BIOSIMILAR MEDICINES

THE ESSENTIALS FOR **HEALTHCARE PROFESSIONALS**

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Visit the **Biosimilar Hub** for information about biosimilar medicines and how they can contribute to a sustainable healthcare system.

- A biosimilar medicine is a **highly similar version** of an already registered biological medicine – the 'reference' biological medicine.[1]
- Biosimilar medicines are **approved on the totality of evidence** gathered through a stepwise approach of comprehensive preclinical assessments and a tailored clinical program.[1–4]
- Australian regulations require a biosimilar medicine to have no clinically meaningful differences and be **therapeutically equivalent to its reference product**.[2]
- With biosimilar medicines approved in Europe since 2006 and Australia since 2010, their use is supported by **over a decade of real-world clinical experience**.[5,6]
- Biosimilar medicines must comply with **post-registration pharmacovigilance requirements**. This can include a Risk Management Plan (RMP) and Periodic Safety Update Reports (PSURs).[7]
- If brand equivalence to the reference biological medicine is deemed sufficient, the PBAC may recommend a biosimilar medicine be given an 'a' flag **allowing substitution at the point of dispensing**.[8,9]
- Savings made from biosimilar medicines use in Australia could be **reinvested into other areas of health** e.g. expanded access to existing biological medicines or funding of new treatments.

Biosimilar medicine facts

>700M

Patient-days of clinical experience in Europe since 2006[5]

90 studies

evaluating 14,225 patients treated with biological medicines for 14 indications

concluded the risk of immunogenicity-related safety concerns or diminished efficacy was unchanged after switching from a biological medicine to its biosimilar.[10]

2010

In 2010, The Therapeutic Goods Administration approved the first biosimilar medicine for use.[6]

References: 1. European medicines agency. *Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substances: non-clinical and clinical Issues.* Effective 1 July 2015. Available at https://www.ema.europa.eu/en/similar-biological-medicinal-products-containing-biotechnology-derived-proteins-active-substance-non. Accessed April 2019. **2.** Aust Gov't DoH. TGA. *Biosimilar medicines regulation. v2.2 April 2018.* Available at https://www.tga.gov.au/sites/default/files/biosimilar-medicines-regulation.pdf. Accessed April 2019. **3.** Dörner T, *et al. Ann Rheum Dis* 2013; 72(3):322–8. **4.** Schneider CK, *et al. Ann Rheum Dis* 2013; 72(3): 315–18. **5.** Medicines for Europe information based on EMA Post-authorisation Safety Update Reports (PSURs) reported by Adrian van den Hoven. *Biosimilar medicines clinical use: an experience based-EU perspective.* FDA Presentation 13, July 2017, Washington D.C., USA. Available at http://www.medicinesforeurope.com/docs/20170713%20-%20Biosimilar%20Medicines%20Group,%20EU%20experience-AVH-US%20FDA%20Adcom.pdf. Accessed February 14, 2019. **6.** Aust Govt DoH. *Which biosimilar medicines are available in Australia?* Available at http://www.health.gov.au/internet/main/publishing.nsf/content/biosimilar-which-medicines-are-available-in-australia. Accessed March 2019. **7.** Aust Govt DoH: TGA. *Risk management plans for medicines and biologicals. v3.3 March 2019.* Available at https://www.tga.gov.au/publication/risk-management-plans-medicines-and-biologicals. Accessed April 2019. **8.** Aust Govt DoH. *Who chooses whether the biosimilar medicine or the reference biological medicine is used?* Updated Feb 2019. Available at http://www.health.gov.au/internet/main/publishing.nsf/Content/biosimilar-hp-who-chooses-whether-biosimilar-medicine-or-reference-biological-medicine-is-used. Accessed April 2019. **9.** Aust Govt DoH. Pharmaceutical Benefits Scheme. Public Summary Document – March 2018 PBAC Meeting: *11.04 Considering brand equivalence/substitution for biosimilar medicines.* Available at http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2018-03/Biosimilar%20medicines-psd-march-2018. Accessed April 2019. **10.** Cohen HP, *et al. Drugs* 2018; 78(4): 463–78.

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