Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 14-17 October 2019

Share

News 18/10/2019

**Seven new medicines recommended for approval, including the first Ebola vaccine**

EMA’s human medicines committee ([CHMP](https://www.ema.europa.eu/en/glossary/chmp)) recommended seven medicines for approval at its October 2019 meeting.

The Committee recommended granting a [conditional marketing authorisation](https://www.ema.europa.eu/en/glossary/conditional-marketing-authorisation) for **Ervebo** (Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live)), the first vaccine for active immunisation of individuals aged 18 years and older at risk of infection with the Ebola virus. “This is an important step towards relieving the burden of this deadly disease. The [CHMP](https://www.ema.europa.eu/en/glossary/chmp)’s recommendation is the result of many years of collaborative global efforts to find and develop new medicines and vaccines against Ebola,” said Guido Rasi, EMA’s Executive Director.

Ervebo was supported through EMA’s PRIority MEdicines (PRIME) scheme and reviewed under the Agency’s [accelerated assessment](https://www.ema.europa.eu/en/glossary/accelerated-assessment) programme. For more information, please see the press release in the grid below.

The [CHMP](https://www.ema.europa.eu/en/glossary/chmp) recommended granting a [marketing authorisation](https://www.ema.europa.eu/en/glossary/marketing-authorisation) for **Baqsimi** (glucagon), the first treatment for severe hypoglycaemia (low blood sugar level) that can be administered without an injection in patients with diabetes aged four years and older. For more information, please see the press release in the grid below.

**Quofenix** (delafloxacin) received a positive opinion from the [CHMP](https://www.ema.europa.eu/en/glossary/chmp) for the treatment of acute bacterial skin and skin structure infections in adults when it is considered inappropriate to use other antibacterial agents.

The Committee recommended granting a [marketing authorisation](https://www.ema.europa.eu/en/glossary/marketing-authorisation) for **Rinvoq**(upadacitinib) for the treatment of rheumatoid arthritis.

**Spravato** (esketamine) received a positive opinion for combination treatment in adults with treatment-resistant major depressive disorder.

The [biosimilar medicine](https://www.ema.europa.eu/en/glossary/biosimilar-medicine) **Pegfilgrastim Mundipharma** (pegfilgrastim), intended to reduce the duration of neutropenia (low levels of neutrophils, a type of white blood cell) and the incidence of febrile neutropenia due to chemotherapy, received a positive opinion from the Committee.

**Positive recommendation on a new medicine following**[**re-examination**](https://www.ema.europa.eu/en/glossary/re-examination)

The [CHMP](https://www.ema.europa.eu/en/glossary/chmp) recommended granting a [marketing authorisation](https://www.ema.europa.eu/en/glossary/marketing-authorisation) for **Evenity** (romosozumab), a monoclonal antibody therapy for the treatment of postmenopausal women with severe osteoporosis at high risk of fracture. The Committee had initially adopted a negative opinion for this medicine in June 2019 due to safety concerns. After [re-examination](https://www.ema.europa.eu/en/glossary/re-examination), the [CHMP](https://www.ema.europa.eu/en/glossary/chmp) granted a positive opinion for a restricted [indication](https://www.ema.europa.eu/en/glossary/indication). Additional measures and studies are foreseen to follow its use in practice and to ensure that the medicine is used correctly.

For more information on this positive opinion following [re-examination](https://www.ema.europa.eu/en/glossary/re-examination), please see the question-and-answer document in the grid below.

**Negative opinions on new medicines**

The [CHMP](https://www.ema.europa.eu/en/glossary/chmp) adopted a negative opinion recommending the refusal of a [marketing authorisation](https://www.ema.europa.eu/en/glossary/marketing-authorisation) for **Hopveus**(sodium oxybate). Hopveus was expected to be used to treat alcohol dependence in patients in whom other treatments are not effective or cannot be used.

The Committee also adopted a negative opinion for **Vanflyta** (quizartinib). Vanflyta was expected to be used to treat adults with acute myeloid leukaemia (a cancer of the white blood cells).

For more information on these negative opinions, please see the question-and-answer documents in the grid below.

**Four recommendations on extensions of therapeutic**[**indication**](https://www.ema.europa.eu/en/glossary/indication)

The Committee recommended extensions of [indication](https://www.ema.europa.eu/en/glossary/indication) for **Darzalex**, **Kalydeco**, **Keytruda** and **Toujeo**.

**Negative opinions on extension of therapeutic**[**indication**](https://www.ema.europa.eu/en/glossary/indication)**following**[**re-examination**](https://www.ema.europa.eu/en/glossary/re-examination)

The applicants for **Revolade** (eltrombopag) and **Translarna** (ataluren) requested [re-examination](https://www.ema.europa.eu/en/glossary/re-examination) of the Committee's negative opinions issued in June 2019 to extend the therapeutic [indications](https://www.ema.europa.eu/en/glossary/indication) of these medicines. After considering the grounds for these requests, the [CHMP](https://www.ema.europa.eu/en/glossary/chmp) re-examined the two initial opinions and confirmed its previous recommendations.

For more information on these negative opinions, please see the question-and-answer documents in the grid below.

**Update on nitrosamine impurities**

EMA has updated the [questions-and-answers document](https://www.ema.europa.eu/en/documents/referral/nitrosamines-emea-h-a53-1490-questions-answers-information-nitrosamines-marketing-authorisation_en.pdf) for [marketing authorisation holders](https://www.ema.europa.eu/en/glossary/marketing-authorisation-holder) who are currently reviewing their medicines for the possible presence of nitrosamines and testing products at risk. The updated document lists potential sources of nitrosamine contamination that have been identified to date. This information can support companies in their ongoing review of their manufacturing processes.

For information on the review, please see [our website](https://www.ema.europa.eu/en/news/ema-advises-companies-steps-take-avoid-nitrosamines-human-medicines).

**Withdrawals of applications**

Applications for initial [marketing authorisations](https://www.ema.europa.eu/en/glossary/marketing-authorisation) for **Ekesivy** (diclofenamide) and **Nuzyra** (omadacycline) have been withdrawn. Ekesivy was intended for the treatment of a rare muscle disorder called periodic paralysis. Nuzyra was intended for the treatment of community-acquired bacterial pneumonia (lung infection caught outside hospitals) and bacterial infections of the skin and skin structures (the tissue immediately beneath the skin).

An application for an initial [marketing authorisation](https://www.ema.europa.eu/en/glossary/marketing-authorisation) for **Xyndari** (glutamine), for the treatment of sickle cell disease (an inherited form of anaemia), has also been withdrawn. The [CHMP](https://www.ema.europa.eu/en/glossary/chmp) adopted a negative opinion for this medicine in May 2019. At the time of withdrawal, this recommendation was under [re-examination](https://www.ema.europa.eu/en/glossary/re-examination) at the company’s request.

Question-and-answer documents on these withdrawals are available in the grid below.

**Thousandth GCP inspection performed**

On 7 October 2019, the 1,000th[good clinical practice](https://www.ema.europa.eu/en/glossary/good-clinical-practice) (GCP) inspection requested by the [CHMP](https://www.ema.europa.eu/en/glossary/chmp) and coordinated by EMA was performed at a clinical investigator site in Toronto (Canada) by inspectors from Austria and Poland.

GCP is an international ethical and scientific quality standard for conducting [clinical trials](https://www.ema.europa.eu/en/glossary/clinical-trial) involving the participation of human subjects. GCP inspections are an essential tool for verifying compliance and providing public assurance that the rights, safety and wellbeing of the participants are protected, and that clinical-trial data are credible.

The GCP inspection programme started in 1997. Since then, GCP inspections of [clinical trials](https://www.ema.europa.eu/en/glossary/clinical-trial) submitted to the Agency have taken place in 70 countries. More information is available in [this infographic](https://www.ema.europa.eu/documents/leaflet/infographic-1000-gcp-inspections-requested-chmp_en.pdf) .

**Agenda and minutes**

The agenda of the October 2019 meeting is published on EMA's website. Minutes of the September 2019 [CHMP](https://www.ema.europa.eu/en/glossary/chmp) meeting will be published in the coming weeks.

[**CHMP**](https://www.ema.europa.eu/en/glossary/chmp)**statistics**

Key figures from the October 2019 [CHMP](https://www.ema.europa.eu/en/glossary/chmp) meeting are represented in the graphic below.