

## EMA/HMA share definitive EU-wide position on biosimilar medicines interchangeability

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The Biosimilar medicines group, a Medicines for Europe sector group, is pleased to note the EMA/HMA jointly closing the discussion on biosimilar medicines interchangeability.

The [statement](#) reflects a harmonised view on today's common clinical practice in many European Member States whereby prescribers and their patients can safely choose from all available authorised options of a given medicine and 'without a patient experiencing any changes in the clinical effect'. This statement is a real improvement over previous national perspectives where different wordings or the absence of a clear position left stakeholders confused when making decisions on treatment options.

Adrian van den Hoven, Director General of Medicines for Europe stated: "We appreciate the strong statement from Europe's medicine regulators (EMA/HMA) for two reasons. First, it provides a clear and harmonised view across all Member States. Second, it is unambiguous and backed by the wealth of European regulatory and clinical experience with biosimilar medicines. With the issue of biosimilar interchangeability now formally clarified, an important barrier to biosimilar medicines uptake has been solved. The European medicines agencies network can now focus on other significant regulatory issues such as the modernisation of the regulatory sources of evidence, the streamlining of development and the continued leadership of the EU on biosimilar medicines at the international level".

### Resource hub

The full EMA/HMA statement and associated resources can be accessed at

<https://www.ema.europa.eu/en/news/biosimilar-medicines-can-be-interchanged>

### The Biosimilar medicines group

The Biosimilar Medicines Group is a sector group of Medicines for Europe representing the leading companies developing, manufacturing and/or marketing biosimilar medicines across Europe. With more than 15 years of positive patient treatment experience, biosimilar medicines provide today a huge opportunity to deliver significantly improved access to modern therapies for millions of European patients in both chronic and acute care. Our members bring competition to the biological medicines market, thereby increasing access to highly innovative treatments to patients, in Europe and around the world, and supporting the sustainability of the European healthcare systems.