



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Generic/hybrid/biosimilar products

SmPC training presentation

Note: for full information refer to the European Commission's [Guideline on summary of product characteristics \(SmPC\)](#)

SmPC Advisory Group

An agency of the European Union





Definition

- **Generic:** a generic medicine is a medicine that is developed to be the same as a medicine that has already been authorised, called the “reference medicine” (as per Art. 10(1) of Directive 2001/83/EC)
- **Hybrid:** in cases where the medicinal product does not fall within the definition of a generic medicinal product as provided in paragraph 2(b) or where the bioequivalence cannot be demonstrated through bioavailability studies or in case of changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration, vis-à-vis the reference medicinal product, the results of the appropriate pre-clinical tests or clinical trials shall be provided (as per Art. 10(3) of Directive 2001/83/EC)
- **Biosimilar:** a similar biological or 'biosimilar' medicine is a biological medicine that is similar to another biological medicine that has already been authorised for use (as per Art. 10(4) of Directive 2001/83/EC)

See also [Q&A on generic medicines](#) and [Q&A on biosimilar medicines](#)



SmPC information

- In general, the content of the SmPC should be consistent with the reference medicinal product
- Any differences with the reference medicinal product should be justified
- Guidance can be found in the [QRD general principles regarding the SmPC information for a generic/hybrid/biosimilar product](#)



Thank you for consulting this
training presentation

SmPC Advisory Group