U.S. FOOD & DRUG ADMINISTRATION

The Global Generic Drug Supply Chain and Need for International Dialogue

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Sarah Ibrahim, Ph.D.
Associate Director of Stakeholder and Global Engagement (Generic Drug)
Office of Generic Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Disclaimer: This presentation reflects the views of the author and should not be construed to represent FDA's views or policies.

Value of Generic Drugs Globally

Increases competition

Promotes innovation

Improves access to medicines

Reduces global healthcare costs

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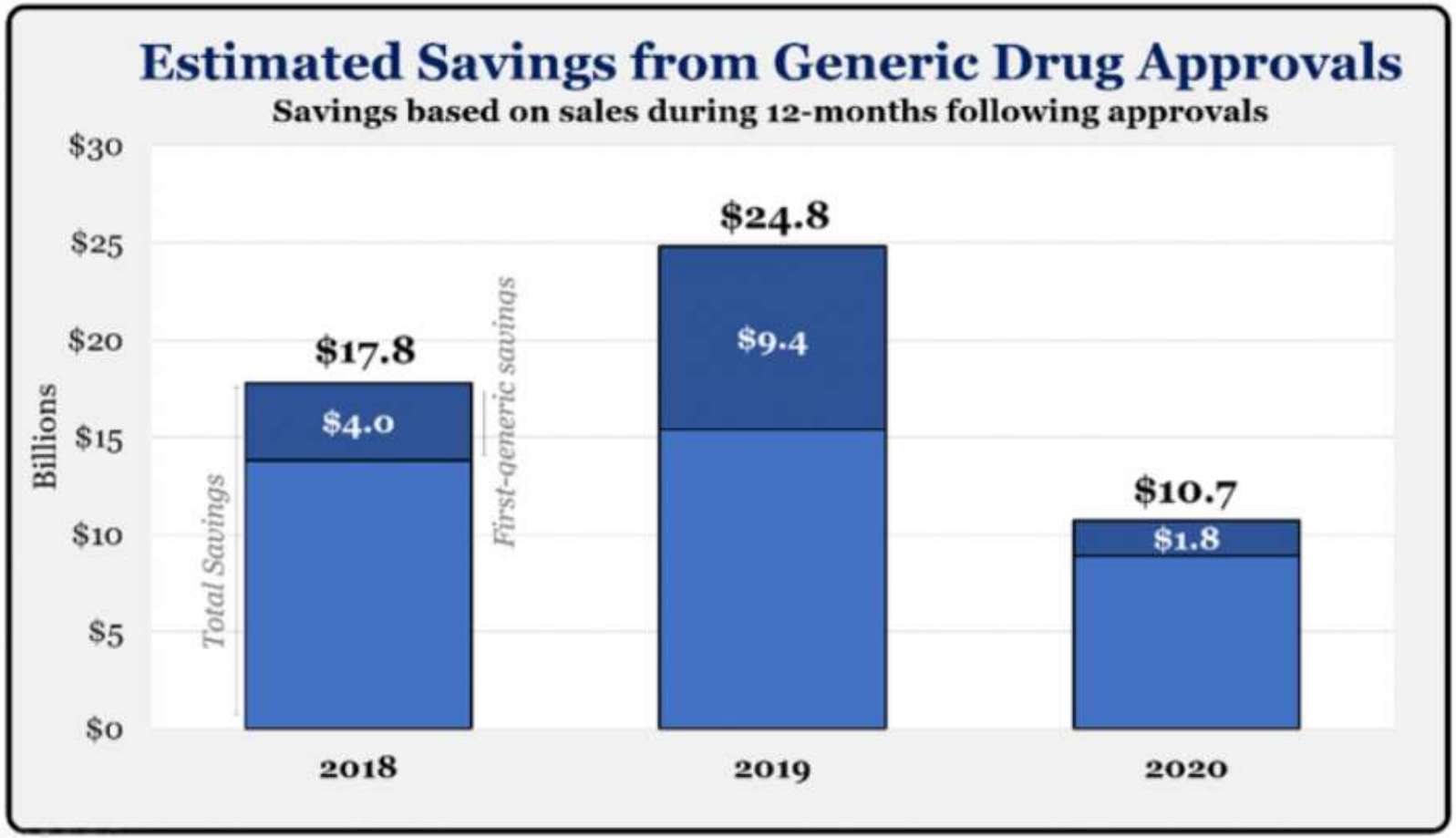
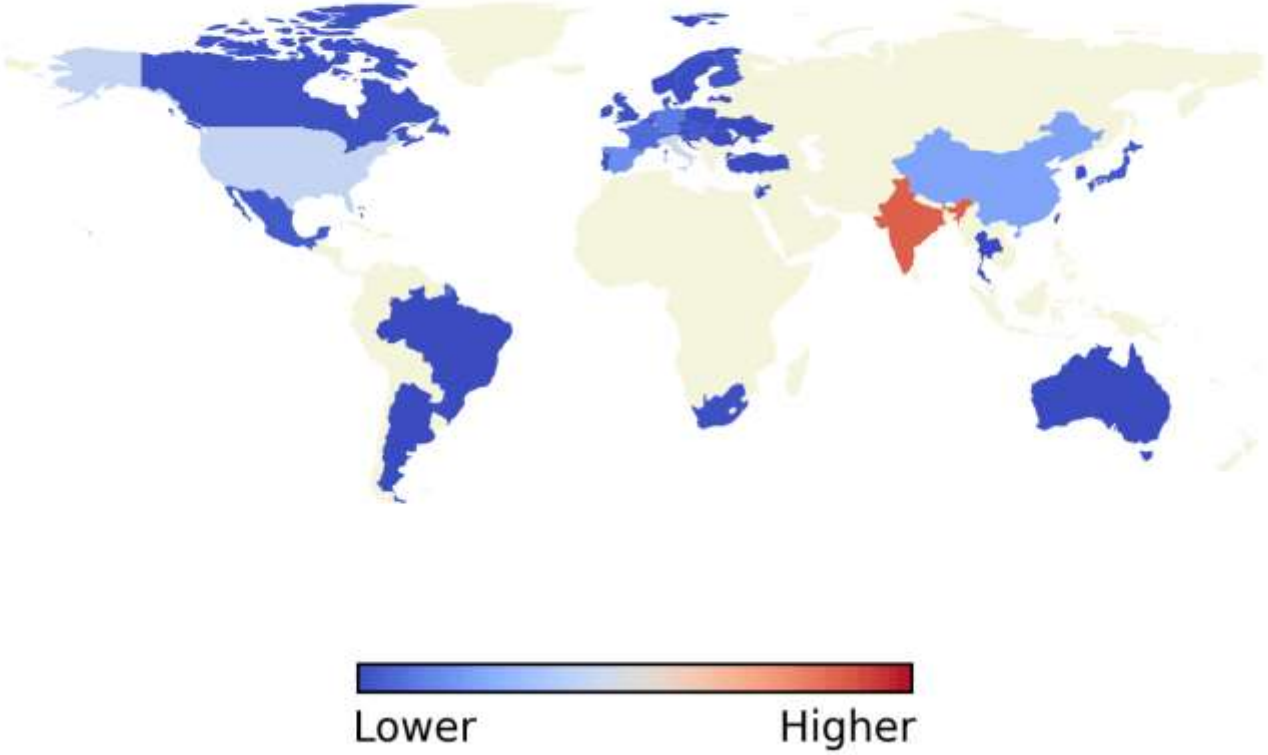


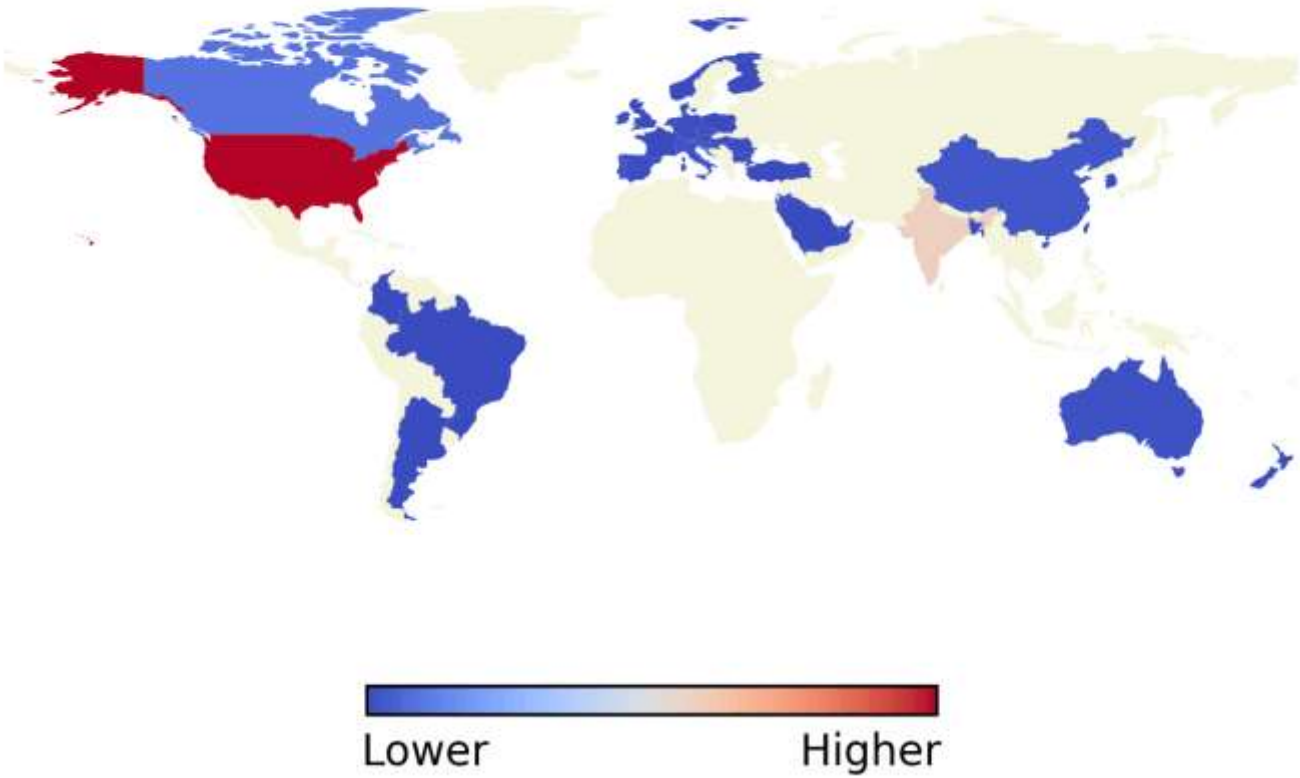
Generic Competition and Drug Pricing

*savings from new generics

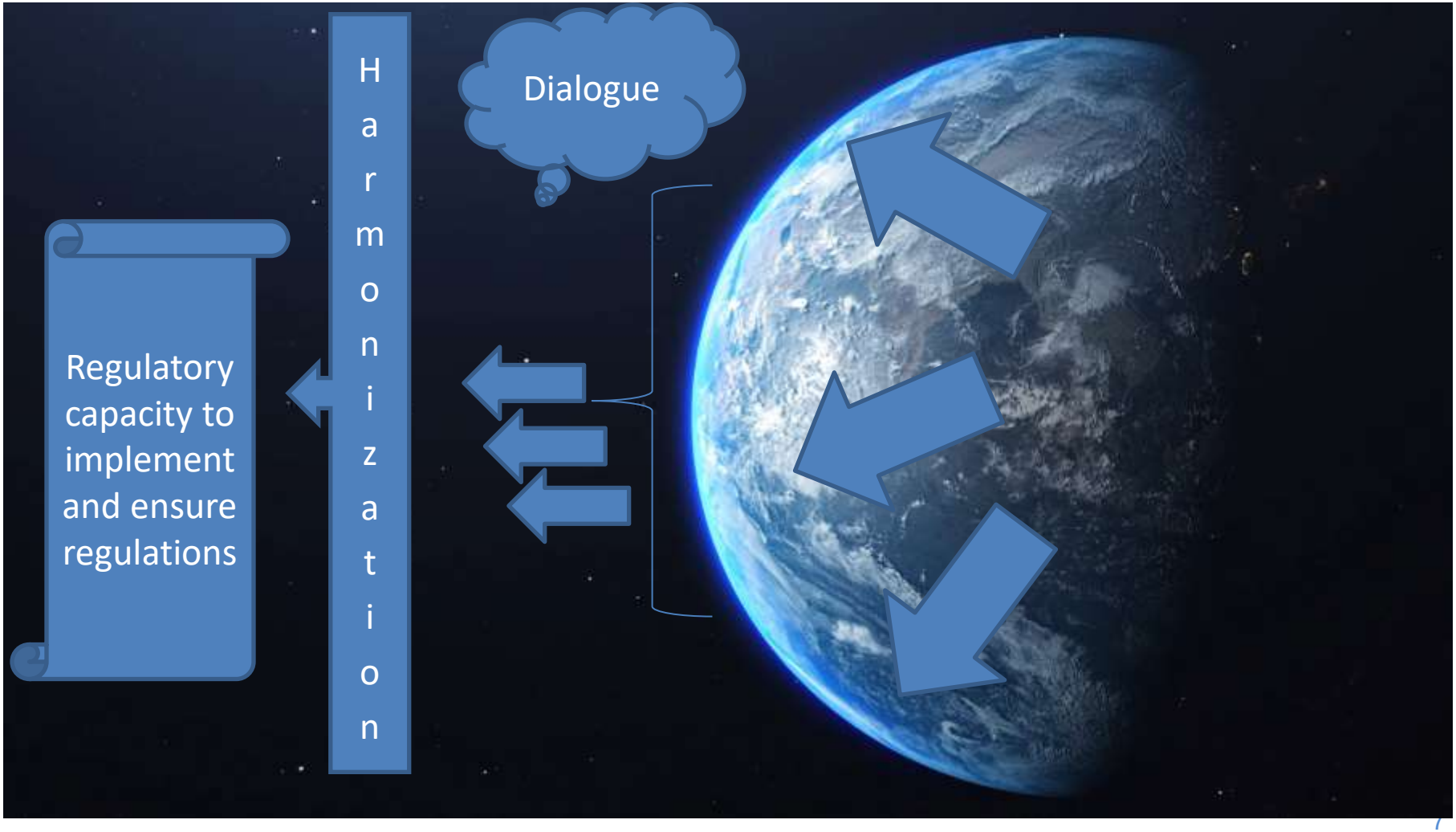
API Manufacturing for Sold ANDAs 2017



FDF Manufacturing for Sold ANDAs 2017



GLOBAL SUPPLY CHAIN



REGULATORY HARMONIZATION

- Reducing duplication and inefficiency
- Improving quality and safety
- Facilitating access to medicines
- Enhanced transparency and traceability
- Improving clinical study standards

GENERIC DRUG GLOBAL AFFAIRS PROGRAM

- Ensuring a strong FDA impact by promoting a high level of quality culture and standards
- Information collection and dissemination to assist in making better regulatory decisions about the pharmaceutical products that are being developed and exported for the U.S. market
- Identify emerging regulatory changes and manage proactive engagement with stakeholders concerning issues related to the pharmaceutical regulations
- Engage proactively and consistently with regulatory counterparts and industry representatives to facilitate FDA's domestic mission of assuring the safety, efficacy, and quality of FDA-regulated products

OGD GLOBAL AFFAIRS INTERNATIONAL EFFORTS

Convergence through international collaboration and dialogue

Regulatory harmonization efforts

Regulatory strengthening and capacity building

GENERIC DRUG GLOBAL AFFAIRS PROGRAM

Bioequivalence Working Group for Generics (BE WGG)

Discussions on implementation and interpretation of bioequivalence requirements, procedures and tools for the assessment of bioequivalence in generic drug products.

Nanomedicine Working Group for Generics

To disseminate nanomedicine knowledge between the agencies thereby improving their understanding and capability to effectively regulate these products

IPRP
International Pharmaceutical Regulators Programme

ICHM13 A

ICH harmonisation for better health

FDA

The harmonized M13A guideline provides recommendations on:

- BE study design
- Principles for conducting BE studies
- BE standards for IR solid oral dosage forms

Benefits and next steps

- This harmonized guideline reduces the need for additional in vivo BE studies and supports streamlined global drug development
- The process of harmonization will continue with M13B and M13C

Generic Drug Global Engagement Generic Drug Cluster, Parallel Scientific Advice (PSA) Updates

PROSPECTIVE HARMONIZATION EFFORTS

CONSENSUS BUILDING - TECHNICAL DOCUMENT

CONSENSUS ON TECHNICAL DOCUMENT / DRAFT GUIDELINE ADOPTION BY REGULATORS

REGULATORY CONSULTATION AND DISCUSSION

ADOPTION OF AN ICH HARMONISED GUIDELINE

IMPLEMENTATION

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COMPLEX GENERICS AND GLOBAL MARKET ACCESS

Partnership between industry, academia, and regulatory bodies

Development of a robust regulatory framework

Extensive scientific exchange of information enabling accelerated product development

Streamlining scientific recommendations and clarifying divergent regulations

Encouraging developers and manufacturers

Research and investment

GENERIC DRUG CLUSTER

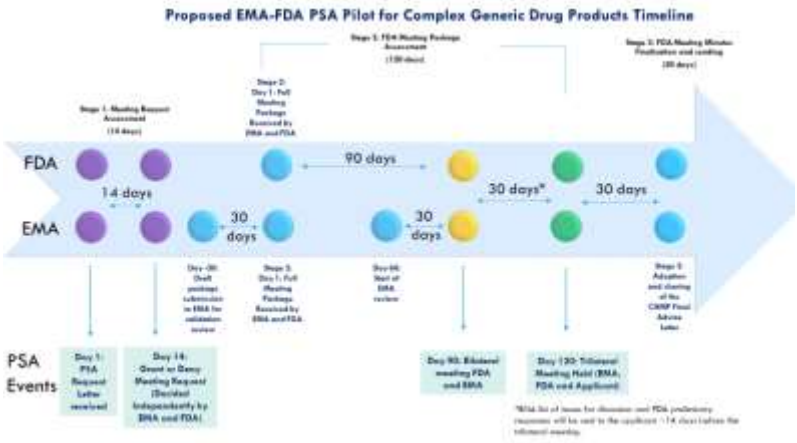
https://www.fda.gov/drugs/generic-drugs/global-generic-drug-affairs

- Current review challenges
- Regulations and guidances under development
- Data integrity and information sharing
- Data where regulatory requirements vary
- Generic drug pipeline challenges
- Accessibility challenges due to emerging global regulatory changes

PARALLEL SCIENTIFIC ADVICE (PSA)

To provide a mechanism for EMA and FDA assessors to concurrently exchange with applicants their views on scientific issues during the development of **complex generic drug/hybrid products**

- increase dialogue between the two agencies and applicants from the beginning of the lifecycle of a complex generic drug product
- provide a deeper understanding of the basis of regulatory decisions
- optimize product development
- avoid unnecessary replication of studies or unnecessary diverse testing methodologies



WWW.FDA.GOV

ASSESSING THE PSA PILOT

Reviewing pilot documents

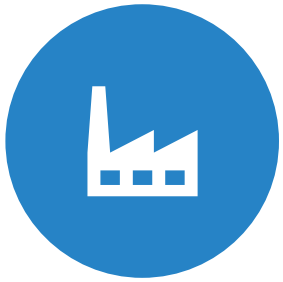
Interviewing FDA, EMA, applicants, AAM

Surveying EMA staff

The goal is to identify good practices, challenges, and areas for improvement to better improve the experience and outcomes for applicants.

FDA has already begun incorporating early feedback into the pilot.

REGULATORY STRENGTHENING AND CAPACITY BUILDING



BUILDING REGULATORY CAPACITY

STRENGTHENING REGULATORY ENFORCEMENT

STRENGTHENING REGIONAL AND INTERNATIONAL COOPERATION

We Are OGD

Ask me why...

"We **monitor** the **safety** of **generic** drugs for as long as they are in the market."

"When I reach for the medicine cabinet, I know I am safe, am a patient, too!"

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FDA

FDA
We Are OGD
Ask me why...
"We collaborate beyond our borders to safeguard our patients."
"As a single mom in school, I had to find the means to afford my son's pneumonia medication and compromising my son's wellbeing is never an option."
www.FDA.gov

We Are OGD

Ask me why “We research ways to bring generics to the American Public”
”After a life altering accident leaving me with multiple bone fractures, seeing my bill for a blood thinner made me appreciate the work I do everyday”

We Are OGD

Ask me why...

"I make sure that the **generic** drug and the **brand** drug work **the same**."

"The first time I was able to buy my son's inhaler as a generic and realized that my out of pocket dropped, I cried and was able to breathe a sigh of relief."

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