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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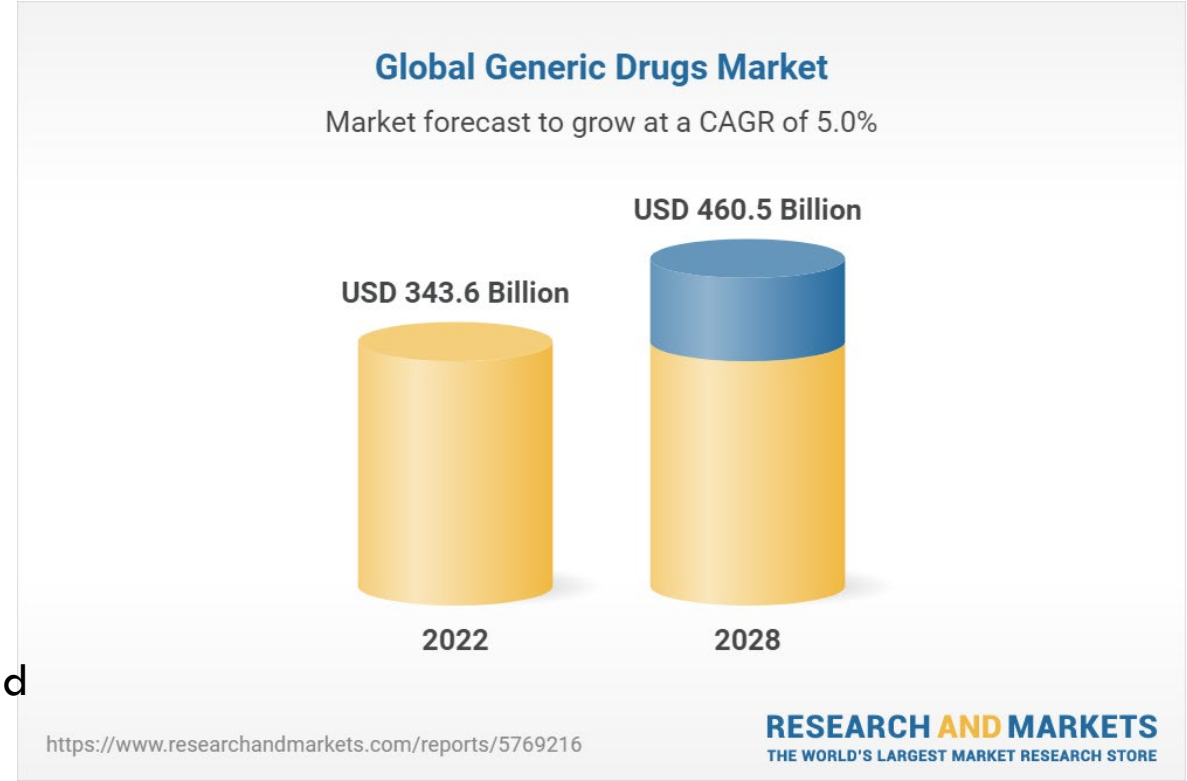
GLOBAL GENERIC DRUGS MARKET

Aging population and growing prevalence of chronic diseases

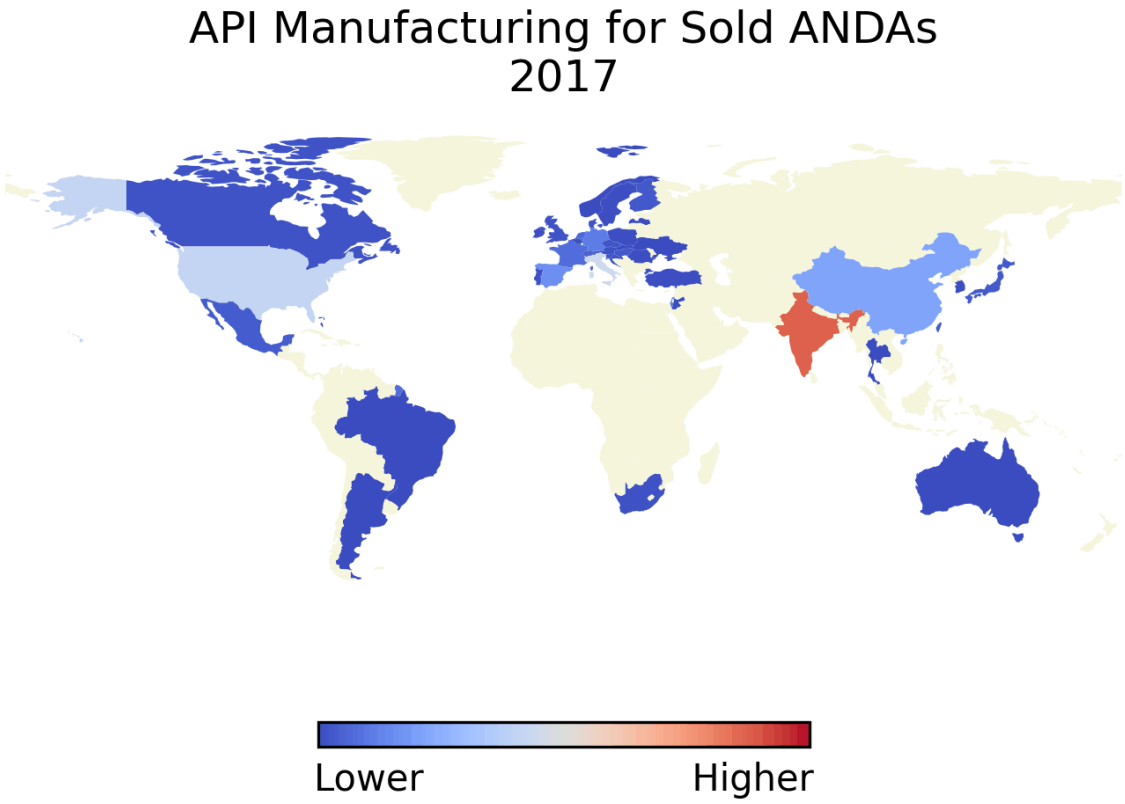
Governments of developed countries have been working to decrease the spending on healthcare by endorsing development of generics.

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



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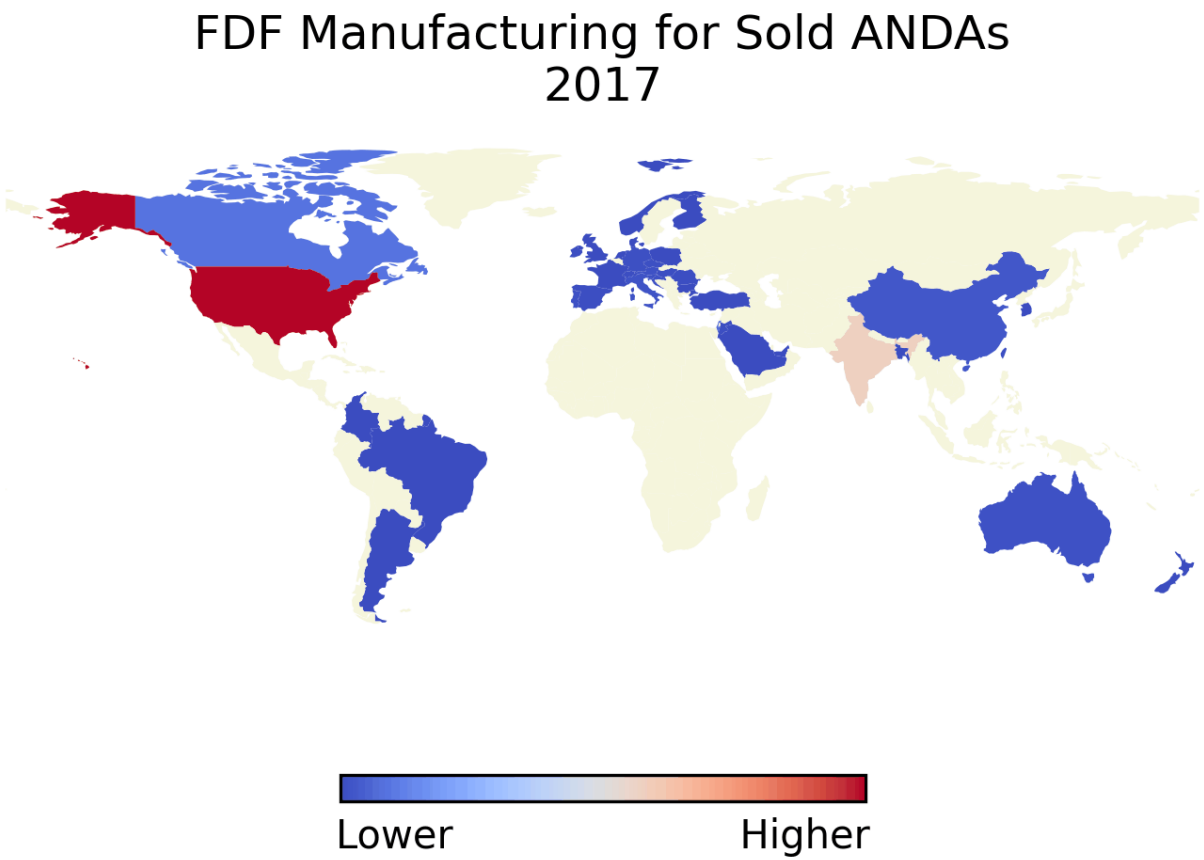


GENERIC DRUG GLOBAL AFFAIRS PROGRAM

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

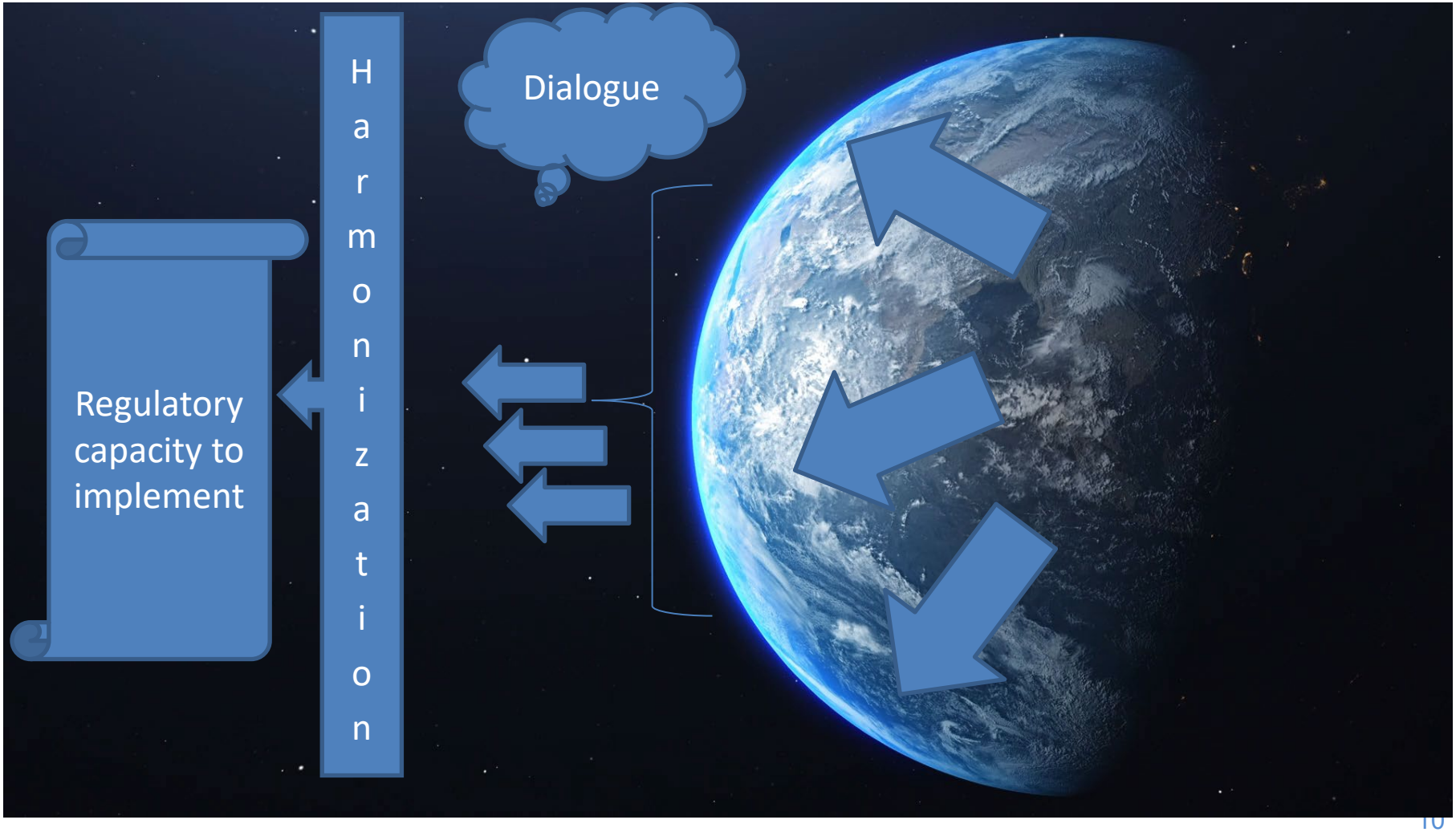
REGULATORY CONSULTATION AND DISCUSSION

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

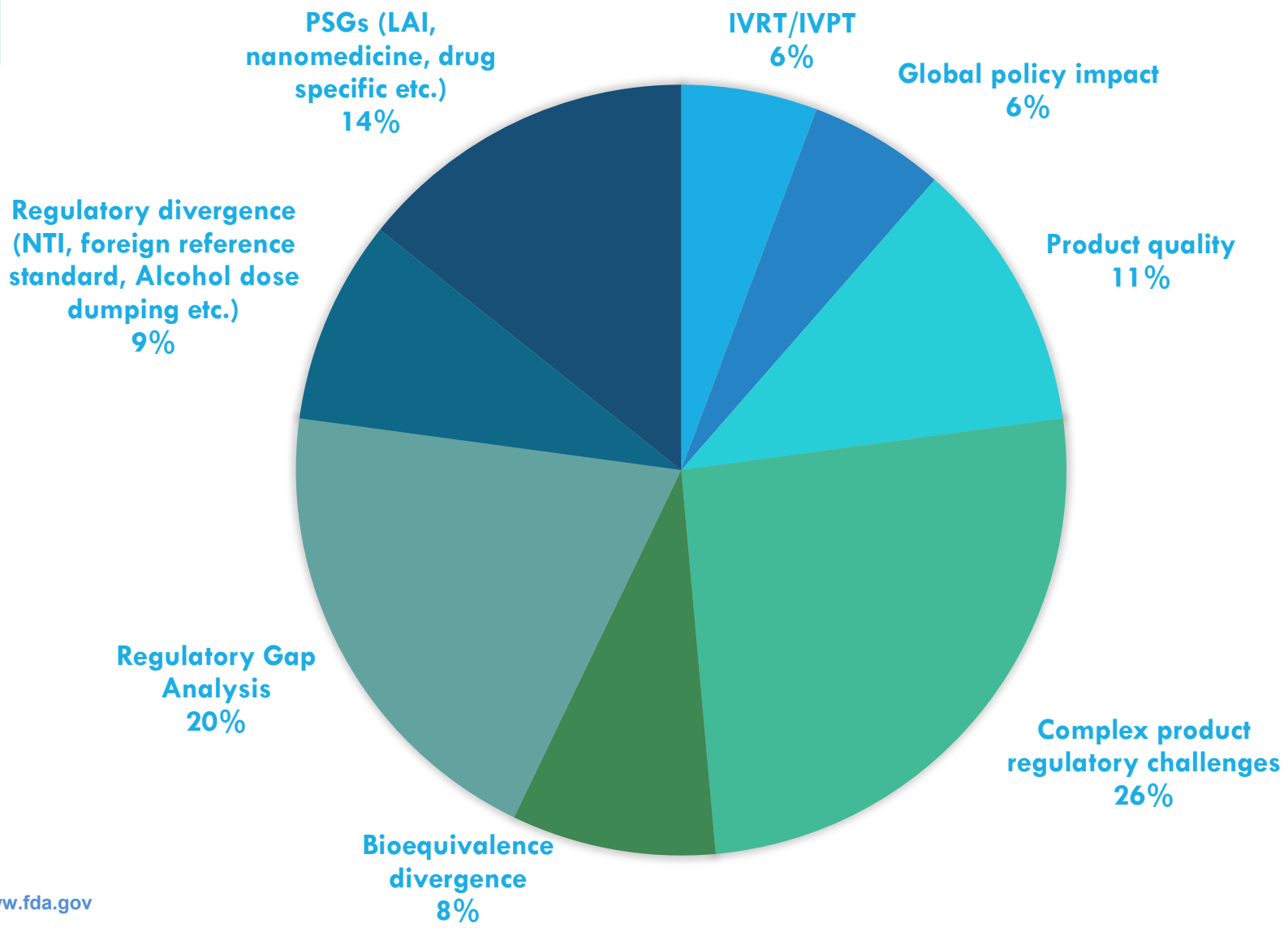
Data integrity and information sharing

Data where regulatory requirements vary

Generic drug pipeline challenges

Accessibility challenges due to emerging global regulatory challenges

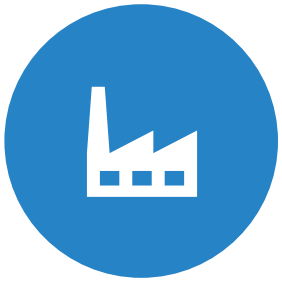
CLUSTER ONGOING INFORMATION SHARING



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