## Biosimilars: what does a primary care clinician need to know?

Biosimilars are biological medicines that are developed to be comparable versions of an existing, approved, biological medicine once patent protection on the original has expired. Worldwide, biosimilar medicines are available for the treatment of cancer, diabetes and diseases with an inflammatory or immune component, such as rheumatoid arthritis and inflammatory bowel disease. In New Zealand, two biosimilar medicines are currently approved and subsidised: Zarzio (filgrastim, for neutropenia) and Omnitrope (recombinant human growth hormone); more biosimilars are likely become available as patents expire in the next few years.

Key points for primary care clinicians:

 Biosimilars are not just generic versions of a biological medicine; manufacturing and analysis complexities mean that biosimilars cannot be made, or cannot be demonstrated to be, exactly the same as an existing biological medicine. In comparison, generic medicines can be synthesised to be identical to the original patented pharmaceutical.

## Improving the safety of community-based chemotherapy

Traditionally, chemotherapy is carried out in a hospital setting. However, oral chemotherapy is now increasingly being dispensed in the community and taken by patients at home. To improve patient safety and treatment effectiveness, clear, and preferably documented, communication is required between patients, oncologists, general practitioners and pharmacists.

General practitioners can improve the safety of communitybased chemotherapy by:

- Discussing the treatment plan with the patient, pharmacist and oncologist
- Being aware of all medicines the patient is taking, including over-the-counter or complementary and alternative medicines and assessing the risk of interactions with the chemotherapy regimen

- The same degree of clinical benefit is expected to be achieved with a biosimilar as with the original biological medicine
- When a biosimilar medicine is subsidised in New Zealand, whether the original biological medicine will continue to be funded will vary on a case by case basis; the innovator versions of Zarzio and Omnitrope are no longer subsidised
- Decisions regarding switching a patient from a biologic to a biosimilar are likely to be managed in secondary care, but primary care clinicians may help to monitor treatment response and adverse effects
- A patient could have adverse effects, including immune reactions, with a biosimilar that they did not experience while using the original biologic, or vice versa, or from different batches of a biologic or biosimilar medicine
- If a patient develops an adverse reaction after initiating or switching to a biosimilar medicine, the clinician managing the patient's care should be advised and an adverse drug reaction report submitted to the Centre for Adverse Reactions Monitoring (CARM)

Ge For further information, see: "Biosimilars - what does a primary care clinician need to know?", BPJ 71 (Oct, 2015).

- Ensuring that the patient has been provided with clear written instructions, including start and stop dates for each chemotherapy cycle
- Providing support to the patient throughout treatment and regularly monitoring them for adverse effects, particularly those requiring immediate referral to secondary care

Pharmacists need to recognise when they receive a prescription for a cytotoxic medicine, and have additional safety procedures in place, e.g. confirming medicines dispensed match those on the treatment protocol, checking any calculations based on the patient's body surface area are correct, checking that quantities for chemotherapy cycles are appropriate, and including the start and stop dates for cycles of treatment on prescription labels. Pharmacists should verify at dispensing that patients understand their treatment protocol.

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