20 January 2023

European Medicines Agency

Q&A on the Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU

Following the publication of the joint EMA-HMA statement on interchangeability of biosimilar medicinal products approved in the EU, both EMA and NCAs have received questions for clarification. To address the issues raised in these questions the following Q&A is considered to be added to the statement on the EMA's website.

Q1. *Does the interchangeability of biosimilars also cover situations where multiple switches are taking place – independent of frequency of switches and number of products involved?*

A1. Yes, if all switches are taking place within the group of products that have the same reference product, or between the reference product and its biosimilars. The comprehensive comparability exercise required for establishing biosimilarity makes negative consequences of switching highly unlikely. Such practice is already taking place in some EU member states without any signs of change in efficacy or safety for the patients. The interchangeability statement relates to the active substance and the formulated product and does not include potential issues related to the handling of different administration devices (e.g. the need for patient training when using a new device) or physician or patient perception (of biosimilars). As for any biological medicinal product, traceability should also be ensured for biosimilars to allow for proper root cause analyses in case of adverse drug reactions (ADRs) occur.

Q2. *Does interchangeability – including the possibility for multiple switches as discussed in Q1 – apply to all kinds of biosimilars, e.g. also those with a more complex molecular structure?*

A2. Yes, the EU regulatory and scientific requirements for establishing biosimilarity are tailored to meet the challenges posed by differences in molecular complexities, thereby allowing for interchangeability of all EU-approved biosimilars.

Q3. *Does the joint EMA-HMA statement on interchangeability of biosimilars mean that switching to or between biosimilars are allowed in my country?*

A3. No, EMA does not regulate prescribing practices or issue clinical guidance; these matters fall under national remit and are issued by the relevant bodies in each Member State. The statement on interchangeability of biosimilars is a general statement on the scientific principle highlighting that biosimilars can be used interchangeably and detailing the scientific references supporting this position. The statement is meant to advise those Member States that want to allow for biosimilar prescribing, including any national decision on switching and/or (automatic) substitution. However, each Member State will decide on how this is applied in their territories, e.g. which biological medicines are available

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

for prescribing in their country and whether automatic substitution with biosimilars is allowed at pharmacy level.