

CHMP feedback to PCWP and HCPWP

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CHMP activities with contribution of patients and HCP

- **Scientific Advice and Protocol assistance.**
- **Early dialogue with patients and HCP for MAA.**
- **Scientific advisory groups/Ad-hoc expert groups.**
- **Oral explanations.**
- **Information on CHMP authorisations**

Interactions of patients with CHMP activities between 2023-2025

Activity	Number of interactions
Scientific Advisory Groups/ Ad hoc Expert Groups	2024 – 27 2025 – 5 to date
Scientific advice, protocol assistance	2024 – 70 2025 – 34 to date
Oral explanations	2024 – 14 2025 – 4 to date
Early dialogue	2024 – 22 2025 – 12 to date

Interactions of healthcare professionals with CHMP activities between 2024-2025

Activity	Number of interactions
Scientific Advisory Groups/ Ad hoc Expert Groups	2024 – 186 2025 – 80 to date
CHMP Early dialogue	2024 – 35 2025 – 18 to date

Data on CHMP opinions in 2025

CHMP positive opinions (January 2025 – September 2025)

New medicinal products: 85 (including 37 biosimilar products and 10 generics and 18 orphan medicines).

Extensions of the indications: 65

CHMP positive opinions (January 2025 – September 2025)

Vimkunya (chikungunya vaccine (recombinant, adsorbed)), a new vaccine to protect young people from 12 years of age and adults against disease caused by the Chikungunya virus. This medicine was supported through EMA's PRiority MEdicines (PRIME) scheme.

Vyjuvek* (beremagene geperpavec, ATMP) received a positive opinion to treat wounds in patients of all ages with dystrophic epidermolysis bullosa, a serious, ultra-rare genetic skin blistering disease caused by mutations in the collagen type VII alpha 1 chain (*COL7A1*) gene.

Imreplys (sargramostim) for the treatment of people with haematopoietic acute radiation syndrome, when the bone marrow produces fewer blood cells leading to a higher risk of infection and bleeding, following acute exposure to radiation.

CHMP positive opinions (January 2025 – September 2025)

Duvyzat (givinostat), as a treatment for Duchenne muscular dystrophy (DMD) in patients from the age of six who can walk. DMD is a rare, ultimately lethal genetic disease in which the muscles progressively weaken and lose function.

Zurzuvae (zuranolone) received a positive opinion from the CHMP for the treatment of postpartum depression in adults.

Lynkuet (elinzanetant) received a positive opinion from the CHMP for the treatment of moderate-to-severe vasomotor symptoms, also referred to as hot flushes or night sweats, associated with menopause.

CHMP positive opinions

Leqembi received a positive opinion for the treatment of mild cognitive impairment (memory and thinking problems) or mild dementia due to Alzheimer's disease (early Alzheimer's disease) in patients who have only one or no copy of *ApoE4*, a certain form of the gene for the protein apolipoprotein E (November 2024).

Kisunla, intended for the treatment of early symptomatic Alzheimer's disease in adults who are apolipoprotein E ϵ 4 (ApoE ϵ 4) non-carriers or heterozygotes (July 2025)



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