EFPIA, EBE and EuropaBio welcome European Commission Consensus Information Document on biosimilars in the European pharmaceutical environment

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The European Federation of Pharmaceutical Industries & Associations (EFPIA), its specialised group the European Biopharmaceutical Enterprises (EBE) and the European Association for Bioindustries (EuropaBio) welcome the consensus information document on biosimilars that was approved by the European Commission Steering Group on Access to Medicines in Europe on 17th April. The Commission will present the document at the BIO international Convention in Chicago on 23rd April. The document discusses the specifics around biosimilar medicinal products, the requirements for their marketing authorization in the EU, their market performance, and the necessary conditions within the EU pharmaceutical market to ensure there is informed and adequate use of these medicines.

Some key highlights of the document findings include:

- Biosimilars enhance existing market competition in the European Union (EU) and may offer a less-costly alternative to existing biological medicinal products which have lost their exclusivity rights.
- Biosimilars are available in every EU member state, providing additional therapeutic options for physicians and patients.
- All classes of biosimilars are experiencing annual double-digit sales growth without automatic substitution, demonstrating the power of effective competition.
- Patients must be fully involved in the decision to take any biological medicine following thorough discussion with their prescribing doctor of all the treatment options.

"*We welcome this document which shows that biosimilars are not generic medicines, but a different and valued version of biological medicines which lose their market exclusivity. It is important to recognise how they are giving physicians and patients an additional treatment option while allowing payers to better manage healthcare expenses and enabling access to a larger number of patients"* explains Richard Bergström, EFPIA's Director General. *"This consensus information document highlights the importance of understanding the value of all biological medicines, including biosimilars, to help improve patient care and outcomes."*

"*EuropaBio supports the document's findings and will continue educating the public on the opportunities and challenges associated with biotechnology, including biologic and biosimilar medicines. The development and manufacturing process for all biologic medicines, including biosimilars, is more complex compared to the processes associated with generics and other chemical, small molecule products*," commented EuropaBio Secretary General Nathalie Moll. *"This is why it is important to maintain a robust regulatory and risk management framework, enhance label transparency and continue education on biosimilars and all biological medicines, to ensure that patients and physicians fully understand either type of therapy."*

The document's findings were formally approved by consensus from key stakeholders across Europe, including; European Commission, health reimbursement authorities from EU member states, patient, physician and payer representatives as well as industry representatives drawn from the key European trade bodies including EFPIA and EuropaBio.

The document shows that the price differentials between biosimilar medicinal products and their reference medicinal products have not been as substantial as expected and that the most important conditions for market uptake of biosimilars lie within the commercial marketplace in each country and not in forced utilisation measures such as automatic substitution, which is not authorised in any EU member state. *"Applying the generics approach to biological medicines would not be sensible because biological medicines, including biosimilars, are structurally more complex, thus making them similar, not identical. Furthermore automatic substitution of biologics or biosimilars would make post marketing surveillance more complicated, and determining potential lack of efficacy or suspected adverse events to specific molecules would be extremely difficult",* said Roberto Gradnik, President of EBE.

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Notes to Editors

Please view the Commission statement here

Biosimilars

A biosimilar is a biological medicine which is similar to another biological medicine that has already been authorised for use (the 'reference medicinal product'). A biosimilar and its reference medicinal product are expected to have the same safety and efficacy profile, and biosimilars are authorised either for all or select indications of the reference medicinal product on a case-by-case basis.

The Project Group on Market Access and Uptake of Biosimilars, which formally approved the findings of the research by consensus, included the European Commission, health reimbursement authorities from EU member states, as well as patient, payer and industry representatives drawn from the key European trade bodies in the form of EFPIA and EuropaBio.
In September 2010, the European Commission launched the Process on Corporate Responsibility in the field of Pharmaceuticals, focusing on, amongst other areas, non-regulatory conditions for better access to medicines following their marketing authorisation.
Under its Platform, "Access to Medicines in Europa", Member States, EEA countries and relevant stakeholders were invited to join the Project Group on Market Access and Uptake of Biosimilars, in order to take stock of the availability of biosimilar medicinal products in European national markets and define the necessary conditions for informed and adequate patient access to these products. As well as looking into topics related to improving information about the concept of biosimilar medicinal products, the group also looked at the science and process behind approval. All aspects related to interchangeability and/or substitutions were deemed to be outside of the project group's scope.
In close cooperation with the Commission, the group developed a report that provides patients, physicians and payers with adequate information on biosimilar medicinal products. The European Medicines Agency also contributed to the paper.
In addition to the European Commission, EFPIA and EuropaBio, The Project Group on Market Access and Uptake of Biosimilars includes: European Patients Forum (EPF); Bureau Européen des Unions de Consommateurs (BEUC); Standing Committee of European Doctors (CPME); European Hospital and Healthcare Federation (HOPE); Association Internationale de la Mutualité (AIM); European Social Insurance Platform (ESIP); and European Generic medicines Association (EGA).

The Project Group's report and other relevant materials (including an IMS survey on the uptake of biosimilars in the various EU and EEA member states) is available on the Commission website (hyperlink to be added). The project Group on access and uptake of biosimilars is one the six project groups set up in the context of Vice-President Tajani platform on access to medicines in Europe, whose scope aims at enhancing collaboration among member states and relevant stakeholders in order to find common, non regulatory approaches to timely and equitable access to medicines after marketing authorisation. The other project groups, whose outcomes should be available on the Commission's website in the coming weeks, focus on capacity building on managed entry agreements for innovative medicines, mechanism of coordinated access to orphan medicinal products, facilitating supply in small markets, promoting good governance for non-prescription medicines and identify areas of highest medical needs.