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Press release

New guide on biosimilar medicines for healthcare professionals

Increasing understanding of biosimilar medicines

The European Medicines Agency (EMA) and the European Commission have published an information guide for healthcare professionals on biosimilar medicines. Biosimilars are biological medicines that are highly similar in all essential aspects to a biological medicine that has already been authorised.

The objective of the guide is to provide healthcare professionals with reference information on both the science and regulation underpinning the use of biosimilars.

“Today, biosimilars are an integral part of the effective biological therapies available in the EU,” said Professor Guido Rasi, EMA’s Executive Director. “Given the role of healthcare professionals on the front line of patient care, it is vital that they have access to reliable information on these medicines: what they are and how they are developed, approved and monitored.”

The guide is a joint initiative of EMA and the European Commission. It was developed in collaboration with EU scientific experts, in response to requests from healthcare professionals. Organisations from across the EU representing doctors, nurses, pharmacists and patients have also shared useful views, to ensure that the guide adequately addresses questions relevant to healthcare professionals.

The guide was launched today at the European Commission’s third stakeholder event on biosimilar medicines, a discussion forum that provides a platform for stakeholders interested in biosimilars, including healthcare professionals, patients, payers, regulators and industry.

Presenting the guide at the launch, Dr Juan Garcia Burgos, head of EMA’s Public Engagement Department emphasised that “this comprehensive reference material is a joint effort to support information and continuous education of healthcare professionals in the EU, and facilitate dialogue with patients.”

The EU has pioneered the regulation of biosimilar medicines by establishing a solid framework for their approval and by shaping biosimilar development globally.

Since the EU approved the first biosimilar in 2006, the evidence gained from clinical experience shows that biosimilars approved in the EU are as safe and effective in all their approved indications as other

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biological medicines. To date, the Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended 28 biosimilars for use in the EU.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Read more on biosimilar medicines here: http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/document_listing/document_listing_000318.jsp&mid=WC0b01ac0580281bf0.
3. See also the European Commission's Q&A on biosimilar medicines for patients: http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=9066
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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