biosimilar medicines
better access. better health.

Position Paper

Biosimilar Medicines Group Position on EuropaBio Paper

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Medicines for Europe and its Biosimilar Medicines Group took note of the EuropaBio paper on physician preference regarding biosimilar labels (SmPC)[1] which attempts to create an unnecessary differentiation between biosimilar medicines and their reference products, despite the stringent science-based EU approval process guaranteeing full comparability in efficacy and safety.

Biosimilar medicines are assessed and authorised based on a head-to head comparison and the 'totality of evidence' available, which includes the experience and knowledge gathered for the originator medicine and well captured in the 'same label' approach, which is consistent with the EU legal, scientific and regulatory framework.

The first part of the study clearly demonstrates the increased trust and acceptance by the medical community of biologics, including biosimilar medicines, in general as, according to the survey, 88,6% of doctors know what biosimilar medicines are and 59% have already prescribed biosimilar medicines as a high quality treatment for their patients. This is a major step forward compared to surveys of just two years ago and proves the robustness of the EU regulatory framework, which now has ten years of positive experience in approving these safe, high quality and efficacious biosimilar medicines.

Regrettably, the second part of the paper fails to acknowledge some fundamental elements:

- Healthcare Professionals (HCPs) and Patient communities have been voicing general concerns with product information (SmPC and PIL) for years. The study should therefore have analysed these information tools for all medicines, instead of focusing exclusively on biosimilar medicines. The value of this study could have been to draw conclusions on needed improvements on labels in general and for biologics more specifically. In doing so, the paper ignores the ongoing work in this field.
    - The European Commission and the European Medicines Agency (EMA), in line with pharmacovigilance legislation, are looking into ways to improve product information for all medicines (e.g. Nivel report).
    - Medicines for Europe collaborates with EFPIA and AESGP on making concrete proposals for the improvement of product information.
- The main HCP and patient community concerns appear to be the accessibility of information (where can it be found?) and the suitability of the information (is it understandable?). The availability of unbiased information from regulatory agencies is typically not an issue thanks to transparent policies where, for example, anyone can access the European Public Assessment Report for any centrally authorised medicine on the EMA website. HCPs and patients' communities also recognise that beyond labelling, further information and education resources are needed.

[1] Physicians prefer greater detail in the biosimilar label (SmPC) – Results of a survey across seven European countries, A.Hallersten et. al, http://www.sciencedirect.com/science/article/pii/S0273230016300654

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- Medicines for Europe is engaged in many multi-stakeholder platforms to facilitate the accessibility and understanding of the information.

- The objective of SmPC as set in the legislation is to inform on how to use a medicine and its content is defined by law. Biosimilars are only approved when the applicant has demonstrated that the biosimilar and the reference product have comparable safety and efficacy profiles and the biosimilar is authorised to be used in the same way as the reference product. Consequently, the label of the biosimilar has to be almost identical to the label of the reference product.
    - The US FDA recently published (March 2016) a draft labelling guidance which essentially confirms the 'same label' approach as the way forward for biosimilar medicines for this reason. In Europe additional information on every medicinal product authorised by the EU, including a detailed description of the clinical studies conducted, is available in the European Public Assessment Report on the homepage of the European Medicines Agency[2].
- The 'same label' approach is applied across biologic medicines labelling, e.g. labels for "original" biologic medicines are not currently reflecting the data generated during the life of the "original" product, particularly after manufacturing changes and line extensions, but contain only the information necessary to ensure safe and effective use.

Therefore, Medicines for Europe sees a number of opportunities for the industry, regulators and stakeholder communities to collectively engage in a broader reflection on how to further improve and enhance access and suitability of the information available on all medicines as a cornerstone to better access and health equality.

About the Biosimilar Medicines Group

The Biosimilar Medicines Group is a sector group of Medicines for Europe and represents the leading companies developing, manufacturing and marketing biosimilar medicines across Europe. Our members bring competition to the biologic medicines market, thereby increasing access to highly innovative medical treatments to patients in Europe and around the world, and supporting the sustainability of the European healthcare systems.

About Medicines for Europe

Medicines for Europe (formerly EGA) represents the generic, biosimilar and value added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members employ 160,000 people at over 350 manufacturing and R&D sites in Europe, and invest up to 17% of their turnover in medical innovation.

Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar

2 http://www.ema.europa.eu/ema/index.jsp?curl=/pages/medicines/landing/epar_search.jsp&mid=WC0b01ac058001d124

medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients.

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