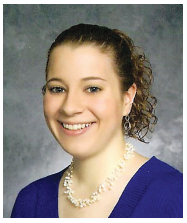
Impact of Biologic and Biosimilar Naming Suffixes



by Ann Johnson, Pharm.D.

THE FDA'S FINAL GUIDANCE on "Nonproprietary Naming of Biological Products Guidance for Industry" requires the use of a four-character suffix on all original biologics approved via 351(a) applications, and biosimilar products approved via 351(k) applications. For originator biologic products without a suffix that are already on the market, a recent 2019 statement from the FDA makes it clear that these products will not need a retrospective name change to add a suffix.

Because biologics and biosimilars can have different indications for use, suffixes act to differentiate similar products sharing the same chemical name. Ideally, these suffixes would allow practitioners to prescribe agents covering a patient's specific indication needs. For tracking and adverse event reporting purposes, having a unique suffix allows for manufacturer-specific reports and provides greater clarity.

For new biologics and biosimilars, manufacturers should propose up to 10 suffixes to the FDA, in the order of preference. Suffixes are proposed at the time of licensure, either during the investigational new drug application (IND) stage or at the time of BLA (biologics license application) submission. See the box at right for suffix requirements..

Each suffix is associated with a different manufacturer's product, and it is highly likely that not all healthcare providers will be familiar with the individual suffixes and the corresponding manufacturers and product indications. Based on this mindset, it is conceivable to expect many healthcare providers to simply select the first agent listed when looking to prescribe. Because of the propensity of electronic health records (EHRs) and pharmacy management systems to list agents in alphabetical order, manufacturers may wish to submit suffix options that appear early in the alphabet. For originator biologics on the market, not having a suffix may give these products an unfair advantage over biosimilars, as the originators will be listed first in systems displaying products alphabetically

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Per the FDA, suffixes must be:

- Unique.
- Devoid of meaning.
- Four lowercase letters, of which at least three are distinct.
- Nonproprietary.
- Attached to the core name with a hyphen.
- Free of legal barriers that would restrict its usage.

Suffixes should not:

- Be false or misleading, such as by making misrepresentations with respect to safety or efficacy (e.g., drugumab-best).
- Include numerals and other symbols, aside from the hyphen attaching the suffix to the core name (e.g., drugumab-1#go).
- Include abbreviations commonly used in clinical practice in a manner that may lead the suffix to be misinterpreted as another element on the prescription or order (e.g., drugum-ab-caps).
- Contain or suggest any drug substance name or core name (e.g, drugumab-mdma.)
- Look similar to or be capable of being mis-taken for the name of a currently marketed product (e.g., should not increase the risk of confusion or medical errors with the product and/or other products in the clinical setting).
- Look similar to or otherwise connote the name of the license holder (note that Sandoz's biosim-ilar filgrastim-sndz was approved prior to the FDA guidance).
- Be too similar to any other FDA-designated nonproprietary name suffix.

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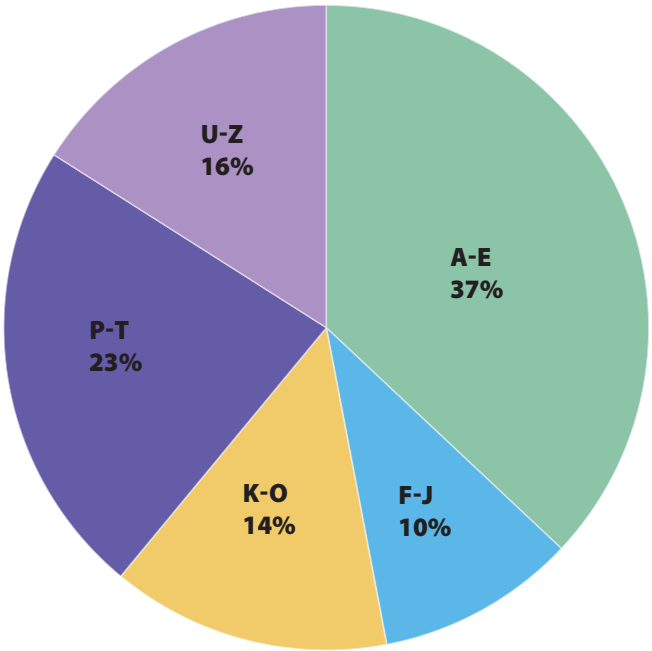
by chemical or generic name (i.e., "nothing" listed before "something"). Currently, no biosimilars have been deemed "interchangeable" by the FDA. Biosimilars and originator biologics also have different GPIs (generic product identifiers), GCNs (generic code numbers), and RxCUIs (RxNorm concept unique identifiers), meaning that most software systems do not currently link the products for prescribing or dispensing purposes. If an originator product without a suffix is initially selected, biosimilars are unlikely to be shown as alternatives.

Between the FDA's *Purple Book* and a review of Wolters Kluwer (Medi-Span's) drug compendia database, I identified 51 products that contained a four-character suffix attached to the chemical name via a hyphen. As expected, a high number of these suffixes begin with "a" or another letter seen early in the alphabet. A breakdown of suffixes for these 51 products is shown in the chart at right.

Based on these findings, it is apparent that manufacturers are evaluating how suffixes will affect their product appearance and the order in which their product is displayed in EHRs, pharmacy management systems, and wholesaler ordering systems. In order to increase the likelihood of having their products listed before a competitor's product, biosimilar manufacturers are even more likely to begin suffixes with an "a." Of the 19 biosimilars listed in the *Purple Book*, seven (37%) begin their suffix with an "a."

As insulins are transitioned to biologics in 2020, expect the number of biosimilars, and consequently the number of suffixes, to increase. Although no products have obtained the elusive "interchangeable" status yet, the increasing number of biologics and biosimilars means that drug compendia and their subscribers will need to develop ways to deal with the lack of product linkages and substitution/interchange options. In the future, we expect the compendia to include information on a biologic's biosimilar or interchangeable status. Whether this will be done in the *Orange Book* TEE (therapeutic equivalence evolutions) code field or another field remains to be seen. Wolters Kluwer has announced plans for a file that helps customers determine potential substitution options for biologics, so it is probable that other compendia will follow suit. As more products launch with suffixes starting with an "a," it will be interesting to see how the FDA's approval of proposed four-character suffixes change. For practicing pharmacists, this information will hopefully be used to better understand the suffix assignment process and recognize how these products will be displayed in wholesaler ordering and pharmacy management systems. **CT**

Biologics/Biosimilar Suffix Names Beginning with...



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