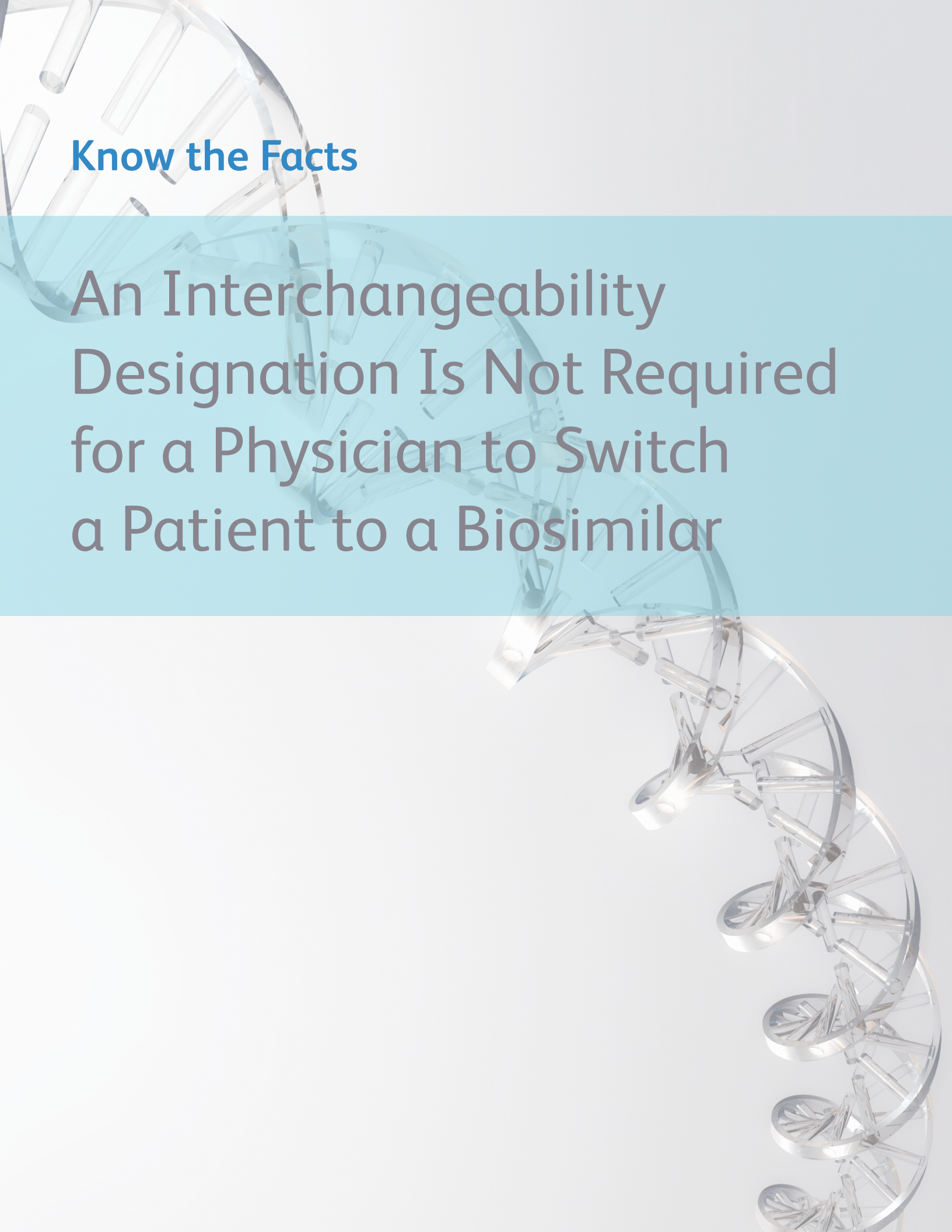
Know the Facts

An Interchangeability Designation Is Not Required for a Physician to Switch a Patient to a Biosimilar



Know the Facts

An Interchangeability Designation Is Not Required for a Physician to Switch a Patient to a Biosimilar

The Interchangeability Designation

According to the US Food and Drug Administration (FDA), products designated as interchangeable may be substituted at the pharmacy level for the reference biologic without the intervention of the prescribing healthcare provider.[1,2]

To be designated as interchangeable[1]:

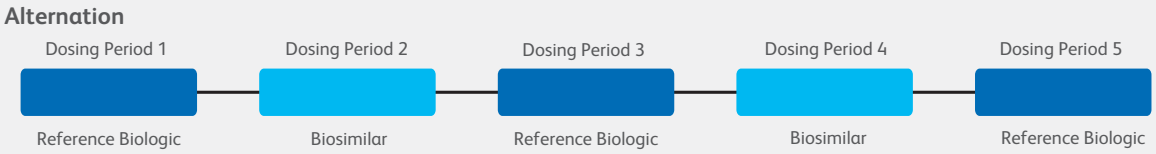
The biological product

- Must be biosimilar to the reference biologic
- Must be expected to produce the same clinical result as the reference biologic in any given patient

For a biological product administered more than once to a patient

- The risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference biologic is not greater than the risk of using the reference biologic without such alternation or switch

An interchangeability designation considers the potential for alternation (multiple switches) between a biosimilar and reference biologic without physician intervention.[1]

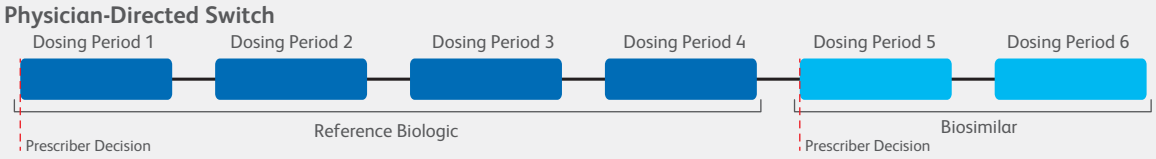


On July 28, 2021, the FDA approved the first interchangeable biosimilar, an insulin product.[3]

A Physician-Directed Switch

- Biosimilars are highly similar to reference biologics with no clinically meaningful differences in terms of safety, purity, and potency[1]
- A physician-directed switch (eg, from a reference biologic to a biosimilar) is a prescribing decision made by a patient's physician[4]

The decision to prescribe a biosimilar to a patient currently stable on the reference biologic is not restricted by FDA guidance or the BPCIA[1,4,5]



BPCIA, Biologics Price Competition and Innovation Act.

Physicians may prescribe a biosimilar in the same manner as they would prescribe other medications. This physician-directed decision may include prescribing a biosimilar for a patient who is currently stable on the reference biologic (eg, single transition or switch)[4,5]

References: 1. US Food and Drug Administration. *Guidance for Industry: Considerations in Demonstrating Interchangeability With a Reference Product*. Silver Spring, MD: FDA; 2019. **2.** US Food and Drug Administration. Prescribing interchangeable products. https://www.fda.gov/media/108107/download. Accessed January 28, 2022. **3.** FDA approves first interchangeable biosimilar insulin product for treatment of diabetes. News release. US Food and Drug Administration; July 28, 2021. https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-insulin-product-treatment-diabetes. Accessed January 28, 2022. **4.** McKinley L, Kelton JM, Popovian R. Sowing confusion in the field: the interchangeable use of biosimilar terminology. *Curr Med Res Opin*. 2019;35(4):619-621. **5.** US Food and Drug Administration. Prescribing biosimiliar products. https://www.fda.gov/media/108103/download. Accessed January 28, 2022.

For more information, please visit PfizerBiosimilars.com

PP-BIO-USA-0910

February 2022