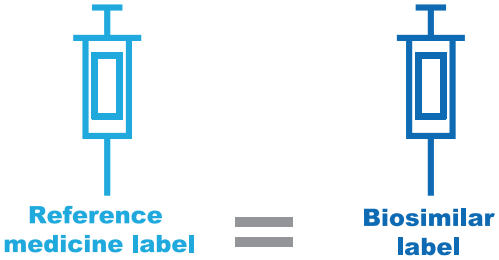
Labeling

A biosimilar should have the same label as the reference medicine.

Because it is approved as a biosimilar, it matches the reference medicine in terms of efficacy, safety and quality. Therefore a biosimilar should have the same INN as the reference biologic medicine.

Additional information should be included if approved indications, presentations, or the administration device of a biosimilar differ from those of the reference medicine.



Sandoz, a Novartis division, supports the use of the same label for a biosimilar and the reference medicine. This includes data supporting expected efficacy and safety.

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SANDOZ A Novartis Division

Regulators such as the FDA and the EMA make decisions on labeling