

Experience from the Generic Drug Cluster

***SBIA 2023—Advancing Generic Drug Development:
Translating Science to Approval***

***Day 2, Session VIII: Global Collaboration to Support Efficient
Generic Product Development & Regulatory Assessment***

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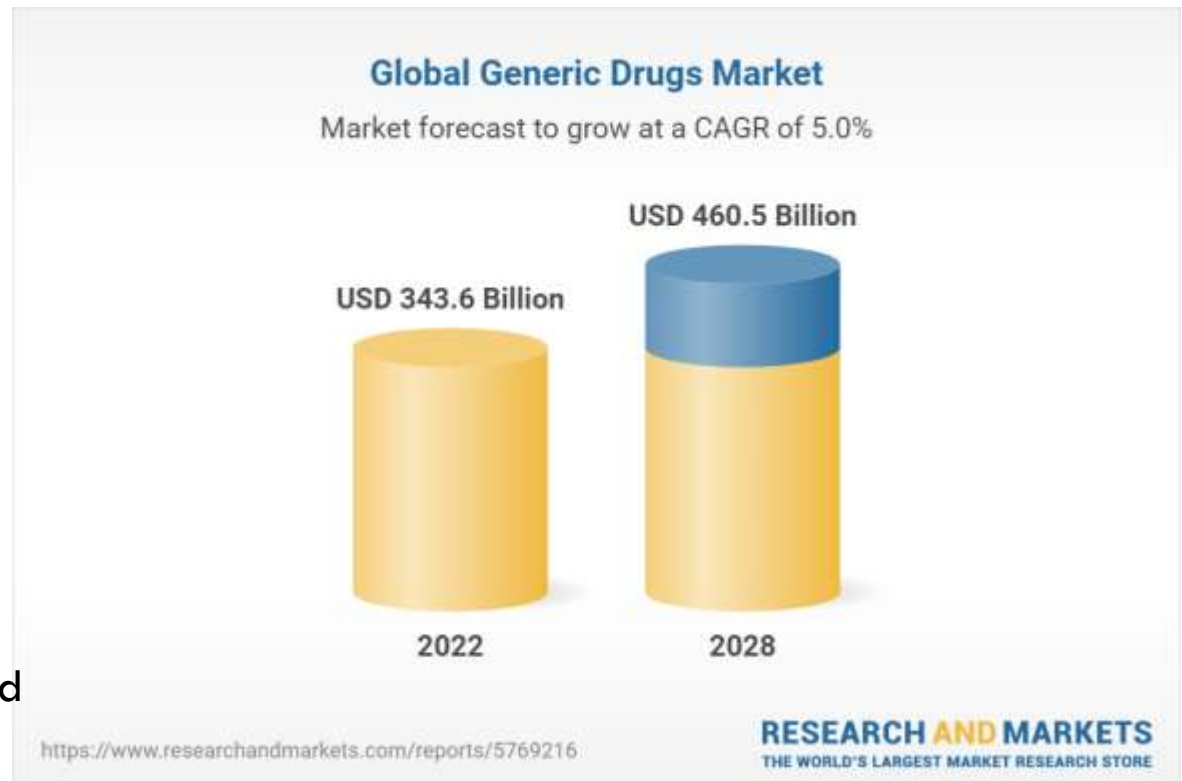
September 14, 2023

GLOBAL GENERIC DRUGS MARKET

Aging population and growing prevalence of chronic diseases

Governments of developed countries have been working to decrease the spending on healthcare by endorsing development of generics.

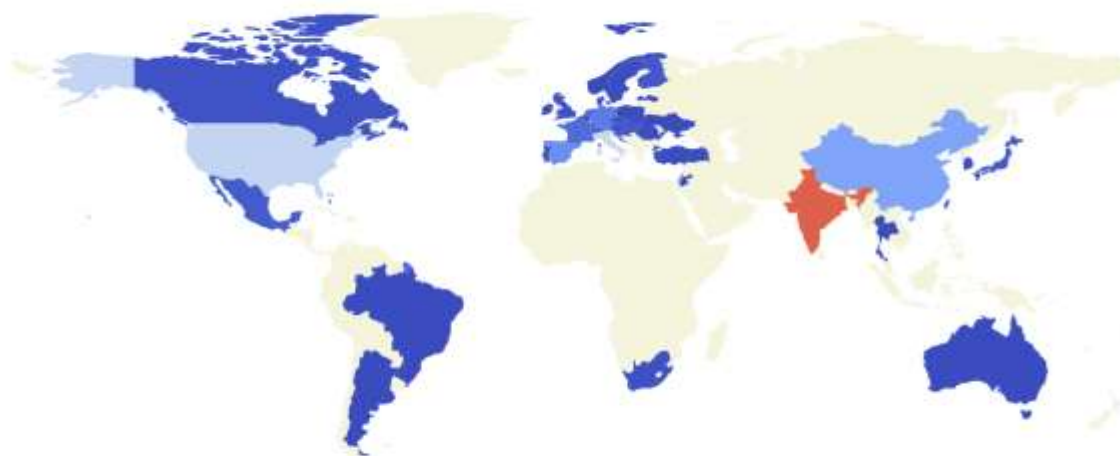
In developing countries, generic drugs may solve affordability and accessibility challenges faced by the healthcare industry.



The global generic drugs market size reached US\$ 343.6 Billion in 2022. The market to reach US\$ 460.5 Billion by 2028, exhibiting a CAGR of 5% during 2022-2028.

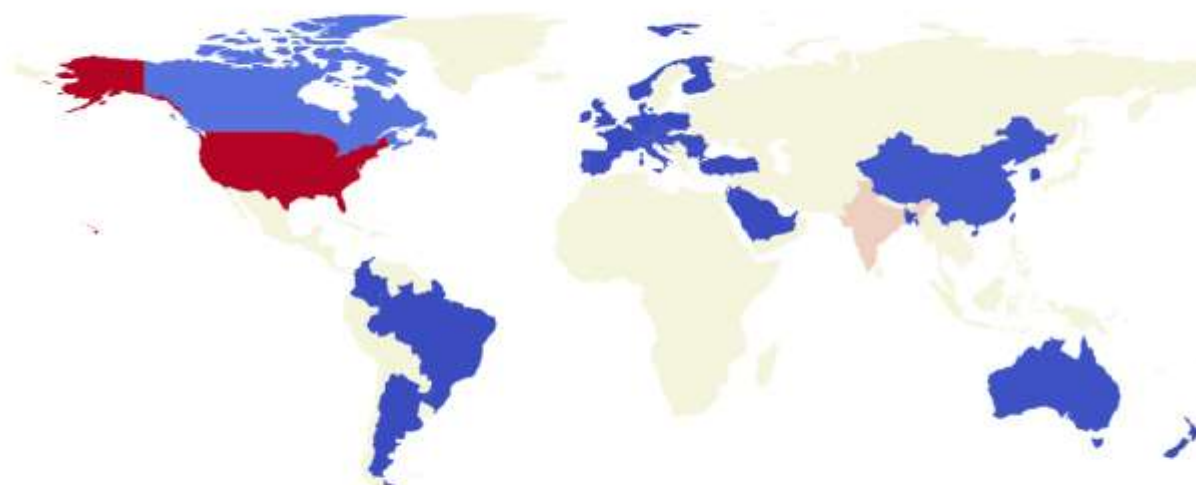
ANDA *MANUFACTURING* LOCATION WEIGHTED BY APPLICATIONS

API Manufacturing for Sold ANDAs
2017



ANDA *MANUFACTURING* LOCATION WEIGHTED BY APPLICATIONS

FDF Manufacturing for Sold ANDAs
2017



Lower Higher

GENERIC DRUG GLOBAL AFFAIRS PROGRAM

Strengthen the
FDA's global
collaboration

Communicate
effectively with
stakeholders

Identify
opportunities for
early regulatory
alignments

Engage
proactively with
regulatory
counterparts

OGD GLOBAL AFFAIRS INTERNATIONAL EFFORTS



Generic Drug Cluster fostering critical global partnerships



Building partnerships to address global challenges and opportunities



Efficiency in the harmonization process



Establishing targeted outreach to support FDA regulatory needs



Regulatory strengthening and capacity building of regulatory systems

REGULATORY HARMONIZATION

Reducing duplication and inefficiency

Improving quality and safety

Facilitating access to medicines

Enhanced transparency and traceability

Improving clinical study standards

PROSPECTIVE HARMONIZATION EFFORTS

CONSENSUS BUILDING

TECHNICAL DOCUMENT /
DRAFT GUIDELINES SHARING

REGULATORY CONSULTATION
AND DISCUSSION

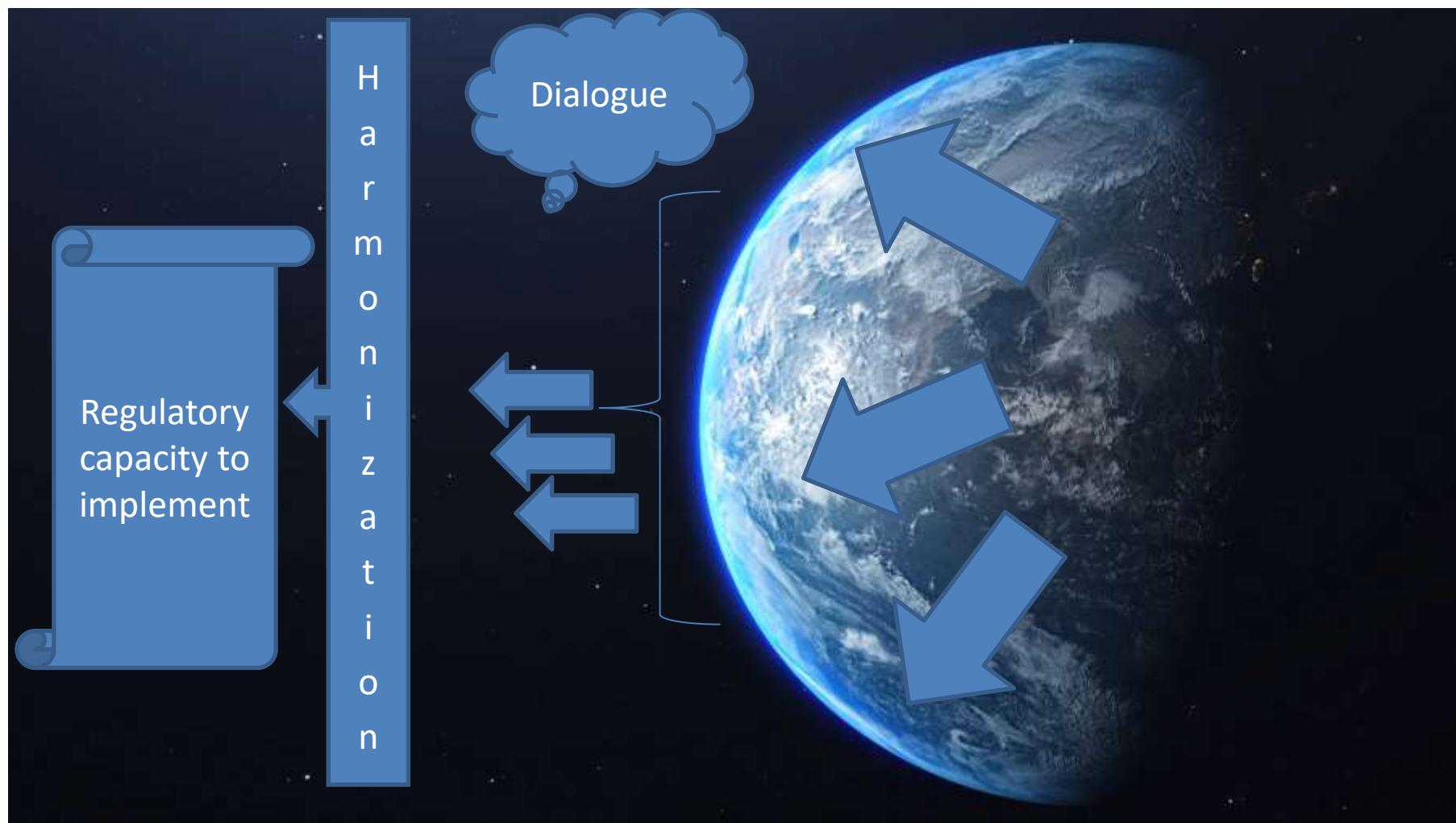
ADOPTION OF ICH
HARMONIZED GUIDELINE

IMPLEMENTATION



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

GENERIC DRUGS GLOBALLY



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

GLOBAL RESPONSE

| | |
|---------------------|---|
| Monitor and analyze | Monitor and analyze the emerging trends and developments in the global arena that may affect the regulatory agency and its policies. |
| Review | Review the existing policies or new policies to address the gaps, challenges, opportunities, and risks posed by the global changes and policies. |
| Assess | Assess the impacts and implications of the global changes and policies on the regulatory agency and its policies. This may involve scenario analysis, risk assessment. |
| Evaluate and report | Evaluate and report on the performance and outcomes of the policies in relation to the goals and objectives of the regulatory agency and the global changes and policies. |

GLOBALIZED GENERIC DRUG SUPPLY

Shortages

**Quality, safety,
and efficacy
issues**

**Compliance
challenges and
enforcement**

**Innovation and
development
challenges**

**Access to
generics
globally**

GENERIC DRUG CLUSTER



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

Approvability
/Current review
challenges

Regulations and
guidances under
development

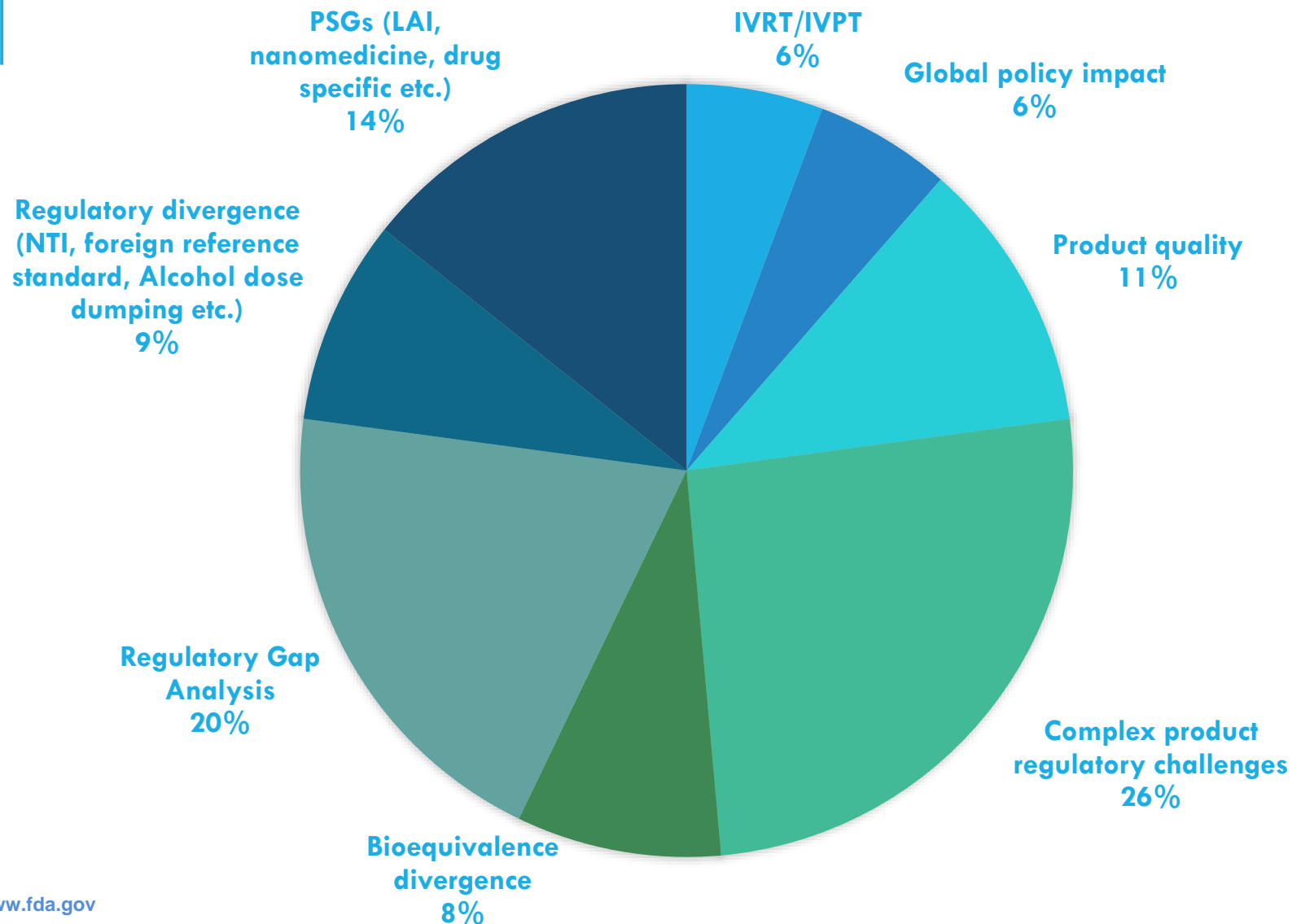
Data integrity and
information sharing

Data where
regulatory
requirements vary

Generic drug pipeline
challenges

Accessibility
challenges due to
emerging global
regulatory challenges

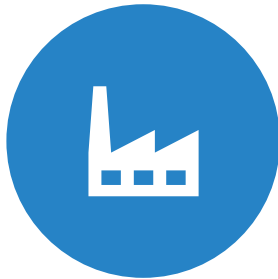
CLUSTER ONGOING INFORMATION SHARING



CLUSTER TOPIC EXAMPLES TO DATE

- Evaluating the API sameness, particularly the peptide functionality/activities, using in vitro and in vivo assays.
- Complex products with no generic competition
- Understand other generic cluster member agencies' approval standards, rationales behind, and review experiences, specifically pAUC recommendation for this product.
- Presentation on member agency use of foreign comparator
- Comparison of NTI classification and NTI BE approach among different agencies.
- Discussed the challenges with assessing the data from Alcohol Dose Dumping studies.
- Safety data of BE studies conducted in healthy subjects vs patient population (Complex product where BE subject variation exists among agencies)
- Investigation on the PK profiles of parenteral nanotechnology products.

REGULATORY STRENGTHENING AND CAPACITY BUILDING



BUILDING
REGULATORY
CAPACITY



STRENGTHENING
REGULATORY
ENFORCEMENT



STRENGTHENING
REGIONAL AND
INTERNATIONAL
COOPERATION

QUESTION 1

The generic drug cluster :

1. Consists of seven regulatory agencies
2. Is a confidential forum for information and knowledge sharing
3. Allows for a dialogue that builds a more robust coherent regulatory infrastructure for generic drugs globally
4. All the above

QUESTION 2

Cluster members focus the discussions on:

1. Guidances under development
2. Agency actions to address global supply chain and development challenges
3. Current and past ANDA review challenges
4. All the above

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 well-being is never an option."

www.fda.gov

