Title
Biosimilar medicines in clinical practice – Important role for hospital pharmacists?

Abstract
Hospital pharmacists play and will continue to play an increasingly important role in the debate of biosimilar medicines as many of them are initiated, dispensed and used in the hospital setting. As an expert of medicines within the hospital, hospital pharmacists play a crucial role in this debate: making informed decisions on hospital formularies and procurement, educating physicians, nurses and patients, ensuring traceability and pharmacovigilance, collecting feedback on clinical experience, etc. Biosimilar medicines can be a game changer by providing access to modern therapies for all patients that need it while ensuring the sustainability of healthcare systems. The role of the hospital pharmacist is omnipresent and only with their informed decision making can we make sure that all stakeholders benefit from these opportunities.

Biologic medicines have revolutionised the management of diseases over the last three decades. However, the full potential of biologic medicines is yet to unfold so that all patients across Europe who would need these state-of-the-art treatments can effectively access them. Biosimilar medicines, containing versions of existing biologic medicines, provide an opportunity to further deliver on the potential of biologic medicines by creating additional therapeutic options for physicians and patients, increasing access both in terms of number of patients that can be treated and considering these modern therapies earlier in the treatment cycle.

A biosimilar medicine is a biological medicinal product that contains a version of the active substance of an already authorized original biological medicinal product (reference product). A comprehensive comparability exercise ensures that biosimilar medicines have the comparable quality, safety and efficacy as the reference product. Over 20 biosimilar medicines have been approved in the EU for several therapy areas and since the introduction of the first biosimilar medicine in 2006, EU approved biosimilar medicines have already generated more than 400 million patient days of safe clinical experience. Continuous information and education on the safety,
efficacy, interchangeability\(^1\) (physician-led switching) and traceability of biosimilar medicines remains a must, especially since biosimilar oncology products will enter the market soon.

In this session, hospital pharmacists will navigate the following areas:

- Introducing biosimilar medicines in the hospital: What are the key aspects to be taken in consideration?
- Understanding the scientific concept of biosimilar medicines and the clinical experience with them
- How best to communicate on the safety and efficacy of biosimilar medicines? The role of pharmacists as information channel for carers and patients
- Medical switch practice applied to biologics: how can pharmacists ensure traceability in the hospital setting?

\(^1\) 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.