Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 22-25 July 2019

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**Five new medicines recommended for approval**

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

The Committee recommended granting a [conditional marketing authorisation](https://www.ema.europa.eu/en/glossary/conditional-marketing-authorisation) for **Vitrakvi** (larotrectinib), the first ‘histology-independent’ treatment in the European Union for solid tumours with a neurotrophic tyrosine receptor kinase (NTRK) gene fusion. NTRK gene fusions occur very frequently in a number of rare cancers. For more information, please see the press release in the grid below.

The [CHMP](https://www.ema.europa.eu/en/glossary/chmp) granted a positive opinion for **Epidyolex\*** (cannabidiol) for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome, two forms of epilepsy. Epidyolex contains an [active substance](https://www.ema.europa.eu/en/glossary/active-substance) derived from cannabis and is the first to receive a positive opinion in the EU [centralised procedure](https://www.ema.europa.eu/en/glossary/centralised-procedure).

**Inbrija** (levodopa) received a positive opinion for the treatment of symptoms of ‘off’ periods in Parkinson’s disease.

The Committee adopted a positive opinion for **Trogarzo** (ibalizumab), for the treatment of HIV infection.

The [CHMP](https://www.ema.europa.eu/en/glossary/chmp) recommended for approval the [generic medicine](https://www.ema.europa.eu/en/glossary/generic-medicine) **Deferasirox Mylan** (deferasirox), for the treatment of chronic iron overload due to blood transfusions in patients with beta thalassaemia major, non-transfusion-dependent thalassaemia syndromes and other anaemias.

**Start of re-examination of recommendation for new medicine**

The applicant for **Evenity** (romosozumab) has requested a [re-examination](https://www.ema.europa.eu/en/glossary/re-examination) of the Committee's negative opinion for this medicine adopted at the June 2019 meeting. The [CHMP](https://www.ema.europa.eu/en/glossary/chmp) will re-examine the opinion and issue a final recommendation. For more information on this negative opinion, please see the question-and-answer document in the grid below.

**Eight recommendations on extensions of therapeutic indication**

The Committee recommended extensions of [indication](https://www.ema.europa.eu/en/glossary/indication) for **Empliciti, Keytruda, Lonsurf, Lucentis, Soliris, Stelara, Tecentriq and Zerbaxa**.

**Start of re-examination of recommendations on extension of therapeutic indications**

The applicants for **Revolade** (eltrombopag) and **Translarna** (ataluren) have requested [re-examination](https://www.ema.europa.eu/en/glossary/re-examination) of the Committee's negative opinions for these medicines adopted at the June 2019 meeting. The [CHMP](https://www.ema.europa.eu/en/glossary/chmp) will re-examine the opinions and issue final recommendations. For more information on these negative opinions, please see the question-and-answer documents in the grid below.

**Updated restrictions for Gilenya**

The [CHMP](https://www.ema.europa.eu/en/glossary/chmp) recommended that the multiple sclerosis medicine Gilenya (fingolimod) must not be used in pregnant women and in women able to have children who are not using effective contraception. If a woman becomes pregnant while using Gilenya, the medicine must be stopped and the pregnancy will have to be closely monitored. This is because the [active substance](https://www.ema.europa.eu/en/glossary/active-substance) in Gilenya, fingolimod, can harm the unborn baby and may cause birth defects. For more information, please see the public health recommendation in the grid below.

**Agenda and minutes**

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

**CHMP statistics**

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

\*This product was designated as an [orphan medicine](https://www.ema.europa.eu/en/glossary/orphan-medicine) during its development. [Orphan designations](https://www.ema.europa.eu/en/glossary/orphan-designation) are reviewed by EMA's [Committee for Orphan Medicinal Products](https://www.ema.europa.eu/en/glossary/committee-orphan-medicinal-products) ([COMP](https://www.ema.europa.eu/en/glossary/comp)) at the time of approval to determine whether the information available to date allows maintaining the medicine's orphan status and granting the medicine ten years of [market exclusivity](https://www.ema.europa.eu/en/glossary/market-exclusivity).