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Press Office

Press release

European Medicines Agency recommends approval of first two monoclonal antibody biosimilars

Recommendation marks extension of biosimilar concept to new product-class

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended granting of marketing authorisations for the first two monoclonal antibody biosimilars.

Remsima and Inflectra both contain the same known active substance, infliximab. In the application dossiers, they have been shown to be similar to the biological medicine Remicade, a monoclonal antibody that has been authorised in the European Union since 1999. Remsima and Inflectra are recommended for authorisation in the same indications as Remicade, covering a range of autoimmune diseases such as rheumatoid arthritis, Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and and psoriasis.

Monoclonal antibodies are structurally complex substances that can locate and bind to specific molecules, in the case of infliximab to tumour necrosis factor (TNF) alpha, a protein promoting inflammatory response, which causes many of the clinical problems associated with autoimmune disorders. It is the first time that the biosimilar concept has been successfully applied to such a complex molecule, resulting in the recommended approval of a biosimilar version of infliximab. The biosimilar concept foresees that a biological medicine can be authorised if it can be demonstrated that it is a close copy of a biological medicine that has already been authorised for use in the European Union.

Since the approval of the first biosimilar medicine in Europe in 2006, the regulatory framework in place for the approval of biosimilars has produced a total of 12 authorised biosimilar medicines. The framework consists of a number of overarching guidelines which define and describe key concepts of biosimilar development programmes. The overarching guidelines are complemented by product-specific guidelines, which give more detailed guidance to applicants in relation to the respective class of products.

The product-specific guideline for monoclonal antibodies has been in force since December 2012. As for all biosimilars, the emphasis in the development programme is on demonstrating comparability to the reference medicine. An applicant has to submit studies to the Agency that show that the medicine is a

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biosimilar of the reference medicine, i.e. that it does not have any meaningful differences from the reference medicine in terms of its quality, safety and efficacy.

Applicants are also required to implement a risk-management plan to confirm the long-term efficacy and safety of a biosimilar, including the detection of any unexpected rare adverse effects when the medicine is used in clinical practice.

The CHMP opinions on Remsima and Inflectra will now be sent to the European Commission for adoption of a marketing-authorisation decision.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Remsima is Celltrion Healthcare Hungary Kft. The applicant for Inflectra is Hospira UK Limited.
3. More information on biosimilar medicines is available: http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/document_listing/document_listing_000318.jsp&mid=WC0b01ac0580281bf0 .
4. All biosimilar guidelines establishing the regulatory framework for biosimilar medicines can be found here: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000408.jsp&mid=WC0b01ac058002958c
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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