

ESNO Position statement on Biosimilar Medicines

The objective of the statement is to set out the position of ESNO on biosimilar medicines, including interchangeability and the role of the specialist nurse.

Biological medicines contain one or more active substances made by or derived from a biological source i.e. living cells or organisms.

The European Medicines Agency (EMA) defines **biosimilar medicines** as “biological medicines that are developed being similar to an existing biological medicines (the ‘reference product’)” while having the same clinical effect¹ ESNO trusts the EMA process for medicines authorisation and EMA’s experience in regulating biological, including biosimilar medicines. ESNO, as for all other medicines, recommends informed patient involvement and shared decision making.

ESNOs position on matters relating to interchangeability

Endorse that a biosimilar product and other biosimilar(s) to the same reference product are interchangeable and therefore can be switched;

Supports that decisions regarding medicinal product exchange or replacement should involve all relevant stakeholders (patients, prescribers, nurses, pharmacists and others);

Acknowledges that such medicinal product exchange or replacement policies (e.g. physician-led switching or pharmacy-led substitution) are developed at a national level, involving all relevant stakeholders (patients, prescribers, nurses, pharmacists and others);

ESNOs position on matters relating to the role of the specialist nurses

Advocates for the use of the specialist nurses’ knowledge and experience in providing and sharing information and education about biosimilar medicines with both patients and other health care professionals.

Contributes in cooperation with physicians, pharmacist and other health professionals to clinical trials and encourages the active involvement of nurses in data collection including pharmacovigilance for biologic medicines, particularly the trade name and batch number.

Takes a role in developing programs and guidelines, takes a role as stewardship and participate in advocacy groups and other relevant fora.

European Specialist Nurses Organisations (ESNO)

The goal of the European Specialist Nurses Organisations (ESNO) is to facilitate and provide an effective framework for communication and co-operation between the European Specialist Nurses Organisations and its constituent members. ESNO represents the mutual interests and benefits of these organisations to the wider European community in the interest of the public health. Members of ESNO consist of individual European specialist nurses organizations.

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¹ [European Medicines Agency \(27 Sept 2012\). Questions and answers on biosimilar medicines \(similar biological medicinal products\)](#)