Sandoz US

Public Comment: Creating a pathway for regulatory approval, utilizing a waiver for BE studies conducted with US RLD, based on BE studies conducted using Non-US RLD and in-vitro characterization similarity

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Disclaimer

- The opinions expressed herein are solely those of the presenter and industry collaborators and do not represent statements or opinions specific to Sandoz Inc., or Novartis Pharmaceuticals

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Public Comment Outline

- Concern to Generic Industry and Patients
- Solution Oriented Proposal
- Request to GDUFA Research Team

Concern to Generic Industry and Patients

- Challenge to generic entry world-wide including US due to patient and financial constraint to develop generic drugs that require PK/BE studies and/or CE/BE studies in patient populations for registration
  - Each region requires in vivo BE study with a regional RLD; heavy financial strain on generic industry to conduct expensive, lengthy studies with basically same RLD.
  - Unnecessary duplication and drug exposure with no real patient benefit
  - Results in higher health care costs due to lack of generic drug availability

- FDA has granted waivers of PK studies in patients and clinical endpoint studies for generic complex products with Q1/Q2 and characterization similarity (e.g., complex injectables, ophthalmic suspensions, semisolids, etc.). A similar biowaiver concept can be extended to certain qualified products that require PK/BE or CE/BE studies in patients, if additional BE data utilizing a Non-US RLD as a comparator is submitted

Solution Oriented Proposal

- Allow the option of waiving BE studies conducted with US RLD based on BE studies conducted using Non-US RLD if it meets the following criteria:
  - In vitro characterization sameness/similarity of Test product is established to the US-RLD and Non-US RLD using same criteria already described in the US product specific guidance (PSG)
  - PK/BE or CE/BE was established as per US PSG except a Non-US RLD (from a major ICH region) was used as a comparator

- Some drug products to consider:
  - Long term injectables that require patient BE studies
  - Locally acting drug products, including inhalation products, that require CE/BE studies
  - Drug Products with high clinical burden, like oncology or anti-psychotic products

Request to GDUFA Research Team

- Allocate resources to GDUFA research team to explore possibility of providing an optional biowaiver pathway in PSG for drug products with high clinical burden (e.g., requiring PK/BE or CE/BE studies in patients) , utilizing data from PK/BE and/or CE/BE studies conducted using test vs. Non-US RLD and in-vitro characterization similarity between Test vs. Non-US RLD using same criteria described for Test vs. US-RLD in the PSG.
- Explore implementing this innovative regulatory Biowaiver pathway under CFR 320.22 without requiring legislative procedures
- FDA to discuss with ICH partners for harmonization and common understanding for mutual utilization of BE data as much as possible for products that require high clinical burden to register

Reference:

https://pink.pharmaintelligence.informa.com/PS125483/Generic-Industry-Wants-US-FDA-To-Consider-Allowing-Foreign-Reference-Products-For-ANDAs