ACE FACT SHEET

Biologics & Biosimilars

KEY FACTS

- Biosimilars are comparable in terms of quality, safety and efficacy to their reference biologic products.
- In order to be approved by regulators, biosimilars must undergo extensive testing and quality assurance.

BIOLOGICS

Unlike most traditional medicines that are made through chemical processes, biological medicines ('biologics') contain one or more active substances from a biological source such as living cells or organisms. They usually have a more complex structure than other medicines and are used to treat serious diseases such as cancers, diabetes, arthritis and immune disorders.

Use of biologics is increasing rapidly around the world. Approximately US$210 billion is currently spent on biologics worldwide, and this is forecast to grow to US$479 billion by 2024.

In Singapore, expenditure on biologics in the public sector increased by 51% from 2013 to 2016. By comparison, expenditure on other medicines only increased by 20% over the same period. Approximately 74% ($62 million) of the total spent on biologics in 2016 was for the class of biologics called 'monoclonal antibodies', which accounted for approximately 13% of all spending on medicines in public healthcare institutions in Singapore.

The rapid growth in spending on biologics is unsustainable. Payers and healthcare providers worldwide must work to reduce these costs in order to maintain existing services and provide new medicines to patients.

BIOSIMILARS

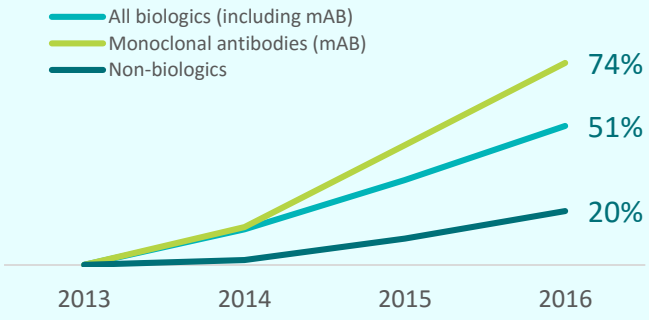
A biosimilar is a biological medicine that is highly similar and clinically equivalent to an existing biological medicine ('reference' or 'originator' biologic). Biosimilars contain the same active substances as their reference medicine.

Natural variability is inherent to all biological medicines because they are made in living organisms. No two batches of a biological medicine, including reference biologics and their biosimilars, are ever exactly the same (even from the same manufacturer).

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.



Expenditure on biologics increased

51%

from 2013 to 2016

Frequently Asked Questions

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:
Biologics Market – Global Industry Analysis, Size, Share, Growth, Trends & Forecast 2016-2024. Transparency Market Research. Accessed from website 18/01/2018: https://www.transparencymarketresearch.com/pressrelease/global-biologics-market.htm

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