biosimilar medicines
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Position

FINAL

Subject: **Biologic pharmacy substitution**

Date: 17 SEPT 2020

The Biosimilar Medicines Group is supportive of the central role for the physician-patient relationship throughout the course of biologic treatment

- The Biosimilar Medicines Group, a Medicines for Europe sector group, has never advocated in favour of pharmacy substitution at the pharmacy level without the involvement of the prescriber. We remain opposed to the introduction of biologic pharmacy substitution as default means to introduce biosimilar medicines use.
- Biologic pharmacy substitution has been envisaged conceptually (sometimes embedded in national law) in a very rare number of instances and implemented in even fewer instances.
- Biologic pharmacy substitution without the involvement of the physician is likely to adversely affect the central role of prescribers and patients (and their relationship): the prescriber-patient relationship is central to the (biologic) therapy selection, patient information and education (e.g. device usage) and clinical oversight over time.
- Close clinical monitoring – specifically for auto-immune conditions – is particularly critical at the time of treatment initiation and involves the coordination of patient care. This underlines the need for an integrated patient/prescriber relationship.
    - e.g. dose titration (treat-to-target) in auto immune condition depends on the patient's actual response to the biologic therapy along with blood serum level testing – the induction phase is all performed under close clinical oversight.
- While all actors (patients and HCPs) of the pharmaceutical system can report adverse effects to the EU and national pharmacovigilance system[1], the understanding and correct attribution of side effects require both pharmaceutical traceability and medical / clinical evaluation.

If biologic pharmacy substitution was to be implemented, a number of carefully thought conditions would need to be defined and implemented with all stakeholders.

The following criteria should have been met[2]:

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

[1] Pharmacovigilance - Directive 2010/84/EU and Regulation (EU) 1235/2010 link

[2]Medicines for Europe – Biosimilar Medicines Group – Position on physician-led switching and pharmacy substitution of Biosimilar Medicines – July 2015: https://www.medicinesforeurope.com/wp-content/uploads/2015/07/position-on-physician-led-switching-of-biosimilar-medicines.pdf

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identification of the medicine prescribed, dispensed or sold in order to maintain traceability as required for appropriate pharmacovigilance for biological medicines.

References and Definitions

- **"*Interchangeability*** *refers to the possibility of exchanging one medicine for another medicine that is expected to have the same clinical effect. This could mean replacing a reference product with a biosimilar (or vice versa) or replacing one biosimilar with another. Replacement can be done by:*
    - ***Switching****, which is when the prescriber decides to exchange one medicine for another medicine with the same therapeutic intent.*
    - ***Substitution*** *(automatic), which is the practice of dispensing one medicine instead of another equivalent and interchangeable medicine at pharmacy level without consulting the prescriber*."[3]
- EU Biosimilar Medicines Group – **Position on physician-led switching and pharmacy substitution of Biosimilar Medicines** (2015): https://www.medicinesforeurope.com/wp-content/uploads/2015/07/position-on-physician-led-switching-of-biosimilar-medicines.pdf

[3] EMA/EC – Biosimilars in the EU - Information guide for healthcare professionals - https://www.ema.europa.eu/en/documents/leaflet/biosimilars-eu-information-guide-healthcare-professionals_en.pdf - Accessed Oct 2019