As a result, there may be some minor differences between a biosimilar and its reference medicine. These differences are not clinically meaningful — no differences are expected in safety and efficacy.

The range of variability allowed for a biosimilar is the same as that allowed between batches of the reference biologic. Strict controls are always in place to ensure that all batches of the medicine are of proven quality and any variability does not affect the way the medicine works or its safety.

Clinical trials are conducted for all biosimilars to demonstrate that they have comparable safety and effectiveness to an approved biological medicine.
Is there a difference in health outcomes between a biosimilar and its reference biologic?
Biosimilars that are approved for use in Singapore have been assessed to have no clinically meaningful differences and to be therapeutically equivalent to the reference biologic. As such, they have similar health outcomes to the reference product, and the incidence of adverse effects or immunogenicity is also no higher than for the reference biologic.

Why are biosimilars important?
Good uptake of biosimilars is expected to deliver significant savings, which can be reinvested into other areas of the Singapore healthcare system and expand access to biological medicines as they become more affordable for patients.

Are biosimilars used around the world?
Biosimilars have been used in many overseas countries for more than a decade. There are over 20 biosimilars currently approved for use globally. In addition, almost 50 distinct biosimilars are currently in development and will likely lead to a more competitive marketplace over the next decade, bringing improvements to patient outcomes and improving affordability.

Are biosimilars available in Singapore?
Yes, the first biosimilar was launched in Singapore in 2013 – biosimilar filgrastim, which is widely used to boost white blood cell counts in patients receiving chemotherapy for cancer. Since then, biosimilars for insulin glargine (for diabetes) and infliximab (for auto-immune disorders) have also become available in Singapore.

Who chooses whether a biosimilar should be prescribed?
Treatment choice should be made by clinicians in consultation with their patients. Healthcare professionals are encouraged to discuss all treatment options, including biosimilars, with their patients and consider the value proposition offered by each choice with respect to the patient’s needs.

Can a patient switch from a reference biologic to a biosimilar?
Yes. Switching between a reference product and its biosimilar should be managed by the prescribing clinician in consultation with their patient, after taking into consideration the cost of treatment and any patient affordability concerns. After switching treatment, appropriate monitoring should be put in place, if relevant.

References:

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