U.S. FOOD & DRUG ADMINISTRATION

Unlocking Global Access to Generic Drugs

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Generic Drugs and Global Healthcare

- Generic drugs have saved billions over the last 30 years, contributing to access and affordability in healthcare
- The cost of medications is a rapidly growing healthcare expense
  - higher prices for innovative medicines
  - increased prescription drug use due to rising rates of chronic diseases
- Despite increases in brand-name drug prices, generic medications have experienced price declines
- Generic Drug Challenges: falling profits for manufacturers, supply chain issues, etc.
- Encouraging the development of generic substitutions to brand medications, is crucial for sustained savings and access

U.S. Health Care Savings

https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf

Generic Drug Value

Competition and Availability

Increased Production

Wider Availability

Cost Reduction and Affordability

Lower Development Costs

Lower Cost Alternatives

Stability in Supply Chain

Diverse Manufacturers

Mitigation of Shortages

Increase Access

Effective Alternatives

Expanded Treatment Options

Diverse Formulations

Risk Mitigation

Risk Diversification

Cost savings are not the sole criterion for evaluating generic medicines

OGD's Efforts

Removal of barriers to generic drug development and market entry.

Facilitating consumer access to needed medicines at lower cost alternatives.

Overall goal Improved access to high-quality, safe, and effective medications.

Generic Drug Industry Challenges

- **Regulatory Complexity**
  - Diverse Approval Processes
  - Evergreening Strategies
- **Market Competition**
  - Thin Profit Margins
  - Price Erosion
- **Supply Chain Vulnerabilities**
  - Dependency on API Suppliers
  - Global Supply Chain Risks
- **Intellectual Property Challenges**
  - Patent Litigation
  - Complex Legal Environment
- **Market Access and Distribution**
  - Pricing Pressure
  - Access Barriers
- **Quality Assurance and Compliance**
  - Manufacturing Compliance
  - Product Recalls
- **Public Perception and Trust**
  - Disinformation
  - Perception of Generic Equivalence
- **Generic Drug Pricing Challenges**
  - Policy
  - Government

Advancing Generic Drugs Globally

Role of Complex Generics in Advancing the Generic Drug Industry

The Need for Global Harmonization

- Consistency in Regulatory Standards
- Accelerated Drug Approval Timelines
- Enhanced Collaboration and Information Sharing
- Increased Access to Medications
- Efficient Use of Resources
- Global Public Health Preparedness
- Encouraging Innovation and Research
- Addressing Health Disparities
- Building Trust and Confidence

Regulatory Agency Strategies

Harmonization of Standards	• Regulatory agencies aim to harmonize standards globally, reducing duplication of efforts and promoting consistent criteria for the approval of generic of drugs.
Streamlined Approval Processes	• Efforts focus on streamlining approval processes, implementing fast-track procedures, and simplifying registration requirements to expedite access.
Mutual Recognition and Collaboration	• Initiatives such as mutual recognition of inspections and collaborative frameworks facilitate cooperation between regulatory agencies, allowing for shared expertise and efficient approvals.
Quality Assurance	• A strong emphasis is placed on ensuring compliance with Good Manufacturing Practices (GMP) and international quality standards to guarantee the quality and safety of generic drugs.
Communication and Collaboration with Industry	• Regulatory agencies actively engage with the pharmaceutical industry, fostering communication, and collaboration to address challenges and ensure a transparent regulatory environment.

Generic Drug Cluster: 2021– Present

- The first forum dedicated to Generic Drug development
- Established by the FDA in 2021 as quarterly videoconferences

Generic Drug Cluster

Establishment of Generic Drug Cluster

- Multi-country forum to understand regulatory requirements.
- Increase scientific alignment for generic drug development.
- Collaborative meetings on regulatory topics.
- Importance of collaboration in a globalized pharmaceutical market.

Importance of Collaboration

- Actions in one country affect others.
- Harmonization through transparent understanding.
- Streamlining interactions for timely access.
- Enables early communication and collaborations.
- Prospective communication for convergence and harmonization.

Confidentiality Commitments

- The discussions at the Generic Cluster are supported by 21 CFR 20.89 confidentiality commitments.
- 21 CFR 20.89 confidentiality commitments cover the following:
  - Trade secret information (TSI) sharing requires prior written sponsor consent
    - 'trade secrets' refers to CMC, quality and information regarding composition of drug products including excipients
  - Confidential commercial information (CCI) can be shared for drugs (human and animal), biologics, and foods but not devices
  - Pre-decisional information can be shared for drugs (human and animal), biologics, foods, and tobacco products
  - Personal Privacy Information (PPI) can be shared but typically is not
  - Law enforcement information can be shared as long as no CCI, TSI, PPI or pre-decisional information is shared

Source: Office of Global Policy and Strategy Information Sharing e-learning modules
Module 6 can be viewed at https://www.youtube.com/watch?v=gpCiNYea0QI

Collaborative Forum

How are Topics Proposed

Internal FDA

GAMC internal to OGD

Submission form internal database

Quarterly Data Call to all cluster members

Agency specific topic selection

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

Recurring Regulatory Updates

Regulatory Updates: Product-specific guidances to be published or under review, Q&A, etc.

Gap Analysis: Discussions are held typically in bilateral/trilateral meetings

Identification of Harmonization/Convergence Opportunities

Respective Agency Sovereignty

Number of Cluster Meetings

Topic Leads

Number of Generic Drug Cluster videoconferences
June 2021- January 2024

CLUSTER TOPICS 2021-2023

Recent Discussions

- Complex Products approval variations acro jurisdictions
- Model-Integrated Evidence (MIE)
- Model-based bioequivalence (BE) for developing generic long- acting injectable products
- Bioequivalence of topical anesthetic formulations
- In-Vitro Release Test (IVRT) for Topical Products
- Foreign reference standards and case studies
- Data Integrity screening tools used to assess pharmacokinetic profile; Tools used by Cluster Agencies
- Transition to low global warming propellant
- Recombinant peptide products

Highlight Efforts

- **Oncology Treatment Assessment:**
  - Cluster meetings facilitated data gathering and assessment by participating agencies.
  - Combined data assessment may lead to a faster approval pathway for oncology drugs, addressing critical needs in cancer treatment.
- **Mental Health Treatment Assessment:**
  - Agreement reached for data gathering and assessment to evaluate bioequivalence of mental health drugs.
  - Combined data assessment may expedite approval pathways for drugs treating mental health disorders.
- **Human Testing Data Sharing:**
  - Agreement to share data on human testing, particularly in cases with discrepancies between patient and healthy volunteer populations.
  - Combined data assessment could converge testing population recommendations, potentially widening the pool of test volunteers and expediting drug approval timelines.

What next?

EXPANDED SCIENTIFIC EXCHANGE

FOCUS ON COMPLEX GENERIC PRODUCTS

ENHANCED DATA SHARING MECHANISMS

RAPID RESPONSE TO PUBLIC HEALTH CRISES

PATIENT-CENTRIC APPROACHES

COLLABORATION ON GLOBAL HEALTH PRIORITIES

ALIGNMENT WITH INTERNATIONAL INITIATIVES

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."

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