Human medicines in 2025

15 January 2026

104 new medicines recommended for approval; 38 had a new active substance

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In 2025, EMA recommended 104 medicines for marketing authorisation. Of these, 38 had a new active substance which had never been authorised in the European Union (EU) before. This includes medicines representing important innovation or contribution to public health, such as the first medicine to treat non-cystic fibrosis bronchiectasis, a first-in-class treatment to delay the onset of stage 3 type 1 diabetes in children and adults, and the first oral medicine to treat postpartum depression following childbirth.

EMA also recommended 16 medicines for rare diseases, including the first medicine to treat Wiskott-Aldrich syndrome, a rare, inherited disease of the immune system, that affects almost exclusively males, and a disease-modifying gene therapy applied as a topical gel to treat wounds in patients of all ages with a rare condition that makes the skin very fragile (dystrophic epidermolysis bullosa).

EMA also adopted three positive opinions for medicines for use in countries outside the EU, including a medicine for pre-exposure prophylaxis (PrEP) in combination with safer sex practices to reduce the risk of sexually acquired human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents. This medicine will facilitate PrEP uptake and compliance because it only has to be administered twice a year via a subcutaneous injection.

There were also 41 recommendations for new biosimilar products. Biosimilars are interchangeable with reference products, making them a core part of the healthcare system for managing costs and expanding access to essential treatments.

The overview of the 2025 key recommendations published today includes figures on the authorisation of medicines and a selection of new treatments that represent significant progress in their therapeutic areas.

Once a medicine is authorised by the European Commission and prescribed to patients, EMA and the EU Member States continuously monitor its quality and benefit-risk balance and take regulatory action when needed. Measures can include a

change to the product information, the suspension or withdrawal of a medicine, or a recall of a limited number of batches. An overview of some of the most notable safety-related recommendations is also included in the document.

Related documents

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