



NHS TAYSIDE STATEMENT ON THE USE OF BIOSIMILAR MEDICINES

A number of biosimilar medicines are expected to enter the market place over the next few years. These will be an alternative to biological medicines currently used in Tayside. A biological medicine is one derived from living cells or organisms and consists of large, highly complex molecular structures. Due to the complexity of the manufacturing process, all biological medicines can show a degree of batch to batch variation. A biosimilar medicine is not a copy of the reference product but is one that, through comprehensive scientific comparability studies, has been shown to be similar to the reference medicine in terms of quality, structural characteristics, biological activity, safety and efficacy.

Automatic switching to a biosimilar product is currently not permitted at the point of supply, therefore the decision to use a biosimilar medicine needs to be made for each patient who meets the clinical criteria for their use.

The switch to biosimilar medicines, from the currently available evidence, appears to deliver an organisational saving with no detriment to clinical care. Several biosimilar medicines are already used in Tayside such as somatropin, filgrastim and epoetin alfa. Further introduction of biosimilar medicines during 2016/17 has the potential to deliver significantly greater efficiencies for NHS Tayside. Infliximab is the most recently available and use of this product in Tayside started in November 2015. The introduction of biosimilar infliximab is being used to develop an effective mechanism for the introduction of future biosimilars in Tayside. To maximise the identified efficiencies, an organisational commitment to the introduction of biosimilars has been agreed. Each relevant clinical area needs to have a clear implementation plan describing the review of existing patients with a view to switching to the most cost effective product.

The use of biosimilars has been endorsed by Health Improvement Scotland and the Scottish Medicines Consortium. The NHS Tayside Drug and Therapeutics Committee also support their use. The attached table has been adapted from the HIS National Prescribing Framework for Biosimilars.

Recommendations

NHS Tayside Medicines Advisory Group and the Area Drug and Therapeutics Committee endorse the use of biosimilar medicines to provide safe and clinically effective treatment to ensure the most cost effective use of available resources.

The following actions are required:

- 1. A biosimilar brand should be included as first choice in the Tayside Area Formulary for all patients who meet the relevant clinical criteria.**
- 2. All new patients should be commenced on the biosimilar brand.**
- 3. All existing patients should be reviewed at their next clinic appointment with a view to switching to the biosimilar brand. The outcome of this review should be recorded in the clinical record.**

References:

- <https://www.gov.uk/government/publications/what-is-a-biosimilar-medicine>
- http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/programme_resources/biosimilar_medicines_framework.aspx
- [What are biosimilars. UKMi Q & A 300.4. 26/02/15 \(partial revision 21/08/15\)](#)

Table 1: Summary of the frequently asked questions

Frequently Asked Question		NHS Tayside Advice
2.1	Should biosimilar medicines be used in NHS Tayside?	NHS Tayside is supportive of the use of biosimilar medicines and agrees that they should be considered as a treatment option for appropriate patients for whom a biological medicine is being considered as part of their treatment pathway.
2.2	Can patients established on a biological medicine be switched to another biological medicine, for example a biosimilar?	Individual patients may be switched to another biological medicine, including a biosimilar medicine, as part of a clinician-led management programme which has appropriate monitoring in place.
2.3	Are different approaches to the use of biosimilar medicines required in different clinical specialties?	There are differing clinical characteristics within specialties which may be important to consider when using biosimilar medicines. While practice is evolving, some specialties may consider that it is most appropriate to use biosimilar medicines in new patients however the option to switch to a biosimilar should form part of the next clinical review for patients already on treatment. The outcome of the review should be clearly documented in the patient record.
2.4	Are there any specific efficacy or safety concerns associated with the use of biosimilar medicines?	There are no specific efficacy or safety concerns identified for biosimilar medicines but, as for all biological medicines, clinical experience with biosimilar medicines is still emerging to guide their use. As for all new medicines, adverse drug reactions to biosimilar medicines should be reported through the Yellow Card Scheme.
2.5	How should biological medicines, including biosimilar medicines, be monitored?	Clinical outcomes for individual patients on any biological medicine should be measured using established recognised systems for monitoring disease activity and response to treatment. No additional monitoring requirements are necessary for biosimilars. Clinical registries are being established for a number of biological medicines. It would be appropriate to explore the expansion of these databases to capture details of biosimilar medicines.
2.6	How should biological and biosimilar medicines be prescribed and product details recorded?	Biological medicines, including biosimilar medicines, should be prescribed by brand name and the brand name and batch number should be recorded on the patient's prescription, case record or other appropriate clinical system. The system for ordering, prescribing, supplying and administering a biosimilar will be the same as for the reference product.
2.7	What information should be provided to patients?	The manufacturer's patient information leaflet should be supplied to all patients receiving any medicine, including a biosimilar medicine.

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Do you wish to write a Tayside Prescriber?

Do you already have a suitable topic for a Tayside Prescriber?

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