

Biosimilar medicines

Biological medicinal products are fundamentally different from chemically derived medicines in terms of their production, complexity of chemical structure, purity and immunogenicity.

Biosimilar medicines are new biological medicinal products that have demonstrated 'similar' efficacy and safety to an existing biological reference product.

By definition, biosimilar medicines are not generic medicines (and are therefore not interchangeable), since it could be expected that there may be subtle differences between biosimilar medicines from different manufacturers or when compared with the reference product. Changes in the production site and production process (even minor) can affect the complex three-dimensional structure of a biosimilar medicine and other characteristics such as glycosylation. These variations may affect the efficacy and safety of the biosimilar medicine (e.g. increased risk of allergic reactions when compared with the reference product). The European Medicines Agency (EMA) therefore requires evidence (via pre-clinical studies and phase I and III clinical studies) that a biosimilar medicine is similar to the original reference product in terms of quality, efficacy and safety. Biosimilar medicines are usually approved via an abbreviated licensing process with a limited clinical database, hence significant post-approval commitments are required to further characterise immunogenic potential and monitor adverse drug reactions.

Clinical safety of biosimilar medicines must therefore be monitored closely on an ongoing basis during the post-approval phase, including continued risk-benefit assessment. Thus in order to support pharmacovigilance monitoring, biosimilar medicines are required to be prescribed by brand name. If the specified biosimilar medicine is unavailable during dispensing, automatic substitution for the reference product is inappropriate. Substitution should only be considered if the prescribing physician gives prior consent.

SMC believes that the managed introduction of biosimilar medicines into clinical practice in NHS Scotland is desirable. To facilitate this process, from May 2015 SMC will no longer routinely assess biosimilar medicines on the basis of a full submission. These products will be considered 'out of remit' where the reference product has been accepted by SMC/HIS for the same indication(s) and in the same population or was initially licensed and available prior to 31 January 2002. Full submissions will continue to be required for indication(s)/populations where the reference product is not recommended by SMC/HIS. SMC will continue to horizon scan for

emerging biosimilar medicines and reserves the right to request a full submission in the event that it is anticipated to have an impact on NHS Scotland resources.

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