Biosimilar medicinal products

Biological medicinal products have a successful record in treating serious and chronic diseases.

The recent expiry of data protection/ patents for the first original biotherapeutics has led to the development and authorisation of copy versions, termed 'similar biological medicinal products' (biosimilars) by the European Medicines Agency in the European Union (EU).

The principles of biosimilar drug development apply in general to all biological medicinal products.

So far, guidance for the development of biosimilar products has been developed for seven different product classes, with two more currently being drafted.

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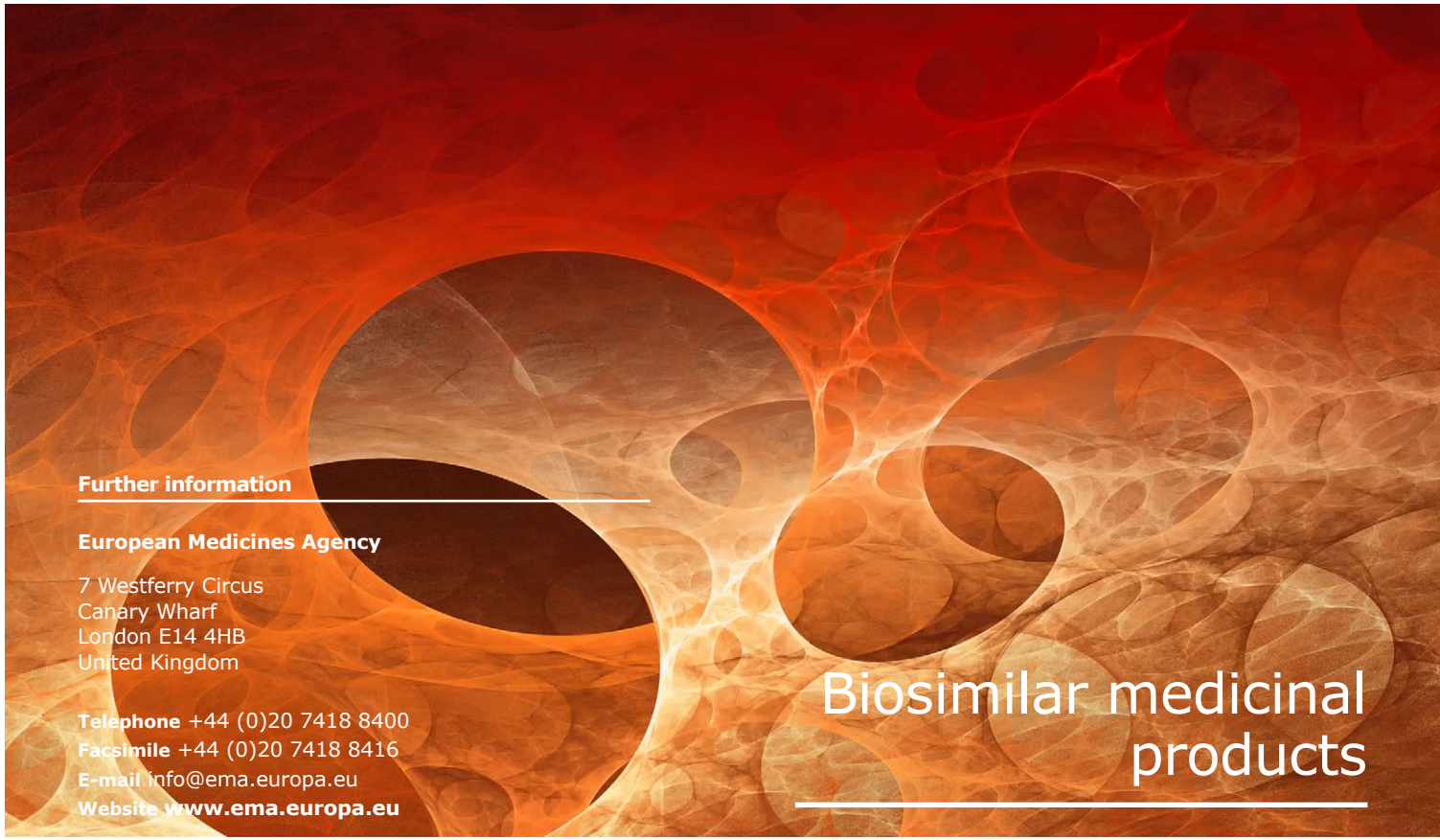

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The Committee for Medicinal Products for Human Use (CHMP) is responsible for preparing the European Medicines Agency's opinions on all questions concerning medicines for human use. The CHMP works with other committees and working parties.

Working parties

The Working Party on Similar Biological Medicinal Products (BMWP), together with the Biologicals Working Party (BWP), has been working under the mandate of the CHMP on the European Union's regulatory scientific framework for biosimilars.

A science-based regulatory framework to ensure high-quality biosimilars in the EU has been established since 2005, and is monitored and updated on an ongoing basis.

The safety and efficacy of medicines, including biosimilars, are coordinated by the Agency's Safety and Efficacy Sector, which also provides secretarial support (scientific and administrative) to the BMWP.

The BMWP focuses on safety and efficacy aspects of similar biological medicinal products and scientific-advice applications received by the Agency, and on related topics and guidelines.

The BMWP is composed of delegates and experts from the EU Member States, meets twice a year in person and holds regular teleconferences in those months when there is no physical meeting.

The Biologicals Working Party (BWP), the Safety Working Party (SWP) and occasionally other specialised working parties are also involved with biosimilars, as is the Pharmacovigilance Risk Assessment Committee (PRAC).

The composition of these groups varies, and their focus is more on safety/efficacy or multi-disciplinary aspects, with the BWP covering quality aspects.

To facilitate a common understanding and efficient operation of the activities of these groups, regular coordination meetings are organised that include all concerned parties.

Scientific feedback/advice

As well as providing draft scientific opinions (at the request of the CHMP) and other scientific activities, the working parties are involved in briefing meetings with sponsors. These meetings are an opportunity for a less formal exchange on technology/scientific issues, outside of the scientific-advice procedure.

The working parties also prepare guidance for industry, which is adopted by the CHMP.

Agency staff can respond to queries on administrative, regulatory and scientific issues related to biosimilars submitted via the 'Send a question' links on the Agency's website.

Biosimilar guidelines

Biosimilar medicines is a growing field. The Agency has established a portfolio of guidance to support the increasing number of applications it is receiving for biosimilar-related marketing authorisations and scientific advice.

Guidance published, or being developed, by the Agency includes overarching biosimilar guidance, non-clinical and clinical aspects for the development of biosimilars, and product-class-specific guidelines in the areas of:

- epoetins;
- filgrastims;
- insulins;
- growth hormones;
- alfa interferons;
- monoclonal antibodies;
- beta interferons;
- follitropins;
- low-molecular-weight heparins (LMWH).

However, the principles of biosimilar drug development apply in general to all biological medicinal products.

Resources on the Agency's website

CHMP working parties

About us > Working parties and other groups > CHMP

Biosimilar medicines

Special topics > Biosimilar medicines

Scientific advice

Regulatory > Human medicines > Scientific advice and protocol assistance > Scientific advice

Guidelines

Regulatory > Human medicines > Scientific guidelines > Multidisciplinary > Biosimilar

Send a question to the Agency

About us > Contacts > Send a question