biosimilar medicines
better access. better health.

Memo

Subject: Medicines for Europe – Biosimilar Medicines Group – Position on physician-led switching[1] and pharmacy substitution[2] of Biosimilar Medicines

Date: July 2015

Biosimilar medicines are developed to be highly similar to the respective reference products and approved as having no clinically meaningful differences. As a consequence, a biosimilar medicine can be switched with its reference products under the supervision of a health care provider[3].

Consideration of individual patient factors[4] is essential during treatment. The role of the clinical decision maker throughout treatment with biological medicines is thus imperative as these patient factors can be understood best by a physician. As a consequence, substitution of biological medicines at the retail pharmacy level – without involvement of the prescriber - should not take place by default, and should only occur if the following criteria have been met:

1. Clear and transparent regulations, supported by clinical decision makers or based on scientific evidence, have been established to permit the substitution of biological medicines at retail pharmacy level and allowing the prescribing physician 'right-to-refuse' if justified for medical considerations; and
2. The biosimilar medicine has been approved for the specific indication; and
3. A system is in place to provide the patient, pharmacist or prescribing physician with access to detailed product and batch information on what product is used throughout treatment, so as to ensure clear identification of the medicine prescribed, dispensed or sold in order to maintain traceability as required for appropriate pharmacovigilance for biological medicines.

[1] Physician-led switching = EU Interchangeability: the medical practice of changing one medicine for another that is expected to achieve the same clinical effect in a given clinical setting and in any patient on the initiative, or with the agreement of the prescriber (EC Consensus document 2013).

[2] Substitution: practice of dispensing one medicine instead of another equivalent and interchangeable medicine at the pharmacy level without consulting the prescriber (EC Consensus document 2013).

[3] Fimea (2015) - Interchangeability of Biosimilars – Position of Finnish Medicines Agency Fimea

[4] Examples of individual patient factors can include: a patient has been trained and used to a specific delivery system; a patient has developed neutralizing antibodies to the existing medication without clinical consequence - the physician has to closely monitor the patient and, if needed, switch to another INN and not substituted to another version of the same INN; a situation where a certain dosage form is not available for the biosimilar; etc.

A medicines for europe sector group
Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11 - F: +32 (0)2 736 74 38
www.medicinesforeurope.com