Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 11-14 November 2019 (updated)

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News 15/11/2019

**Seven new medicines recommended for approval**

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

The Committee recommended granting a [marketing authorisation](https://www.ema.europa.eu/en/glossary/marketing-authorisation) for **Isturisa**\* (osilodrostat) for the treatment of Cushing’s syndrome, a rare disorder that occurs when the body produces too much corticosteroid hormone. It leads to patients experiencing weight gain, fat build-up on the face and bruising.

**Mayzent** (siponimod) received a positive opinion for the treatment of adult patients with secondary progressive multiple sclerosis with active disease evidenced by relapses or imaging features of inflammatory activity.

The Committee recommended granting a [conditional marketing authorisation](https://www.ema.europa.eu/en/glossary/conditional-marketing-authorisation) for **Polivy**\* (polatuzumab vedotin) for the treatment of relapsed/refractory diffuse large B-cell lymphoma, a rare type of cancer of the white blood cells. Polivy was supported through EMA’s PRIority MEdicines (PRIME) scheme.\*\*

The [CHMP](https://www.ema.europa.eu/en/glossary/chmp) adopted a positive opinion for **Sunosi** (solriamfetol), for the treatment of excessive daytime sleepiness in patients with narcolepsy (a sleep disorder that causes a person to fall asleep suddenly and unexpectedly) and obstructive sleep apnoea (interruption of breathing).

**Tavlesse** (fostamatinib) received a positive opinion from the [CHMP](https://www.ema.europa.eu/en/glossary/chmp) for the treatment of primary immune thrombocytopenia. This is an acquired immune-mediated disorder characterised by the destruction of platelets and impaired platelet production.

The [CHMP](https://www.ema.europa.eu/en/glossary/chmp) recommended granting [marketing authorisations](https://www.ema.europa.eu/en/glossary/marketing-authorisation) for two [generic medicines](https://www.ema.europa.eu/en/glossary/generic-medicine): **Clopidogrel/Acetylsalicylic acid Mylan** (clopidogrel / acetylsalicylic acid), for the secondary prevention of atherothrombotic events (problems caused by blood clots and hardening of the arteries); and **Deferasirox Accord** (deferasirox), for the treatment of chronic iron overload due to blood transfusions in patients with beta thalassaemia and other anaemias.

**Start of**[**re-examination**](https://www.ema.europa.eu/en/glossary/re-examination)**of recommendation for new medicine**

The applicant for **Hopveus** (sodium oxybate) 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 October 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.

**Two 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 **Kadcyla**and**Revlimid**.

**Outcome of review on Lemtrada**

The Committee recommended restricting the use of the multiple sclerosis medicine Lemtrada (alemtuzumab) due to reports of rare but serious side effects, including deaths. New measures to identify and manage the serious side effects are also recommended. The side effects include cardiovascular disorders (affecting the heart, circulation and bleeding as well as stroke) and immune-related disorders (caused by the body’s defence system not working properly).

For more information, please see the public health recommendation in the grid below.

**Outcome of review on Xeljanz**

The [CHMP](https://www.ema.europa.eu/en/glossary/chmp) concluded that Xeljanz (tofacitinib) could increase the risk of blood clots in the lungs and in deep veins in patients who are already at high risk. As a result, the Committee recommended that Xeljanz should be used with caution in all patients at high risk of blood clots. In addition, the maintenance doses of 10 mg twice daily should not be used in patients with ulcerative colitis who are at high risk of blood clots unless there is no suitable alternative treatment. Due to an increased risk of infections, patients older than 65 years of age should be treated with Xeljanz only when there is no alternative treatment.

For more information, please see the public health recommendation in the grid below.

**Withdrawals of applications**

Applications for initial [marketing authorisations](https://www.ema.europa.eu/en/glossary/marketing-authorisation) for **Linhaliq**(ciprofloxacin) and **Luxceptar** (viable T-cells) have been withdrawn. Linhaliq was intended for the treatment and prevention of flare-ups of non-cystic fibrosis bronchiectasis in patients with long-term lung infection caused by *Pseudomonas aeruginosa*bacteria. Luxceptar was intended for the treatment of patients with blood cancers who are receiving a type of blood stem cell transplant.

The application to extend the use of **Opsumit**(macitentan) to treat chronic thromboembolic pulmonary hypertension, a condition that causes high blood pressure in the lungs, was also withdrawn.

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

**Agenda and minutes**

The agenda of the November meeting is published on EMA's website. Minutes of the October 2019 [CHMP](https://www.ema.europa.eu/en/glossary/chmp" \t "_blank" \o "Committee for Medicinal Products for Human Use -  the committee that is responsible for preparing the Agency's opinions on questions concerning human medicines.   More information can be found under 'Committee for Medicinal Products for Human Use (CHMP)'.)meeting will be published in the coming weeks.

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

Key figures from the November 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).