



# CPME 2011/027 FINAL

## TITLE / TITRE

CPME Policy on Access to Medicines – Biosimilars

## AUTHOR / AUTEUR

CPME Board

## CONCERNING / CONCERNE

All delegations

## PURPOSE / OBJET

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Access to Medicine, Biosimilars



## CPME Policy on Access to Medicines – Biosimilars

The platform on Access to Medicines in Europe was created by the EU Commission in 2010, as one of the work areas of the Process on Corporate Responsibility in the field of Pharmaceuticals. The platform is dedicated to enhancing the collaboration among the EU Member States and relevant stakeholders in order to find common, non-regulatory approaches to timely and equitable access to medicines after their market authorization.

Following the European Commission invitation to join the platform, CPME agreed in 2011 to be member of the following projects:

- Mechanism of coordinated access to orphan medicinal products
- Capacity building on managed entry agreements for innovative medicines; and
- **Market access for biosimilars**

The aim of the project on ‘Market access for biosimilars’ is to define what are the necessary conditions within the pharmaceutical environment, in order to ensure informed and adequate uptake of biosimilars. The project is expected to be completed in July 2012.

**CPME recognises the potential development of the biosimilars in the European market. For the medical professionals it is a key priority to ensure that biosimilars are at least as effective, safe and of good quality as the original reference biopharmaceuticals. To this aim, CPME calls upon the Commission to ensure that the following concerns are taken into account into any future regulatory and non-regulatory action regarding biosimilars:**

1. **Clinical efficiency and safety:** Biosimilars are a collection of large, complex and heterogeneous proteins which are very sensitive to changes during the manufacturing process of the compounds, their transport and their storage. Minor changes may have a significant impact on the quality, purity, biological properties, clinical activity and safety of these compounds. Quality assurance assays for biopharmaceuticals and biosimilars are considered to be less precise than those for small-molecule drugs. Furthermore, the manufacturing process of drugs, original products and their generics may take place outside the EU for financial reasons. In some regions, quality controls are difficult to apply and the surveillance of biosimilars during their manufacturing and transportation may be less strict than within the EU.

2. **Substitution and/or shifting:** Substitution and shifting are already critical with some generics but is even more critical with biopharmaceuticals and biosimilars for the reasons mentioned above. Substitution or shifting must be exceptional and may be accepted only on a case by case basis, after ensuring the highest quality and safety controls. Moreover, the naming and all means used for identifying biosimilars must be thoroughly analyzed to avoid confusion and accidental substitution between biopharmaceuticals and their biosimilars and vice-versa.

3. **Post-marketing surveillance:** It is of utmost importance to apply the strictest monitoring in order to minimize the eventual occurrence of side-effects after the launch of the product.