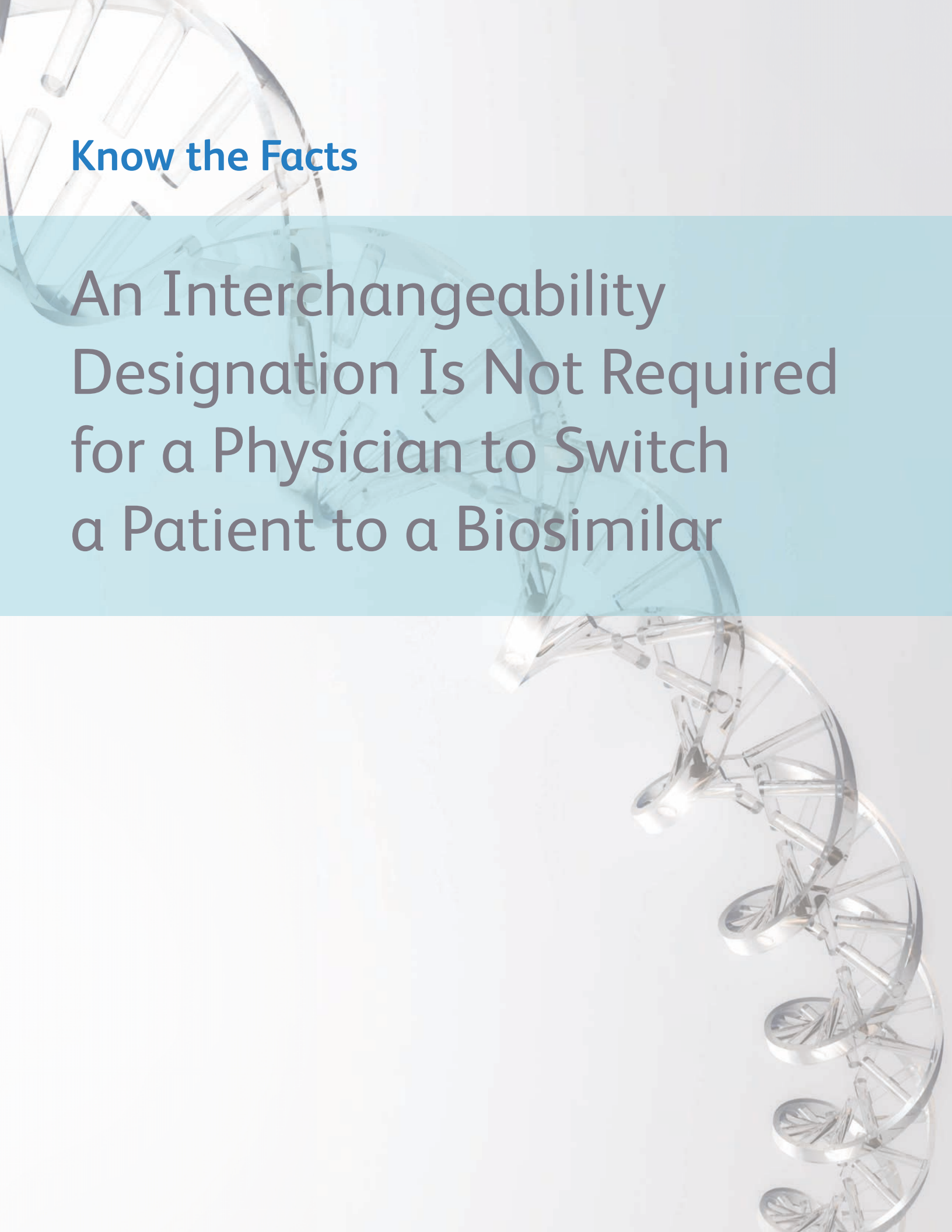
Know the Facts

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



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The Interchangeability Designation

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

To be designated interchangeable[1,2]:

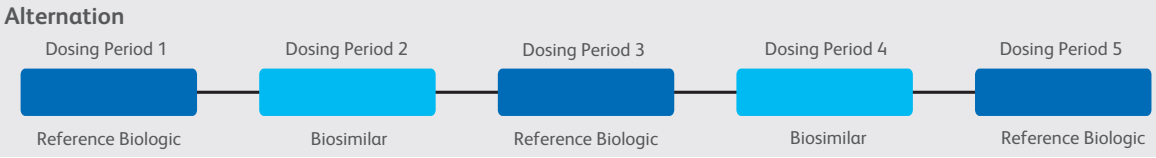
The biological product

- 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.[1,2]

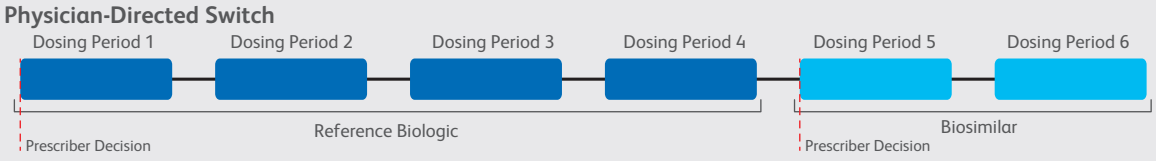


As of April 2017, no biosimilar has been designated interchangeable by the FDA.

A Physician-Directed Switch

- Biosimilars are highly similar to reference biologics with no clinically meaningful differences in terms of safety, purity, and potency[3]
- A physician-directed switch (eg, from a reference biologic to a biosimilar) is a prescribing decision made by a patient's physician[4]

Decisions to prescribe a biosimilar to patients currently stable on the reference biologic are not restricted by FDA guidance or the BPCIA[2,4,5]



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 patients currently stable on the reference biologic (eg, single transition or switch)[4]

References: 1. US Food and Drug Administration. *Guidance for Industry: Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009*. Silver Spring, MD: FDA; 2015. **2.** US Food and Drug Administration. *Guidance for Industry: Considerations in Demonstrating Interchangeability With a Reference Product*. Silver Spring, MD: FDA; 2017. **3.** US Food and Drug Administration. *Guidance for Industry: Scientific Considerations in Demonstrating Biosimilarity to a Reference Product*. Silver Spring, MD: FDA; 2015. **4.** US Food and Drug Administration. *Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*. https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm411418.htm. Accessed April 18, 2017. **5.** US Congress. United States Public Health Service Act, Sec. 262 Regulation of Biological Products. 42USC262. http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap6A-subchapII-partF-subpart1-sec262.pdf. Accessed April 19, 2017.

For more information, please visit PfizerBiosimilars.com

PP-BIO-USA-0331

Printed in USA/April 2017

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