FDA/CBER's Engagements with the World Health Organization (WHO)

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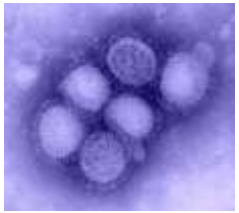
Outline of Presentation

- Strategic priorities and principles for global engagement
- CBER's role as a WHO Collaborating Center
  - Scope and breadth of CBER's collaborations with WHO
- Support for WHO vaccine prequalification program
- Support for regulatory systems strengthening in LMICs



World Health Assembly Resolution on Regulatory Systems Strengthening

"In order to improve the regulation of medical products globally and ensure that medical products are of assured quality, **more emphasis needs to be placed on regulatory strengthening, and promoting collaboration in regulatory systems**."

World Health Assembly Resolution 67.20, 2014

International collaboration and cooperation is important to protect U.S. and global public health.

Fundamental Principles for Global Engagement

- Global environment is increasingly interdependent
- Protection of global public health against infectious disease threats is a U.S. strategic priority
- Strong regulatory systems are the cornerstone for ensuring access to safe and effective biological products
- International regulatory cooperation is essential for addressing challenges efficiently
- Optimize impact of FDA outreach through multilateral engagements

Multilateral Engagements

- Collaborations with WHO at global and regional levels
  - WHO HQ (global reach)
  - WHO Regional Offices (e.g., PAHO, AFRO) and regional networks (e.g., PANDRH, AVAREF)
- WHO facilitates multilateral engagements
  - Collaboration among regulators from developed and developing countries to share knowledge and experience
  - Promote best practices and regulatory convergence
  - Essential for responding to public health emergencies
- Multilateral engagement increases efficiency; avoids duplication of effort; optimizes use of resources

CBER's Role as a WHO Collaborating Center for Biological Standardization




WHO Collaborating Center for Biological Standardization (1)

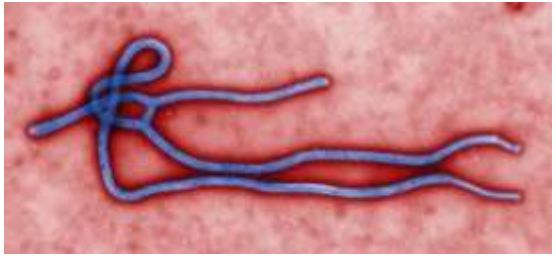
CBER contributes to a broad range of activities*:

- Development & implementation of WHO international standards
  - Physical standards e.g., reference reagents
  - Written standards e.g., WHO Guideline documents
- Regulatory systems strengthening; promoting best practices
- Research to advance standardization of biologicals
- Technical engagement in several WHO global advisory committees

* For products regulated by CBER: Vaccines, blood/blood products, *in vitro* diagnostics for HIV & cellular, tissue, and gene therapies

WHO Collaborating Center for Biological Standardization (2)

- Information sharing to advance product development
- Support WHO vaccine prequalification program
- Serve as an Essential Regulatory Laboratory (ERL) in WHO's Global Influenza Surveillance and Response System (GISRS)
- Preparedness to address threats of (re-)emerging infectious diseases (e.g., pandemic influenza, MERS, Ebola, Zika, COVID-19, monkeypox)



Support for WHO Vaccine Prequalification Program




Vaccine Prequalification (PQ)

- Vaccine PQ is integral to WHO's mission to make high quality, safe, effective, affordable vaccines available worldwide
- Service provided to UN agencies (e.g., UNICEF, PAHO Revolving Fund) that purchase vaccines for global/regional immunization programs
- WHO PQ program can be leveraged by countries to streamline registration of vaccines in own jurisdiction

Integral component of WHO vaccine PQ program: Reliance on oversight by "functional" National Regulatory Authorities (NRAs) to ensure quality, safety, effectiveness of WHO prequalified vaccines throughout product lifecycle

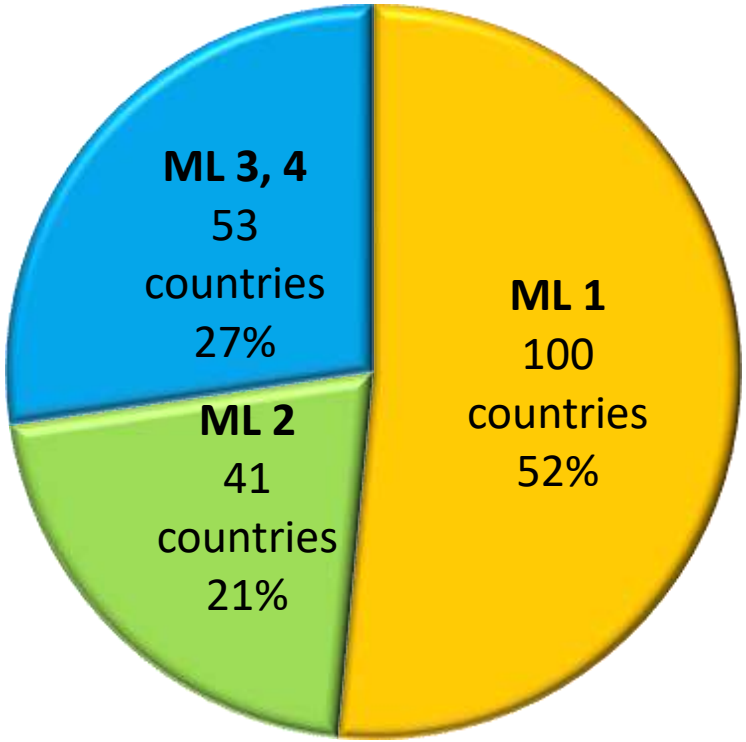
WHO Prequalified Vaccines: Commitments of Reference NRA

- Inform WHO of vaccine lots that fail CBER's lot release
- Inform WHO of product recalls and market withdrawals
- Inform WHO of significant supplements to the Biologics License Application
- Inform WHO of significant inspectional findings that may result in regulatory action
- Notify WHO of serious and unexpected events or vaccine efficacy related problems that have public health implications
- Provide information to WHO on conditions causing interruption to vaccine supply

Support for Regulatory Systems Strengthening




Maturity Level of Regulatory Systems of WHO Member States (2020)

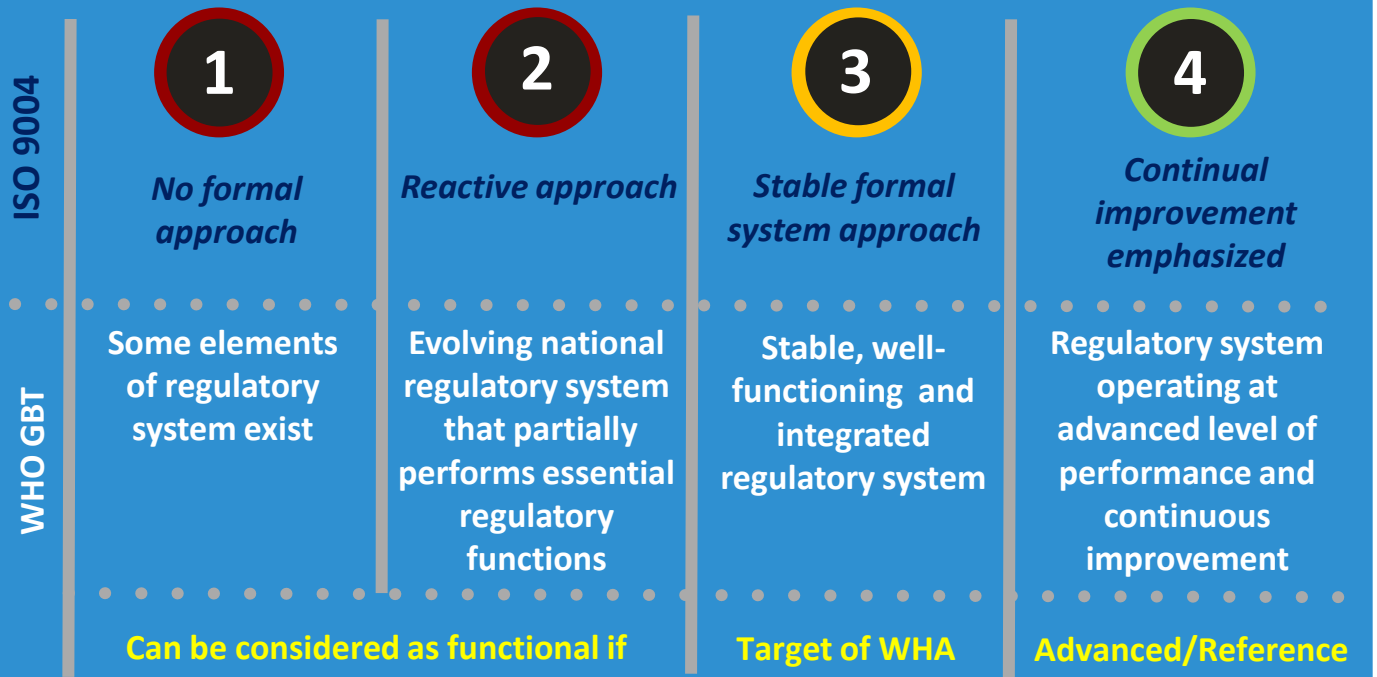


Data from Dr. Ali Khadem
(WHO/RPQ/REG/RSS)

27% countries have functional NRA

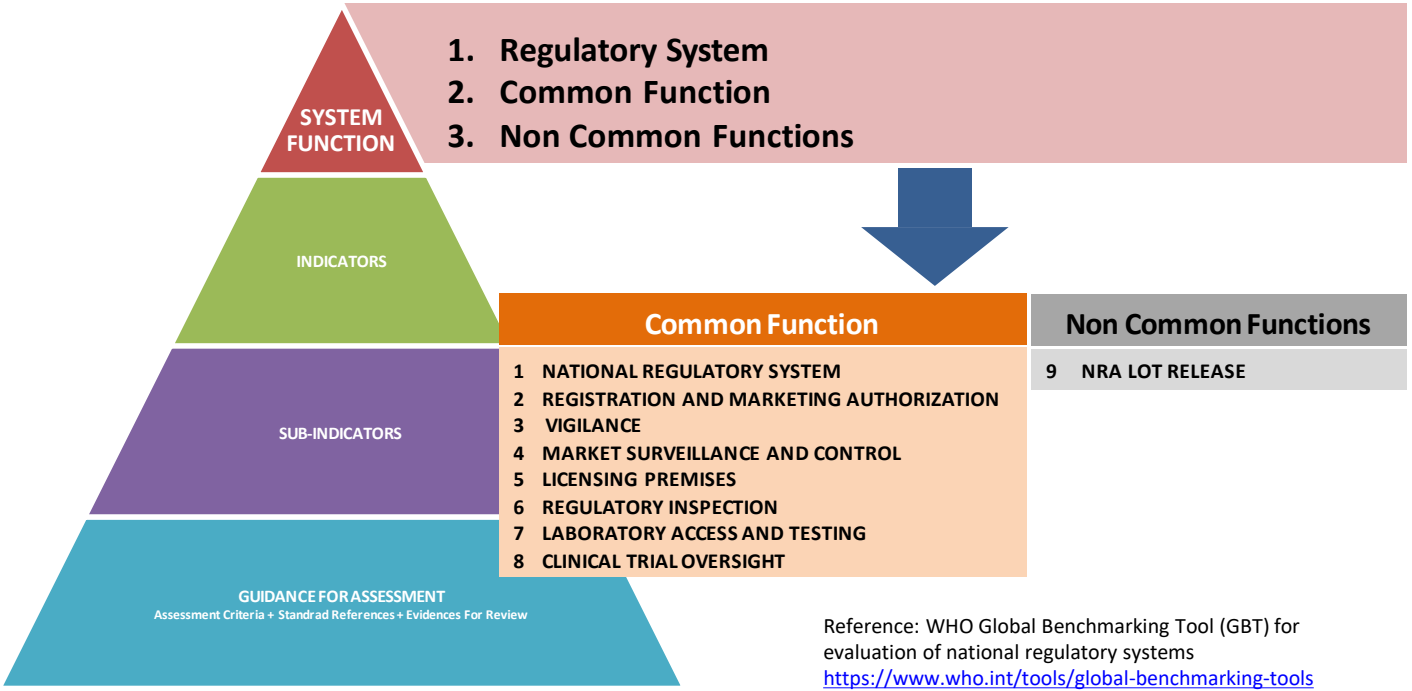
73% countries do not have fully functional NRA

WHO GBT Performance Maturity Levels



Dr. Ali Khadem
(WHO/RPQ/REG/RSS)

WHO Global Benchmarking Tool (GBT) for Evaluation of National Regulatory Systems



Reference: WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems
https://www.who.int/tools/global-benchmarking-tools

From WHO/EMP/ presentation (Claudia Alfonso, 2016)

World Health Organization

WHO Benchmarking Process: Global Standardization using GBT

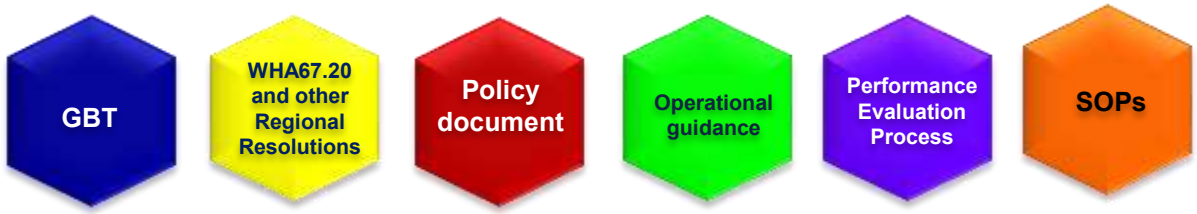
The World Health Organization Global Benchmarking Tool an Instrument to Strengthen Medical Products Regulation and Promote Universal Health Coverage
Khadem Broojerdi et al., Front. Med., 19 August 2020 | https://doi.org/10.3389/fmed.2020.00457

Need for Regulatory Systems Strengthening

- Increased focus on building manufacturing capacity for vaccines in all regions of the world to meet global demands
- Competent NRA (functioning at least at ML3) essential to ensure quality, safety, and efficacy of vaccines manufactured in country
  - Important to invest in strengthening national regulatory systems concurrently with building vaccine manufacturing capacity in country
- Global Benchmarking Tool (GBT) is primary means for WHO to assess regulatory systems; establish Institutional Development Plan (IDP) based on assessment outcomes to address gaps and strengthen NRA

WHO Listed Authorities

- Framework for publicly designating regulatory authorities as WHO Listed Authorities (WLA) based on performance evaluation
- Reaching Maturity Level 3 is entry point for further evaluation for possible WLA designation
- Transparent and evidence-based pathway for globally recognizing regulatory authorities operating at an advanced level of performance
- Facilitate reliance on the work products and decisions of trusted regulatory authorities → Increase access to safe, effective, and quality medical products



CBER-WHO Collaboration for Regulatory Systems Strengthening

Funding support to WHO through Cooperative Agreement for regulatory systems strengthening activities

- Activities associated with benchmarking using GBT
  - Pre-visits; training and other support for self-benchmarking; formal benchmarking (by WHO team); development of IDP; trainings and other support to address gaps; follow up activities to monitor progress
- Trainings for regulators (workshops & other approaches)
- Development of standards (e.g., global and regional guideline documents)
- Other activities

Conclusions

Collaboration with WHO advances CBER's strategic goal to improve national and global public health

- Establish international standards to:
  - Facilitate development and availability of safe and effective biological products
  - Promote global convergence
- Exchange ideas with scientific and regulatory counterparts for insight and perspectives on challenging regulatory issues
- Support regulatory systems strengthening in LMICs
- Maintain communication channels to rapidly address public health emergencies of international concern

Resources

WHO Global Benchmarking Tool
https://www.who.int/tools/global-benchmarking-tools

WHO Listed Authorities
https://www.who.int/initiatives/who-listed-authority-reg-authorities

WHO Vaccine Prequalification Program
https://extranet.who.int/pqweb/vaccines

WHO Collaborating Centers
https://www.who.int/about/collaboration/collaborating-centres

WHO Collaborative Procedure for Accelerated Registration
Medicines: https://extranet.who.int/pqweb/medicines/collaborative-procedure-accelerated-registration
IVDs: https://extranet.who.int/pqweb/vitro-diagnostics/collaborative-procedure-accelerated-registration

World Health Assembly Resolution 67.20 (Regulatory Systems Strengthening)
https://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R20-en.pdf



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謝謝
teşekkür ederim
спасибо
dank je
thank you
gracias
tapadh leat
hvala
mauruuru
bedankt
mochchakkeram
dziękuję
go raibh maith agat
obrigado
sukriya
kop khun krap
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