Opportunities Provided by the ICH Reflection Paper for Generics

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FDA's Reflection Paper on Generic Drug Harmonization

- After ICH meeting in June 2018, FDA discussed the draft with input/comments from a small group formed following the June ICH meeting
  - EMA, PMDA, Health Canada, Swissmedic, TFDA, China FDA, IGBA, JPMA, EFPIA
- In October 2018, FDA sent the new draft reflection paper to ICH Assembly for comments
- The reflection paper was discussed at the November 2018 ICH Assembly Meeting and endorsed

Outline of the Reflection Paper

- Develop a series of ICH guidelines on standards for demonstrating equivalence (e.g., bioequivalence) for
  - (1) non-complex dosage forms
  - (2) more complex dosage forms and products
- Establish a generic drug discussion group
  - To assist in assessing the feasibility of harmonization of standards for generic drugs
  - To prioritize work areas

Regulatory and Scientific Frameworks for "Generic" Drugs

- The reflection paper recognizes that different regions have different regulatory frameworks
  - Tablet and Capsule
    - Not a "generic" in the US
    - Possible "generic" in the EU
- The reflection paper focuses on harmonizing scientific standards for bioequivalence that can be used within the existing regulatory frameworks

Value of Scientific Harmonization

- Bioequivalence studies world-wide can be conducted according to common expectations
  - Increases efficiency of generic drug development
  - Increases quality of generic drug development
- It is the essential first step toward global development of generic products
  - Agreement on bioequivalence standards must come before any practical use of common global reference products

What are the Opportunities?

- Movement toward common standards and global development for generics can improve access to generic products
  - Products with small markets may not be economically viable unless markets can be aggregated across regions
  - Investment in development of complex generics can be supported by entrance into multiple markets


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