Biosimilars Info Sheet

Level 2: Regulatory and Scientific Concepts

Prescribing Biosimilar and Interchangeable Biosimilar Products

All biosimilar products (also called biosimilars) and interchangeable biosimilar products (also called interchangeable biosimilars) meet FDA's rigorous standards for approval for the conditions of use (e.g., indications) described in product labeling. Patients and health care providers can be as confident in the safety and effectiveness of the biosimilar and interchangeable biosimilar as they can be for the reference product (Figure 1).

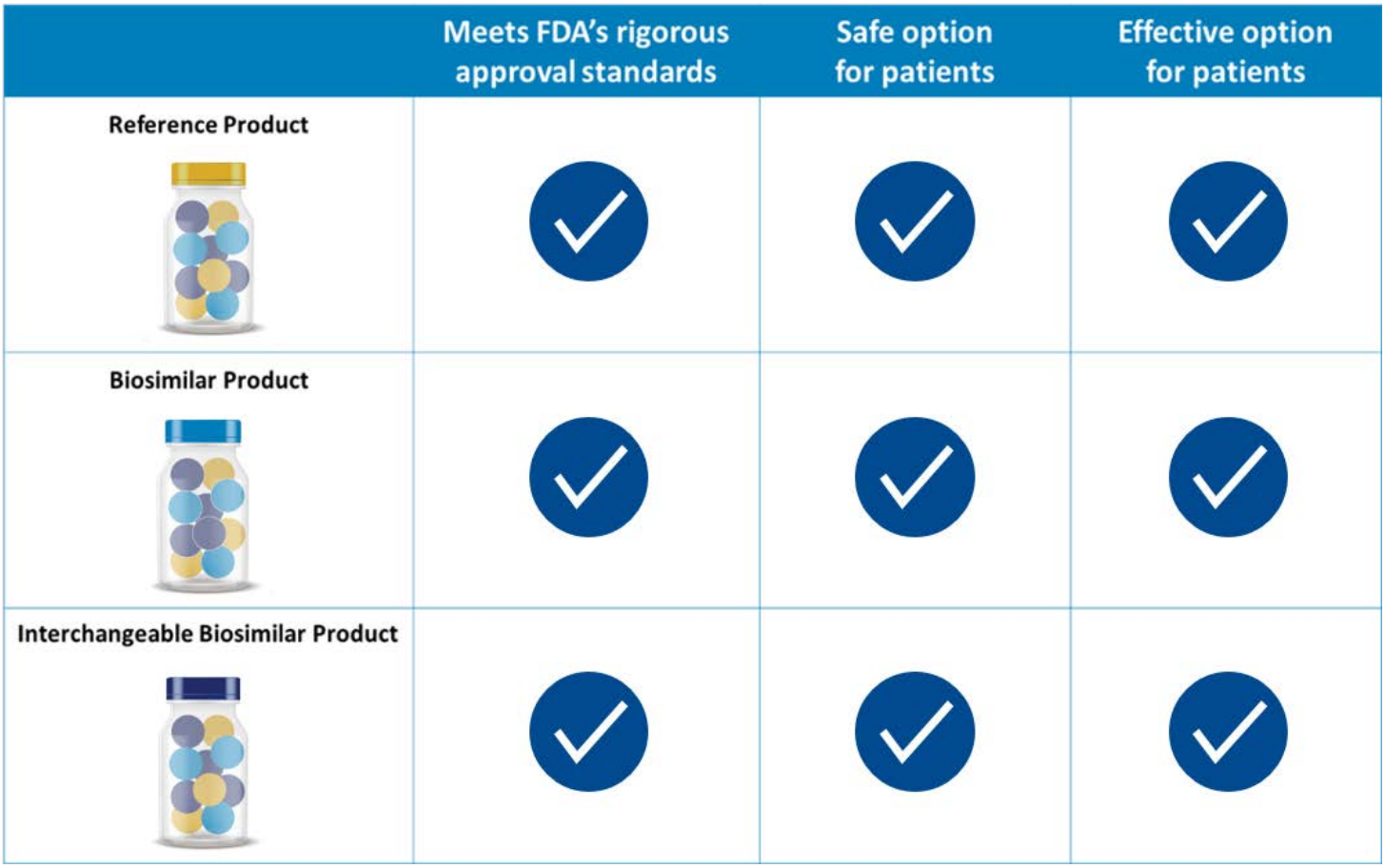

Figure 1: Biosimilar and interchangeable biosimilar products are as safe and effective as their reference products

When prescribing or dispensing biosimilars and interchangeable biosimilars, health care providers should consider the following:

- Biosimilars and interchangeable biosimilars can be used in patients who have previously been treated with the reference product (i.e., treatment-experienced), as well as in patients who have not previously received the reference product (i.e., treatment-naïve).
- Biosimilars and interchangeable biosimilars are expected to have the same kind and amount of immunogenic response as their reference product. For example, if a patient does not respond to the reference product or lost their response because of anti-drug antibodies, then using a biosimilar or interchangeable biosimilar to that reference product would not likely be helpful.

- Health care providers do not need to wait for a biosimilar to be approved as an interchangeable biosimilar to prescribe it. FDA does not approve a product as interchangeable unless a manufacturer specifically seeks an interchangeability determination. Biosimilars are as safe and effective as the reference product they were compared to.
- Health care professionals can generally prescribe biosimilars and interchangeable biosimilars just as they would prescribe other medications. FDA-approved interchangeable biosimilars may be substituted for the reference product without the intervention of the prescribing health care provider, subject to state laws. State laws that address substitution of biological products (also called biologics) at the pharmacy level vary; therefore, it is important for prescribers and pharmacists to understand the pharmacy practices in their state.

Biological Product Naming

In general, for biologics, including biosimilars and interchangeable biosimilars, the FDA designates a nonproprietary name that is a combination of the nonproprietary core name and a distinguishing suffix that is devoid of meaning and composed of four lowercase letters (Figure 2). The naming convention was adopted to facilitate safe use and pharmacovigilance for all biologics. To avoid potential confusion for health care providers and patients, FDA has determined that some reference products approved prior to implementation of the naming convention may not have a suffix; however, all biosimilars and interchangeable biosimilars will have the suffix.

Health care professionals should include the 4-letter suffix when ordering, prescribing, dispensing, and reporting adverse events to MedWatch for these products and in recordkeeping practices.

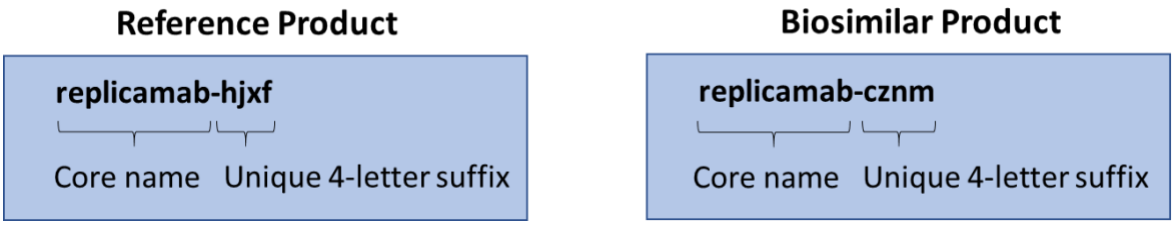

Figure 2: FDA's naming convention for biological products include a shared core name followed by a unique 4-letter suffix

Labeling of Biosimilar Products

Approved prescribing information summarizes the scientific information health care practitioners need for safe and effective use of biosimilars and interchangeable biosimilars. Biosimilars and interchangeable biosimilars have the same route of administration, strength, dosage, expected efficacy, and potential side effects as the reference product.

Biosimilar and interchangeable biosimilar labeling:

- Should incorporate relevant data and information from the reference product labeling, including clinical data that supported FDA's finding of safety and effectiveness for the reference product.
- Contain "Highlights of Prescribing Information" with a "Biosimilarity Statement" or "Interchangeability Statement" describing the product's relationship to its reference product.

Health care professionals are advised to review the labeling (i.e., prescribing information) of the biosimilar to determine the conditions of use (e.g., indications, dosing regimens) and routes of administration for which the biosimilar is approved. A biosimilar can be approved by the FDA for some or all of the same conditions of use, strengths, dosage forms, and routes of administration as the FDA-approved reference product that the biosimilar was compared to.

The Purple Book

The Purple Book (purplebooksearch.fda.gov) is a user-friendly online database with information on FDA-approved biologics. It provides patients, payors, clinicians, and others with an accessible, easy-to-use online search engine with information about FDA-approved biologics, including whether a specific biologic is a reference product, biosimilar, or interchangeable biosimilar (Figure 3). Features of the Purple Book include:

- Simple and advanced search options.
- Auto-suggest search function.
- Additional search filters.
- Data download options.
- Links to product labels (Drugs@FDA).
- Ability to show/hide/sort columns of information.
- Ability to print or export search results.

Figure 3: Information related to reference products, biosimilar products, and interchangeable biosimilar products can be found in FDA's online Purple Book database

Addressing Patient Questions

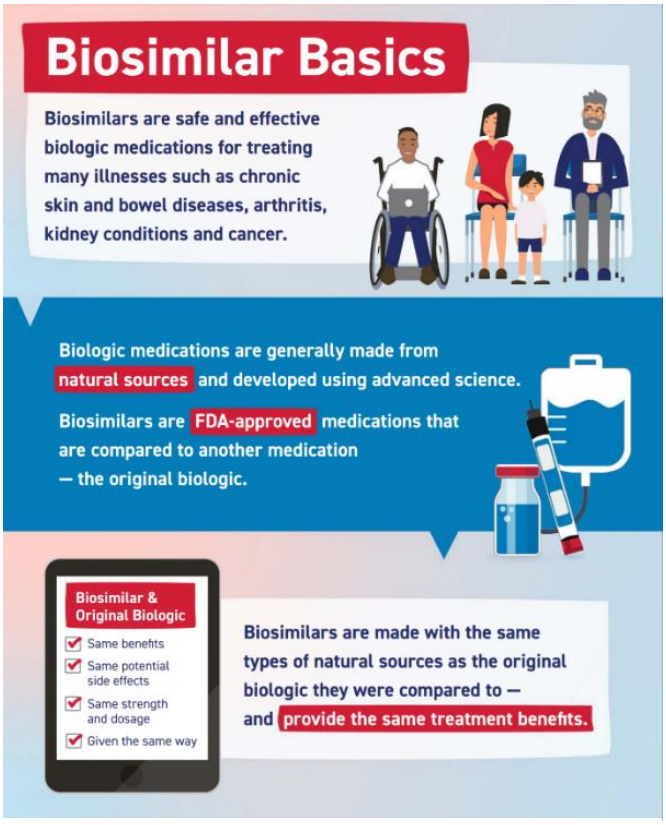

Figure 4: Patient information on biosimilars can be found on FDA's website

Health care providers can encourage shared decision-making by having conversations about biosimilars and interchangeable biosimilars and addressing patient questions. Providers can direct patients to FDA's resources or patient-advocacy/health specialty associations, as appropriate. FDA patient materials include frequently asked questions, infographics, and more (Figure 4).

For more information on patient education, please visit:

https://www.fda.gov/drugs/biosimilars/patient-materials