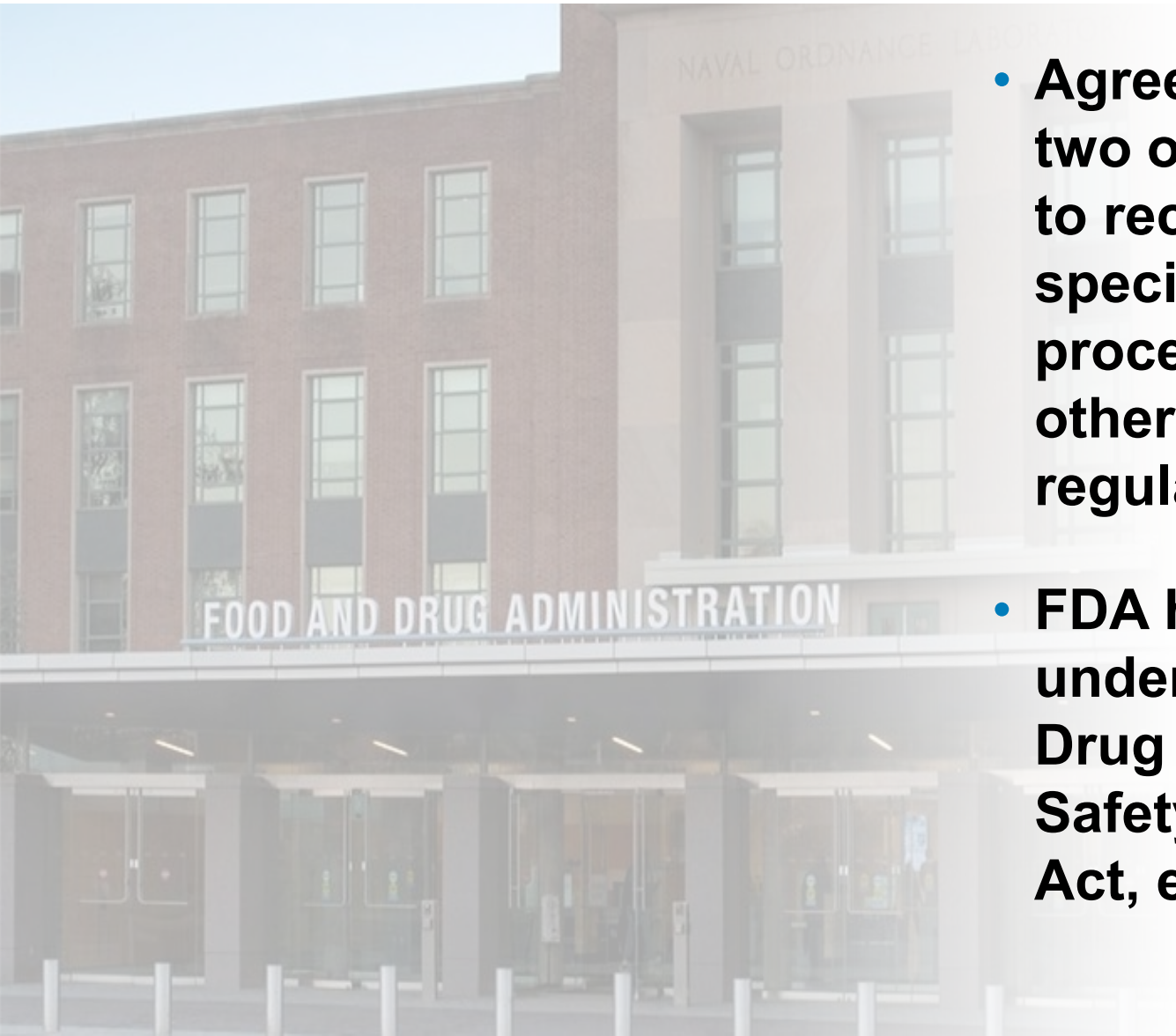
# Mutual Recognition Agreements (MRAs): Overview of MRAs between FDA and Foreign Drug Regulatory Authorities

**Eloisa Noriega**
*International Policy Analyst*
Office of Global Policy and Strategy, Office of the Commissioner

**July 23, 2024**

# What are Mutual Recognition Agreements (MRAs)?



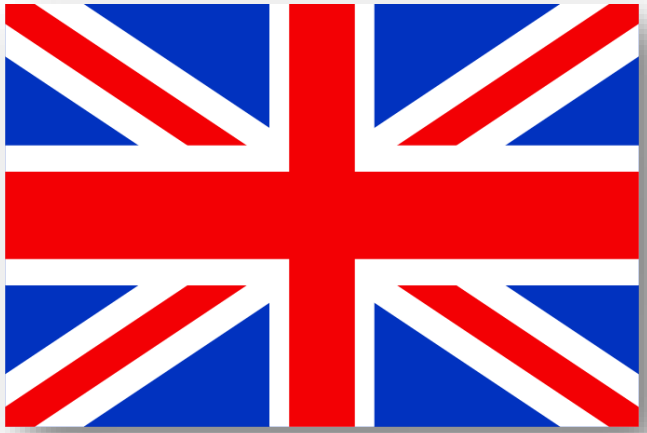

- **Agreements between two or more countries to recognize a specific process or procedure of the other country's regulatory authority.**
- **FDA has the authority under the Food and Drug Administration Safety and Innovation Act, enacted in 2012.**

# Benefits of Mutual Recognition Agreements

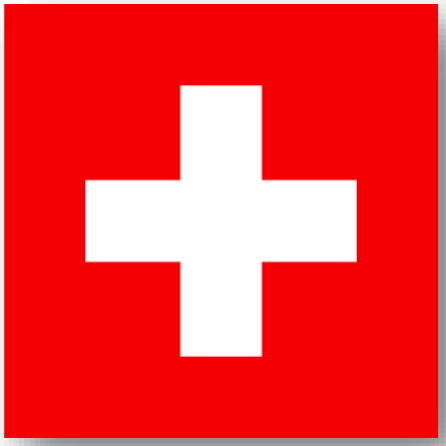
- Primary objectives:
  - Enhance regulatory efficiency
  - Avoid duplication of inspections
  - Enable reallocation of regulatory resources
- The COVID pandemic underscored the need for global partnerships
- FDA is better equipped to maintain and expand its oversight

# FDA's Mutual Recognition Agreements

Entered into force: November 1, 2017

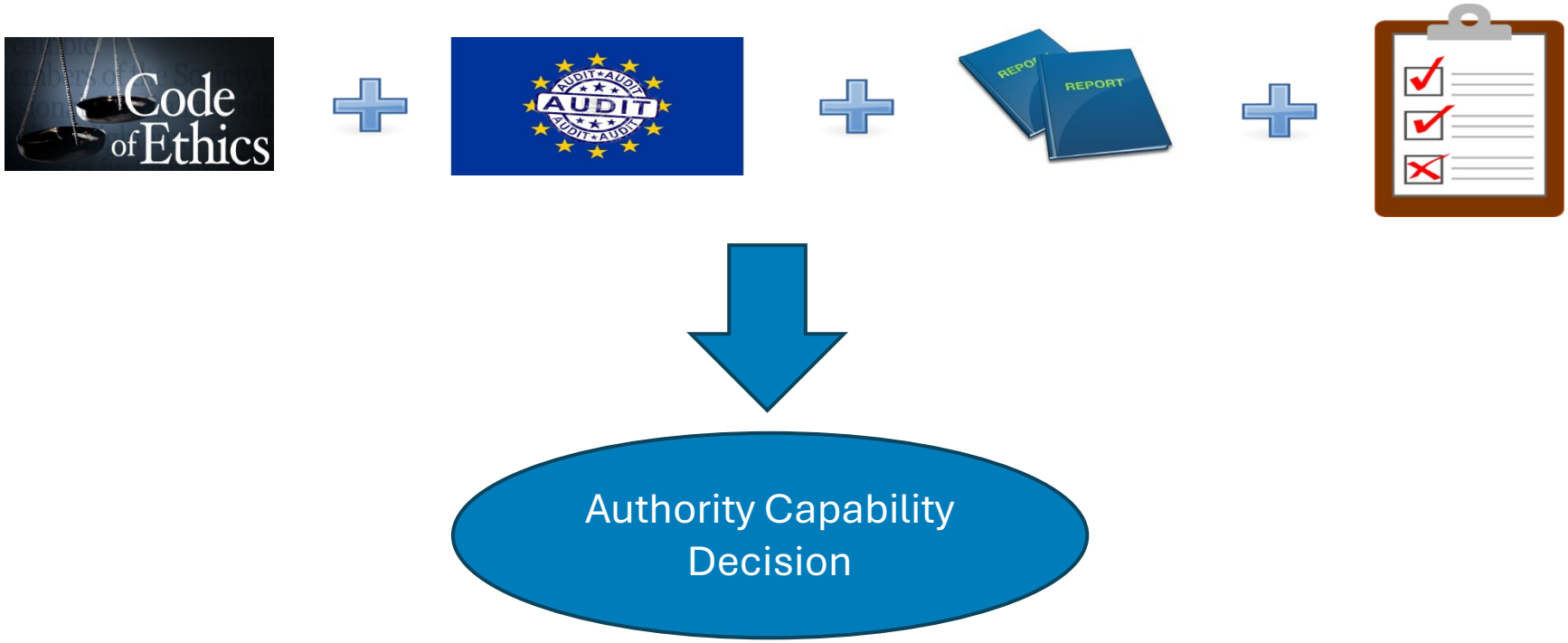


Entered into force: January 1, 2021



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

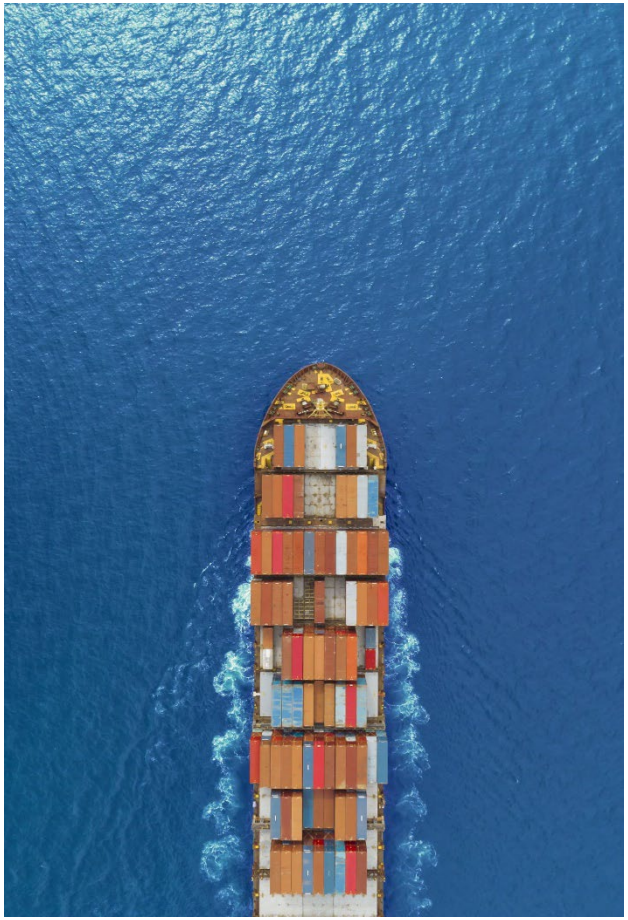
# Impact of FDA's International Arrangements on Pharmaceutical Products

**Azada Hafiz**
*International Policy Analyst*
Office of Global Policy and Strategy, Office of the Commissioner

**July 22, 2024**

# 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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# 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 | • Phase out/down of plastic production, virgin polymers, additives “of concern”<br>• Measures covering pollution from plastic production |
| Product | • Minimum recycled content levels<br>• Reduction/elimination of problematic, single-use plastics<br>• Encouraging use of alternative materials, innovation |
| Downstream | • Circular economy measures (e.g., recycling infrastructure, re-use programs)<br>• Waste management infrastructure and practices<br>• 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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