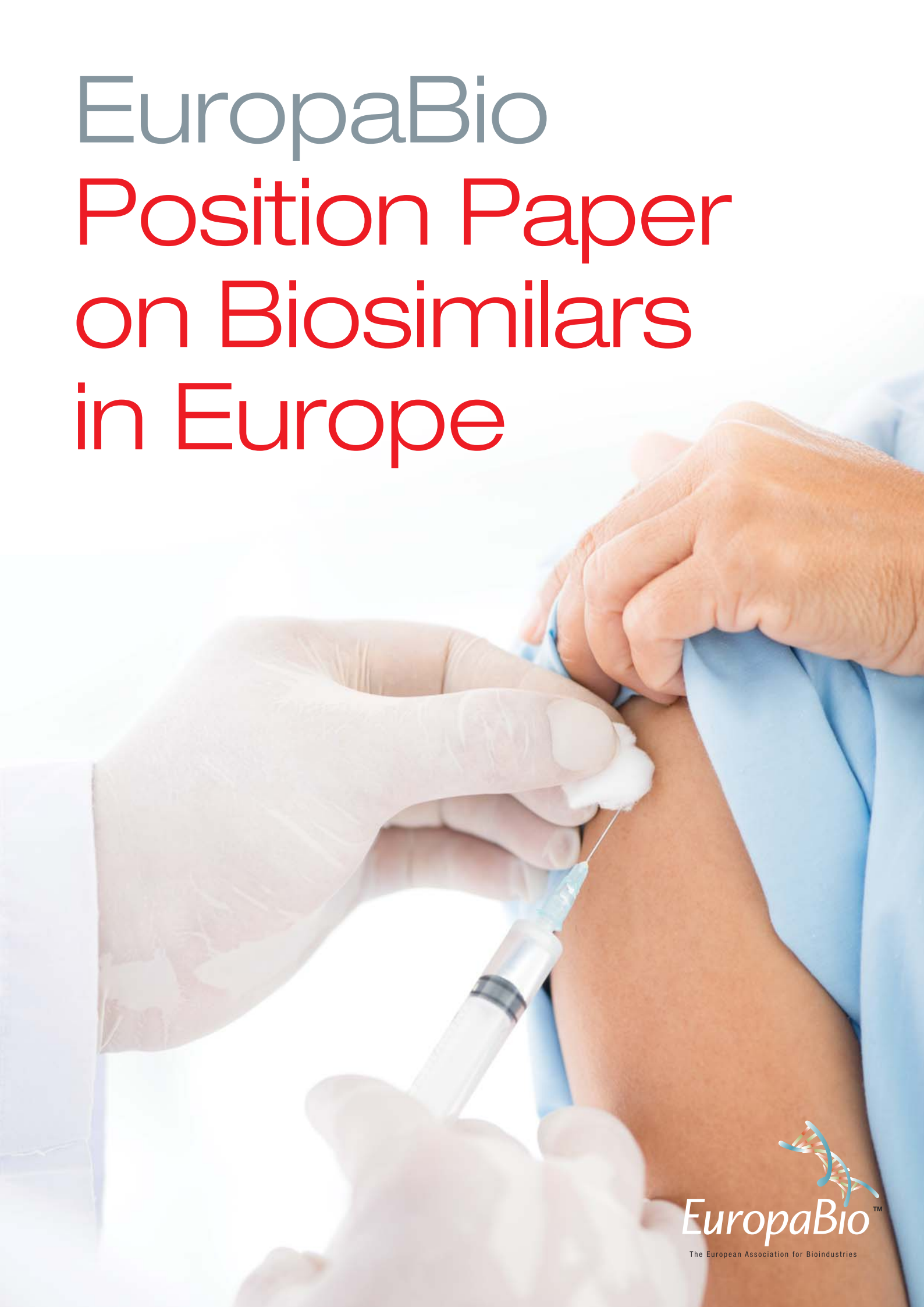
EuropaBio

Position Paper on Biosimilars in Europe



EuropaBio™

The European Association for Bioindustries

Biosimilar medicines are follow-on versions of original biological medicines (known as the "reference product") which can be introduced into the market once exclusivity rights of the original product have expired. Biosimilars are sometimes incorrectly called "generic" versions of innovative biological medicines. Whilst generics are identical copies of chemically synthesised medicines, biosimilars are not identical and can only be highly similar to the original biological medicines.

Did you know that…

1 **Biological medicines, including biosimilars**, are derived from proteins, enzymes, antibodies and other substances naturally produced in the human body or other living organisms. For this reason, they are highly sensitive to minor changes in their physiological environment and potentially more variable than traditional small-molecule pharmaceuticals. This makes them more difficult to characterise and replicate.

2 **A single molecule of the active substance of a biological medicine is generally 200 – 1000 times bigger than** chemically-synthesised small molecule medicines. They are also structurally far more complex.

3 **Manufacturing biological medicines is complex and requires a highly controlled production process to** obtain consistent results and to guarantee the safety and efficacy of the medicine.

4 **In Europe, all biological medicines, including biosimilars, are assessed and regulated centrally by the European Medicines Agency (EMA).**
Whilst the EMA assesses whether a biosimilar demonstrates similar safety and efficacy as the reference medicine, the approval does not contain any assessment or recommendation regarding their interchangeability[1].

5 **Worldwide, nearly 200 biological medicines have contributed to the understanding and treatment of serious illnesses** such as cancer, blood conditions, auto-immune disorders – and neurological disorders.
In Europe, biosimilars represented about 1.5% of the total EU biological medicines market, and about 23.5% of the EU patent-free biological market in 2013.

[1] "Medical practice of changing one medicine for another that is expected to achieve the same clinical effect in a given clinical setting" in European Commission (2013), "What you need to know about biosimilar medicinal products. A Consensus Information Document".

EuropaBio brings together small and large biotechnology companies, many of whom are developing both novel biological medicines and biosimilar medicines. As biosimilars have an important role to play in fostering competition in the market place, and thereby contributing to the sustainability of healthcare budgets, **our members have a stake in ensuring the long-term sustainability of both sectors.** The following considerations deserve particular attention:

Distinguishable non-proprietary names for all biological medicines may enhance traceability

The use of International Non-proprietary Names (INN) of biosimilar products is currently not consistent in Europe, since some biosimilars bear the same INN as their reference product and others do not. Whilst the industry is concerned about the risk of misattribution of adverse events, the Commission is of the opinion that the traceability of biologics is appropriately addressed in the pharmacovigilance regulation. This framework, which came into force in July 2012, requires that all biologicals should be identified by the trade name and batch number. However, EuropaBio members believe that a distinguishable non-proprietary name for all biological medicines, including biosimilars, is a critical measure to further enhance effective pharmacovigilance and patient safety – within Europe and globally. The WHO's current development of a proposal for a biological qualifier for biological medicines (including biosimilar medicines) is an important step that, if designed appropriately, should strengthen the EU pharmacovigilance system – assuming EMA will apply the WHO policy.

Labelling is key to facilitate physicians' and patients' understanding of biosimilars

Biosimilars' labelling is currently governed by the EMA's QRD (Quality Review of Documents) guidance[2] which does not distinguish between biosimilars, generics and hybrid products in terms of labelling. The current approach foresees that the labelling of a biosimilar should be identical to that of the reference product. Since the development of each distinct biosimilar requires generating specific preclinical and clinical data, EuropaBio believes that a biosimilar's label should include information on the biosimilar and the reference product. We believe that a new guidance for transparent labelling for biosimilars will contribute to facilitate physicians and patients' understanding and acceptance of these products.

[2] "European Medicines Agency (2012) „ QRD general principles regarding the SmPC information for a generic/hybrid/biosimilar product" (EMA/627621/2011)

Determining the terms of use for biological medicines/biosimilars substitution

In the EU, decisions regarding (automatic) substitution at pharmacy level and prescription incentives lie within the responsibility of each Member State. At the point in time of publication of the European Commission's consensus information paper[3] in 2013, "no country has explicitly authorised the substitution of biological products from different manufacturers, and a number of EU Member States have put legal, regulatory, and political provisions in place that prevent this practice"[4]. EuropaBio believes that physicians' prescribing authority should be respected, as not all biosimilars will necessarily have all of the same indications, or the same administration devices as their reference medicine. As far as stable and well-treated patients are concerned, it is important that their specific therapeutic needs should always be considered, and that the potentially negative consequences of changing treatment for non-medical reasons should always be taken into consideration.

Focus on the Alliance for Safe Biologic Medicine's physician survey in Europe (2013)

At the end of 2013, the Alliance for Safe Biologic Medicine (ASBM) surveyed 470 European physicians from various specialties about their prescribing habits and understanding of biosimilars. Key findings of the survey highlight European physicians' insufficient knowledge of biosimilars, as well as the need for distinguishable International Non-proprietary Names (INNs) for all biological medicines as a means to further strengthen and facilitate patient safety through effective pharmacovigilance. The survey also provides important information regarding substitution. 72% of prescribers consider it "Critical" or "Very Important" to have the authority to decide whether a patient should receive an innovator biologic medicine or a biosimilar.

EuropaBio's call for action to EU decision-makers

1. Further strengthen measures to support accurate adverse event reporting in particular the correct attribution of an adverse event to a product in order to ensure patient safety and to contribute to global pharmacovigilance;
2. Protect patient-centric decision making by retaining physician choice and prescriber authority;
3. Ensure transparent labelling for biosimilars;
4. Enhance the education of physicians, healthcare professionals and patients on the specificities of biosimilars and their complexity compared to chemically-synthesized small molecule generic medicines.

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Avenue de l'Armée 6
1040 Brussels
Belgium
T. +32 2 735 03 13
F. +32 2 735 49 60
www.europabio.org
Twitter: @EuropaBio

[3-4] European Commission (2013), "What you need to know about biosimilar medicinal products. A Consensus Information Document"