POSITION PAPER

Subject: Position on biosimilar medicines

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Biologic medicines play a major role in the treatment of numerous diseases. In this context, biosimilar medicines represent an asset which guarantees the patient a sustainable access to high quality, safe and effective medicines, while generating cost savings for the healthcare system. The reallocation of savings will lead to improved healthcare and better access for patients to biologic and innovative medicines.

Biosimilar medicines are developed to be highly similar to their already approved products of reference; they receive their Marketing Authorization at European level. Dossiers submissions are rigorously reviewed by the same body within the European Medicines Agency (EMA) which delivers approvals for all biologic products in the European Union. Biosimilar medicines have to prove, through clinical trials, similar efficacy and safety as the reference product. They are approved for the same indications.

When on the market, the companies and the health agencies closely supervise the quality and the safety of biosimilar medicines, according to the same standards which apply to the reference product.

As acknowledged by ANSM[1], biosimilar medicines and their reference product are interchangeable. This act of interchanging two biologic medicines (including biosimilars) may be carried out anytime during the treatment under the supervision of healthcare professionals for an effective follow-up.

The follow-up begins at the start of the treatment and continues throughout its whole duration. The act of interchanging two biologic medicines (including biosimilars) is submitted to a certain number of requirements: information of the patient, traceability of the product and clinical surveillance of the patient. These requirements suppose the collaboration of all health professionals.

The decision to switch a patient to a biosimilar medicine and the follow-up it entails should be valued by a conventional fee financed in part by the savings generated by the use of biosimilar medicines and that will compensate the specific work related to patient follow-up.

In order to favor the use of biosimilar medicines, GEMME supports the establishment of prescription targets in the near future.

For the purpose of ensuring a sustainable development of biosimilar medicines, it is important to opt for a specific economic model which is suitable to the objectives of the healthcare system and which allows full benefit of the potential savings generated by an optimal use of biosimilar medicines.

[1] Etat des lieux sur les médicaments biosimilaires – Rapport ANSM – May 2016

A biosimilar medicine is developed to be highly similar to an existing biologic medicine, allowing increased access for the patient to high quality treatment and involving all healthcare professionals for an effective follow-up during treatment. Biosimilars contribute to the financial sustainability of the healthcare system.