

NAMING BIOLOGICAL MEDICINES

Patients with chronic and complex conditions like rheumatoid arthritis, high cholesterol and Crohn's disease are among the many people who benefit from innovative biological medicines.

Unlike traditional drugs, biological medicines derive from cells or living systems. They are typically infused or injected, either by a health care provider or through a self-injectable device patients use at home.

Biosimilars – follow-on biological medicines – are highly similar to their biologic reference product and offer equally powerful results.

While biologics and biosimilars provide unprecedented treatment options, they also present unexplored policy issues. One important question for regulators has been:

How will these medicines be named? The answer has implications for both access and patient safety.

Q: What names do medicines have?

Medicines in the United States have multiple names. In advertisements, for example, you may see a drug referred to by its proprietary, or brand, name. That name is chosen by the drug's manufacturer.

Medicines also have a non-proprietary name. That name is selected by the United States Adopted Name Council and often reflects the class of drugs to which the medicine belongs.¹ When health care providers write prescriptions and make notes in a patient's medical chart, they typically refer to a medicine by its nonproprietary name.



Q: Why do biological medicines need distinct nonproprietary names?

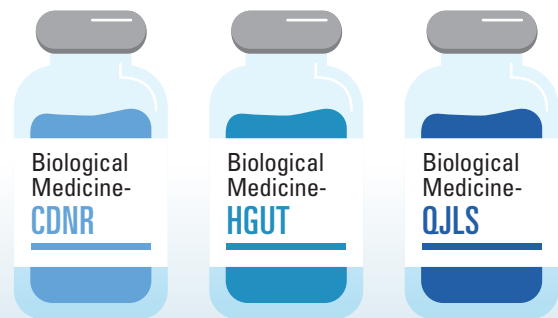
A traditional, chemical drug – like aspirin or ibuprofen – typically shares a nonproprietary name with its generic counterparts. In the early days of biological medicine, some policymakers questioned whether biologics and biosimilars should follow the same naming model. The Food and Drug Administration ultimately determined that each biological medicine, including biosimilars, should have a distinct nonproprietary name – recognizing that no two biological medicines are identical.²

Far from just a question of semantics, the decision was an important one for pharmacovigilance – or “track and trace.” Even medicines that are biosimilar to one another are not identical, and they can sometimes produce different side effects or provide different levels of efficacy for patients. If different biological medicines shared the same name, it would be difficult to pinpoint the exact source when a problem arose. Distinct names, on the other hand, allow patients and health care providers to trace a side effect to the precise medicine, and manufacturer, that caused it.

Q: What did the FDA’s 2017 draft guidance say about naming?

In 2017 the FDA announced that names for similar biological products would carry a four-letter suffix added to the medicine’s nonproprietary name. The drug infliximab, for example, is available as several different products: infliximab-dyyb, infliximab-abda and infliximab-qbtx, among others. This approach distinguishes the medicines from one another for medical records and pharmacovigilance efforts.

FOUR-LETTER SUFFIXES DISTINGUISH BIOLOGICAL MEDICINES FROM ONE ANOTHER



The FDA’s decision was hailed as a win for patient safety. It also promised to encourage health care providers’ confidence in the use of biologics and biosimilars, because it ensured that they could maintain the ability to track and trace these medicines’ impact on their patients.

Q: What changed in the FDA's 2019 updated draft guidance?

While the FDA's 2017 naming guidance marked an important step forward, it presented a complex question. What about biological medicines that were approved before biosimilars became available? Would those be given a suffix? And how would the new names impact track-and-trace efforts for patients who'd begun treatment long before the FDA's naming decision?

After a period of deliberation, the FDA released updated draft guidance in March 2019.³

The agency opted to omit pre-existing biological medicines from the suffix naming convention.

In other words, biological medicines that were licensed before the FDA's naming guidance was implemented will maintain their original non-proprietary names – no suffix included. All newly approved biological medicines, including both innovator biologics and follow-on biosimilars, will carry a four-letter suffix.

Q: Will interchangeable biologics and biosimilars have identical names?

To be deemed interchangeable by the FDA, a biosimilar must be close enough in make-up and effect to the original biologic that it will produce the same effect in any given patient. In return, an interchangeable biosimilar can be substituted at the pharmacy counter in place of the original biologic.

The FDA has not yet finalized guidance about interchangeable biosimilars, and no interchangeable biosimilars have been approved to date. The FDA did, however, decide in its 2019 updated draft guidance that interchangeable biosimilars – like other biological medicines introduced after the FDA's naming guidance – will carry nonproprietary names with a distinct four-letter suffix.

Q: Is this the end of the regulatory discussion on naming?

Not quite. Once the FDA has received and reviewed comments on its draft updated naming guidance, it will then issue a final version of the guidance. A date for that publication has not yet been set.



CONCLUSION

With the benefit of time, a steady increase in new biological medicines, and a growing body of research on these medicines, health care providers continue to become more confident about using biologics and biosimilars to treat their patients. Naming conventions that equip health care providers to differentiate among these medications encourage that trend by allowing for continued pharmacovigilance and ensuring that patients have access to the fullest range of possible treatment options.

REFERENCES

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