EU pharmaceutical legislation reform critical to sustain biosimilar medicines competition for the future

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The EU plans to update its 20-year-old pharmaceutical legislation early next year to improve access to medicines and to make innovation more affordable. The introduction of biosimilar medicines was one of the pioneering and most successful reforms of the previous legislation in 2004. Now we need to update the legislation to make it fit for the future.

The smart use of biosimilar medicines increases the number of treated patients and can encourage huge investments in R&D in Europe. This contributes to lower healthcare budgets. The first biosimilar medicine was introduced over 15 years ago, starting a transformation in therapy by offering broader and earlier access to life-changing biological therapies. Grassroots cooperation among stakeholders was also a key success factor for the uptake of biosimilar medicines in Europe. The success of biosimilar medicines access will be further supported by the recent European Medicines Agency (EMA-HMA) publication that healthcare professionals and patients can confidently choose from any authorised version of a biological medicine.

Looking forward, the cancer and other non-communicable disease communities are calling for more integrated care frameworks for patients. This can be enabled by the use of biosimilar medicines. The €18 billion (at list price meaning that real savings are higher) savings biosimilar medicines have generated for European health systems can be reinvested in better care pathways to improve patient outcomes. The reform of EU pharmaceutical legislation can guarantee future biosimilar medicines competition by updating EU regulations with the latest scientific regulatory developments in the field.

Commenting ahead of the Biosimilar medicines conference BIOS22, the **Chair of the Biosimilar medicines group, Isabell Remus (Sandoz)** said: "*We are on the verge of an unprecedented opportunity to drive further patient access to life-changing biologic medicines. About one in two medicines that will face competition in Europe in the next decade is a biologic. We owe it to the patients and healthcare systems we serve to grasp this opportunity with both hands. The time for action is now: the revision of the EU pharmaceutical legislation is a unique chance to create a framework that supports the development and authorisation of biosimilars – ensuring patients can benefit from their full potential over the next 20 years.*"

Resource hub

Policy experts will discuss the future of biosimilar medicines at the Biosimilar medicines group Conference BIOS22 in Brussels on October 6-7. For more information about the event, see https://www.medicinesforeurope.com/events/bios22/

A dedicated podcast on the role of biosimilar medicines in integrated care can be accessed at https://www.youtube.com/watch?v=AVkQyZxMfGw

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

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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.