FDA's Biosimilar Education and Outreach Campaign

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Bridging the Education Gap: Accelerating the Understanding of Biosimilars to Optimize Patient Care
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Education and Outreach

- FDA has committed to developing effective communications to improve understanding of biosimilars among patients, health care providers and payors.
  - Engaging with health care professional and patient stakeholders
  - Developing educational materials for health care prescribers and pharmacists
- Education is an undertaking that requires multi-stakeholder engagement
- FDA is committed to fulfilling their important role as one of many stakeholders

FDA's Current Campaign

Campaign launched October 23, 2017

The overall goals are to increase:

- Understanding of biologics, reference products, biosimilars and interchangeable products.
- Awareness of FDA's role in the biosimilar approval process.
- Knowledge of the data and information FDA reviews/requires to determine biosimilarity.

The overall objectives are to:

- Educate audiences on the basic definition and details about biologics, reference products, biosimilars, and interchangeable products.
- Inform audiences about the FDA approval pathway for biosimilars and interchangeable products.
- Provide audiences with easily accessible information about the data and information FDA reviews to determine biosimilarity, and how they can find more information.

Target Audience

Primary Audience

- Physicians / Prescribers
  - Dermatologists
  - Gastroenterologists
  - Hematologists
  - Nephrologists
  - Oncologists
  - Rheumatologists
- Pharmacists

Secondary Audience

- Patients
- Patient Advocacy Groups
- Health Foundations
- Health Professional Organizations that provide patient resources

Campaign Materials

- FDA offers a variety of patient and prescriber outreach materials, including graphics, drop-in content, and social media messages, to help promote understanding of biosimilars and interchangeable products.
  - Website re-design
  - Health Care Professional Toolkit (4 Fact sheets, Infographic)
  - Ads for HCP Journals/Professional Society Publications
  - Stakeholder Tools
  - Webinar for HCPs (December 2017)
  - Video Series (May 2018)

Stakeholder Outreach and Involvement

- Stakeholders play a key role in reaching the target audience

- As part of the campaign, FDA provided materials and talking points to facilitate dissemination of content to their audiences through channels unique to each stakeholder

- FDA has robust stakeholder engagement each month to continue momentum and interest in the campaign
  - Monthly targeting of certain topics and/or audiences

Evaluation

FDA will monitor the dissemination and ongoing success of deliverables created for the campaign:

- During the first year of outreach, evaluation efforts will largely focus on establishing baseline measurements to inform future outreach efforts

- Analytics reports that describe the campaign's communication activities for which measurement is possible (e.g., Web visits, resource downloads or shares, YouTube views, number of stakeholders reached, stakeholder activity)

- FDA will adjust communication approaches based on the information collected

Future Communication and Research Plans

- Test materials with health care providers (HCP) audiences
- Research with HCP to assess needs for communicating about biosimilars to their patients
- Research with patient and professional society stakeholder groups
  - Knowledge and attitude research
  - Communication needs
  - Materials needs

Abbreviated Approval Pathway: Key Messages

- The abbreviated licensure pathway **does not mean that a lower approval standard is applied** to biosimilar or interchangeable products than to originator biological products.
  - The ability to rely on FDA's previous finding regarding the reference product to support approval of the biosimilar product allows for a potentially shorter and less costly drug development program. This is what is meant by an **abbreviated** licensure pathway.
  - The **data package** required for approval of a biosimilar or interchangeable product is quite **extensive**.

Biosimilar and Interchangeable products: Key Points

- There isn't a different analytical standard for biosimilar vs. interchangeable (IC) products – **highly similar**
  - Analytical similarity data in a 351(k) application to support approval of an IC product is **not** more, better or different than the analytical similarity data needed to support a biosimilar product
  - A product that is first approved as a biosimilar is not expected to be manipulated or changed in some manner to "become" an IC product
  - Regardless of whether an Applicant is developing a biosimilar or IC product, extended characterization through additional methods and orthogonal testing can **reduce uncertainty** about potential clinical impact stemming from differences between the biosimilar/IC and the reference product (RP)
- **Different and distinct statutory** approval requirements for biosimilar vs. IC products
  - By definition, the showings, data and information needed to support approval of a biosimilar differ from that needed to support approval of an IC product
  - These additional data elements allow FDA to evaluate and conclude whether the product is **one that may be substituted** for the reference product without consulting the prescriber
  - When FDA carries out a scientific review of a proposed biosimilar, the evaluation does **not** include a determination of whether the biosimilar is interchangeable with the reference product and whether the biosimilar can be substituted for the reference product at the pharmacy – a biosimilar is **not** a "failed" interchangeable product

Using Reference, Biosimilars, & Interchangeable Products

- Patients and their physicians can expect that there will be **no clinically meaningful differences** between taking a reference product and a biosimilar when these products are used as intended.
- Patients and their physicians can expect that the interchangeable product will have the same clinical result as the reference product.
- Biosimilar and IC products can be used for the same conditions of use (indications) as previously approved for the RP
  - Treatment naïve and treatment experienced patients
- Although there are distinct approval requirements for reference products and biosimilars, the approval standards that apply to each type of biological product assure prescribers of the **safety and effectiveness** of each type of product.
- The FDA's high standard for approval of biosimilars means that patients and health care providers **can be confident of the safety and effectiveness of a biosimilar product**, just as they would for the reference product.

U.S. FOOD & DRUG ADMINISTRATION

Thank you for your attention.

For more information, go to
www.fda.gov/biosimilars