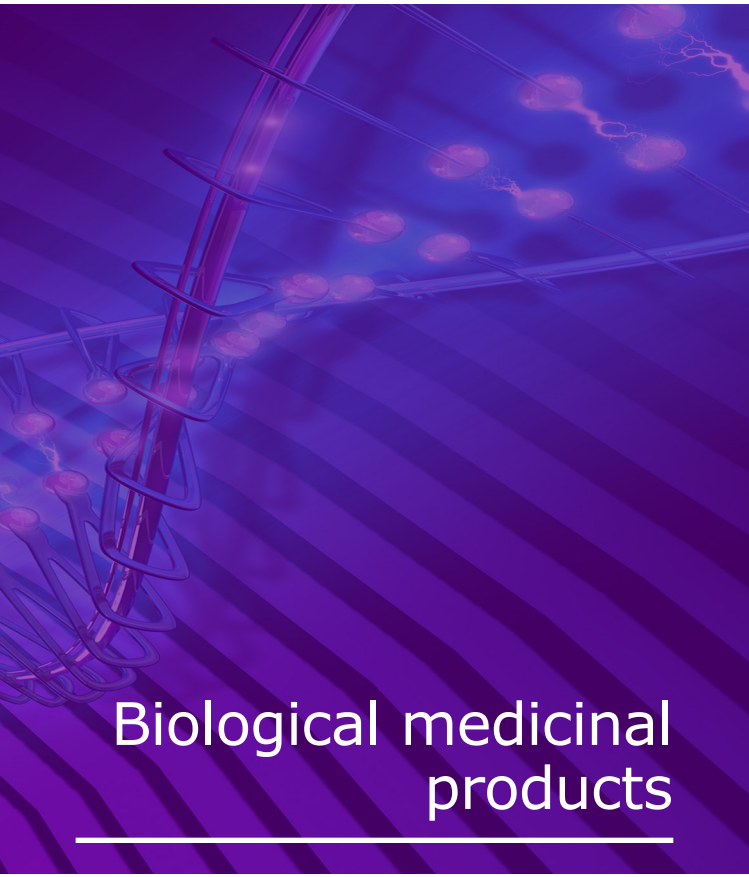
EUROPEAN MEDICINES AGENCY

SCIENCE MEDICINES HEALTH



Biological medicinal products

An agency of the European Union

Biological medicinal products

Biological medicinal products cover a continually evolving and diverse field. In the European Union (EU), many of these are under the responsibility of the European Medicines Agency (EMA) and are authorised via the centralised marketing authorisation procedure, such as products manufactured using biotechnology or advanced therapy medicinal products (ATMPs). Others (e.g. naturally derived biologicals) may be nationally authorised in individual Member States, rather than through the pan-European centralised procedure.

Due to the diverse nature of biological medicinal products, a number of specialised groups have been established within the Agency to supervise and coordinate activities related to these products.

In order to benefit from the best available expertise for the evaluation and assessment of biological medicinal products, EMA involves its committees and working parties, including experts from all over Europe, providing coordination, and scientific and administrative support.

Scientific committees

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

The Committee for Advanced Therapies (CAT) is responsible for preparing draft opinions on ATMP applications submitted to the Agency, with final adoption of opinions by the CHMP.

Working parties

The quality of biological medicinal products is overseen by the CHMP's Biologics Working Party (BWP). The BWP considers the quality aspects of all biological medicinal products and scientific advice applications at the Agency, as well as related topics and guidelines.

A number of other working parties are involved with biological medicinal products, such as the Blood Products (BPWP), Vaccines (VWP), Pharmacogenomics (PgWP) and Biosimilars (BMWP) Working Parties. The focus of these groups is on safety, efficacy or methodological aspects, with multidisciplinary input as needed (e.g. with quality in conjunction with the BWP).

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 stakeholders. These meetings can provide an opportunity for a less formal exchange on technology/scientific issues, outside of the scientific advice procedure.

Further opportunities to receive feedback are through the Innovation Task Force and at business pipeline meetings.

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

Biologicals guidelines

The working parties prepare guidance for industry, which is adopted by the CHMP or, in the case of ATMPs, the CAT.

Quality aspects developed by the BWP cover areas such as process development, validation, comparability, as well as viral and transmissible spongiform encephalopathies safety for biotechnology, plasma-derived, vaccine and other biological products.

Other working parties maintain discipline-specific guidelines, such as the VWP and BPWP who are responsible for guidelines on safety and efficacy aspects of vaccines and blood products, respectively.

These guidelines (and those of other working

parties) can be found on the Agency's website.

Biosimilar medicines continue to be a growing field and come under the responsibility of the BMWP and BWP. The Agency has been at the forefront in this area, establishing a portfolio of guidance and providing advice and support to applicants and international regulators and other stakeholders in recent years.

Resources on the Agency's website

CHMP working parties — Committees > Working parties and other groups > CHMP

Scientific advice — Human Regulatory > Scientific advice and protocol assistance

Innovation Task Force — Human Regulatory > Innovation Task Force

Guidelines — Human Regulatory > Scientific guidelines > Biologicals //

Clinical safety and efficacy > Blood products //

Multidisciplinary > Vaccines

Advanced therapies — Human Regulatory > Advanced therapies

Public Health threats and Pandemic influenza — News and Events > Public health threats and pandemics

Plasma master files (PMF) — Human Regulatory > Non-pharmaceutical products > Plasma master file

Send a question to the Agency — About us > Contact > Send a question

Business Pipeline — businesspipeline@ema.europa.eu

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