Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 16-19 September 2019

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**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 September 2019 meeting.

The Committee recommended granting a [marketing authorisation](https://www.ema.europa.eu/en/glossary/marketing-authorisation) for **Xospata**\* (gilteritinib) for the treatment of adult patients who have relapsed or refractory acute myeloid leukaemia (AML) with a FLT3 mutation. AML is a rare type of cancer of the white blood cells (cells that fight infections). It affects approximately 1 in 10,000 people in the European Union. Xospata was reviewed under EMA's [accelerated assessment](https://www.ema.europa.eu/en/glossary/accelerated-assessment) procedure, reserved for medicines of major public health interest.

**Qtrilmet** (metformin hydrochloride / saxagliptin / dapagliflozin) received a positive opinion from the [CHMP](https://www.ema.europa.eu/en/glossary/chmp) for the treatment of type 2 diabetes mellitus.

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 **Rhokiinsa**(netarsudil) for the treatment of patients with glaucoma or ocular hypertension.

**Senstend**(lidocaine / prilocaine), which was evaluated in an [informed consent application](https://www.ema.europa.eu/en/glossary/informed-consent-application), received a positive opinion for the treatment of premature ejaculation in adult men. An [informed consent application](https://www.ema.europa.eu/en/glossary/informed-consent-application) makes use of data from the dossier of a previously authorised medicine, with the [marketing authorisation holder](https://www.ema.europa.eu/en/glossary/marketing-authorisation-holder) of that medicine giving consent for the use of their data in the application.

The [CHMP](https://www.ema.europa.eu/en/glossary/chmp) recommended granting [marketing authorisations](https://www.ema.europa.eu/en/glossary/marketing-authorisation) for three [generic medicines](https://www.ema.europa.eu/en/glossary/generic-medicine): **Arsenic trioxide Accord** (arsenic trioxide), for the treatment of acute promyelocytic leukaemia; **Bortezomib Fresenius Kabi**(bortezomib), for the treatment of multiple myeloma and mantle cell lymphoma; and **Ivozall** (clofarabine), for the treatment of acute lymphoblastic leukaemia in paediatric patients.

**Eight recommendations on extensions of therapeutic indication**

The Committee recommended extensions of [indication](https://www.ema.europa.eu/en/glossary/indication) for **Bavencio, Benlysta, Docetaxel Zentiva, Dupixent, Lucentis, Remsima, Taxotere and Trulicity.**

**Agenda and minutes**

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

**CHMP statistics**

Key figures from the September 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).