Office of Generic Drugs
Generic Drug Global Program

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

Generic Drugs Forum 2021: Lifecycle of a Generic Drug on Apr. 28-29, 2021

Learning Objectives

Overview of OGD's global affairs program

Generic Drug Global Engagement and Harmonization efforts

Provide an update on new developments in ICH since the publication of the ICH Reflection Paper

THE VALUE PROPOSITION OF GENERIC DRUGS

Generic drugs increase access

Generic drugs are more affordable

Generic drugs are equivalent to the brand-name

Generic drugs are held to the same rigorous FDA standards as brand-name drugs

GENERIC DRUGS AND PATIENT EXPECTATIONS

"Thank you so very, very much for this — you have no idea how this generic brand will change the lives of untold numbers of people who were struggling to pay for their asthma medicine…

I paid $398.96 for my inhaler back in January, and today, when the cashier at the pharmacy told me that my total was only $188.65, I almost broke down in tears! …

Again, thank you from the bottom of my heart!"

— anonymous patient

20%
Generic share of overall drug spending in the U.S.

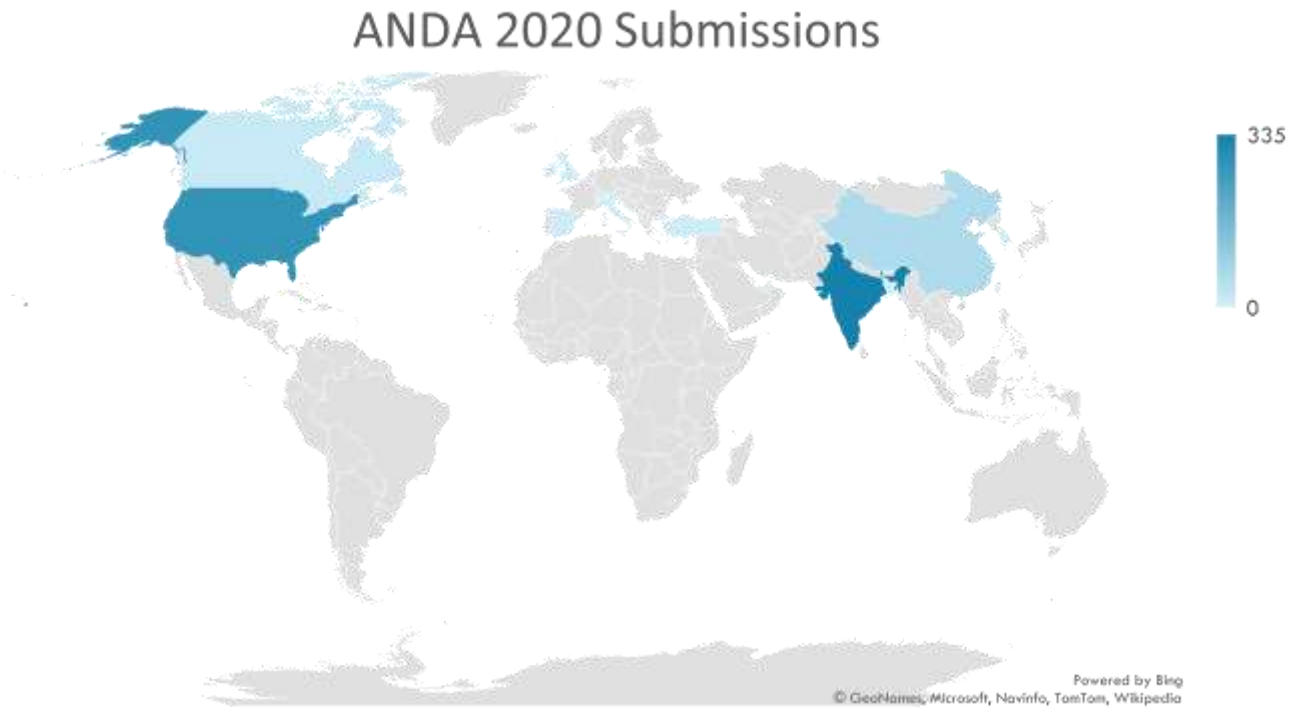
92%
Generic prescriptions filled at $20 or less

$6.97
Generic drug (average co-pay)

$56.32
Brand name drug (average co-pay)

2020 AAM / Generic Drug & Biosimilars Access & Savings Report

ANDA 2020 SUBMISSIONS BY COUNTRY



INTERNATIONAL HARMONIZATION AND OGD

Global Generic Drug Affairs

fice of Generic Drugs (OGD) ensures, through a
and regulatory process, that Americans have
safe, effective, and high-quality generic drugs.
e ways OGD supports generic drug regulatory
is through international engagements. The role of
l Generic Drug Affairs Team is to lead,
ts, and manage OGD's international activities in
tion with FDA Centers and Offices to advance the
ission of OGD and FDA.

WWW.FDA.GOV

ICH AND OGD

- Global harmonization for generic drugs dates back to 2001 WHO report
- FDA strategically leveraged ICH reform initiated at the end of 2015 to propose Generic Drug initiatives
- Established a unique global affair program at OGD at the end of 2015
- Advocating for the expansion of the ICH portfolio to include generic drug standards
- Proposed a generic drug topic to ICH for guidance development to understand the opportunities and challenges of harmonization

KEY PROPOSALS IN THE ICH REFLECTION PAPER

Develop a series of ICH guidelines on standards for demonstrating equivalence [e.g., bioequivalence (BE)] for

(1) non-complex dosage forms

(2) more complex dosage forms and products

- Additional Strength Waiver for IR
- Statistical Analysis for BE
- BE Analysis for HVD
- BE Analysis for NTI

→ M13 Guideline (Series), Annex, or Addendum

- BE for MR oral dosage forms

→ Potential New Guideline

- BE for Complex Products
  - Inhalation
  - Topical Dermatological
  - Long-acting Injectable
  - Other (e.g., Ophthalmic, Otic, Vaginal)

→ New Guideline

- Model-based BE

→ New Guideline

GLOBAL DEVELOPMENT OF IMMEDIATE-RELEASE ORAL SOLID GENERICS COULD BE AIDED BY BIOEQUIVALENCE GUIDANCE BEING DEVELOPED BY THE ICH

This is the first topic specifically focused on the generic medicines industry.

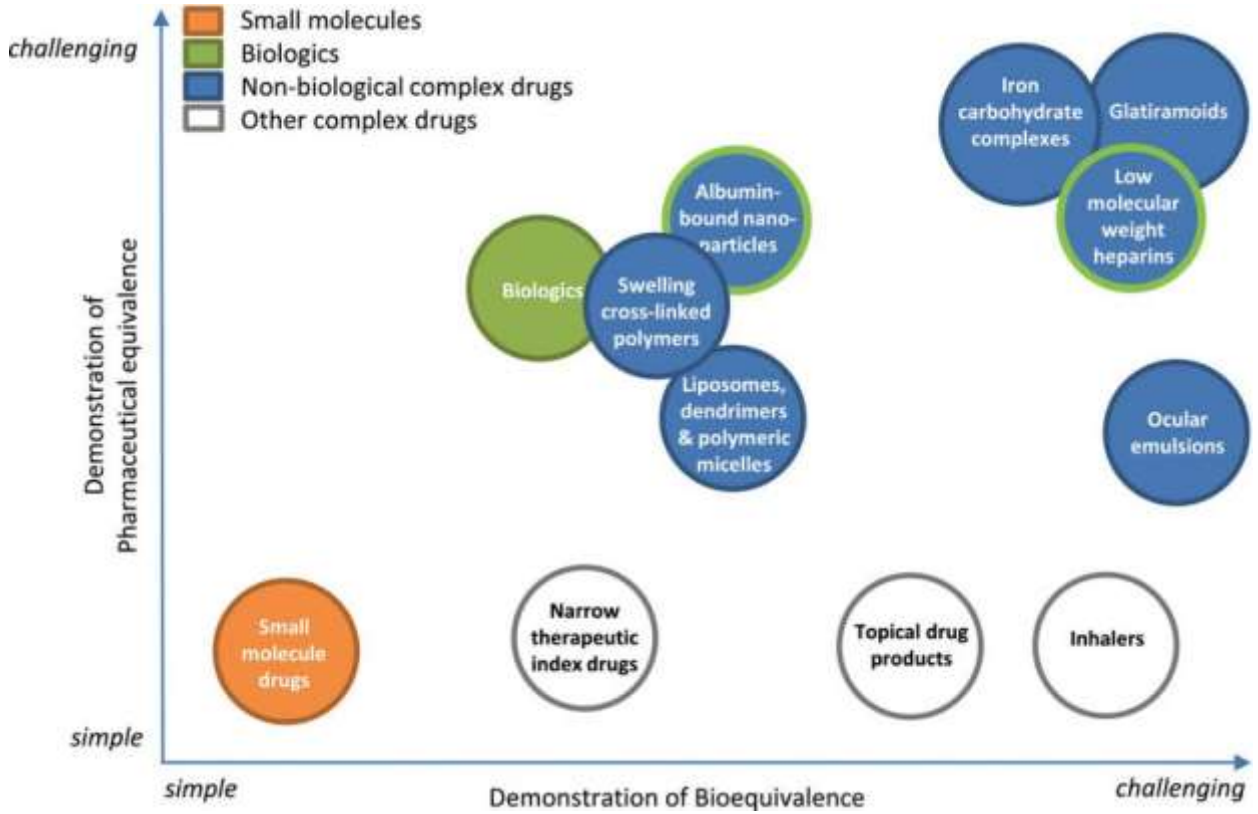
The harmonized study designs in the M13 guidance are recommended for establishing bioequivalence for immediate release solid oral dosage forms.

Scientific harmonization of BE study designs would "allow the streamlining of some important aspects of the conduct of these trials and optimize product development."

"Global Industry Hails Bioequivalence Progress"

https://admin.ich.org/sites/default/files/2019-04/ICH_ReflectionPaper_GenericDrugs_Final_2019_0130.pdf

EQUIVALENCE OF COMPLEX DRUG PRODUCTS: ADVANCES IN AND CHALLENGES FOR CURRENT REGULATORY FRAMEWORKS



The reference to complex drug products in this slide is not necessarily synonymous with the definition of a complex product under GDUFA II

Annals of the New York Academy of Sciences, Volume: 1407, Issue: 1, Pages: 39-49, First published: 26 April 2017, DOI: (10.1111/nyas.13347)

FDA EFFORTS TO SUPPORT COMPLEX GENERIC DRUG DEVELOPMENT

- FDA is dedicated to promote complex generic drug development
  - Fund research studies
  - Translate these research results into product-specific guidance
  - Provide pre-ANDA meeting opportunities
  - Improve quality of ANDA submissions
  - Reduce the number of review cycles required for ANDA approval
  - Complex generics and value added medicines share common challenges on harmonization of regulation, lack of incentives and clarity of guidelines

REGULATORY ALIGNMENT AND CHALLENGES

- Socioeconomic, cultural and political differences –Infrastructure and resources
- Risk tolerance, regulatory policies and decision-making processes differences
- Nomenclature, terminology and labeling
- Critical attributes for assessment of therapeutic equivalence
- Pharmacovigilance and safety reports

SUMMARY

Generic drugs comprise a significant portion of the pharmaceutical market, and common standards for global development for generics can improve access to generic medicines

ICH is uniquely positioned to develop harmonized recommendations as the global venue for harmonization of standards for pharmaceutical products

ICH reflection paper on "Further Opportunities for Harmonization of Standards for Generic Drugs" lays out the strategy for global harmonization for generic drugs

ICH M13 will be developed to harmonize BE standards for Immediate-Release oral dosage form drugs

Discussion of harmonization will lead to global standards for generic product equivalence

Poll Question #1

Before today I….

A. Knew OGD had a Generic Drug Global Program

B. Knew nothing about OGD's Generic Drug Global Program

Challenge Question #1

Which of the following statements is NOT true?

A. ICH is focused only on new drugs

B. ICH impacts both new and generic drugs

C. ICH aimed to provide uniformed standards for pharmaceuticals for human use.

D. ICH guidelines are developed by regulatory and Pharma authorities

Challenge Question #2

ICH M13 …..

A. Is focused on the bioequivalence for immediate-release solid oral dosage forms

B. Will result in product developers NOT having to generate multiple sets of data and information to support marketing authorization in more than one jurisdiction

C. Is the first guideline to be fully dedicated to Generic Drug Development

D. All statements are correct.

Closing Thoughts

- The communal appeal for faster generic drug approvals
- Unprecedented globalization of pharmaceutical industry
- Globalization of generic drug development encourages a more harmonized generic drug development process
- Convergence of the technical requirements among different regulatory agencies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