

Naming

A biosimilar and the reference medicine have the same active ingredient. Therefore a biosimilar should have the same international nonproprietary name (INN) as the reference medicine.



Instead of changing the INN, there are better ways to distinguish between biologics, for example, the use of brand names.



Introducing new naming systems can cause unnecessary complexity and confusion.



ABC

**Reference
medicine**



DEF

Biosimilar



ABC

**Reference
medicine**



ABC

Biosimilar

Sandoz, a Novartis division, believes that new naming systems may lead to treatment errors, and have serious consequences for patients and healthcare communities.

1. Stergiopoulos S et al, Ther. Innov. Regul. Sci. 2015, 49: 706-716

2. Novartis submission to the FDA Draft Guidance "Nonproprietary Naming of Biological Products", December 2017
FDA-2013-D-1543-0172, page 7, Available from: <http://www.regulations.gov/#/documentDetail;D=FDA-2013-D-1543-0172> [Accessed June 2019]

3. Goel N and Chance K. Biosimilars in rheumatology: understanding the rigor of their development, Rheumatology 2017;56:187-97.

4. GaBI Online. Naming and interchangeability for biosimilars in Japan, 2016. Available at <http://www.gabionline.net/Reports/Naming-and-interchangeability-for-biosimilars-in-Japan>; accessed Oct 24, 2017.

5. Government of Canada, Notice to Stakeholders - Policy Statement on the Naming of Biologic Drugs. Available at <https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/biosimilar-biologic-notice-to-stakeholders-drugs-naming-of-biologics.html>



The European Medicines Association³ and Health Canada support to use the same INN as the reference medicine.