21 July 2022
EMA/CHMP/126645/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Genvoya

elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide

On 21 July 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Genvoya. The marketing authorisation holder for this medicinal product is Gilead Sciences Ireland UC.

The CHMP adopted an extension to the indication for Genvoya to include treatment of paediatric patients from 2 years of age. For information, the full indication therefore is as follows:[2]

> Genvoya is indicated for the treatment of human immunodeficiency virus 1 (HIV 1) infection without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir **in adults and paediatric patients aged from 2 years and with body weight at least 14 kg**. ~~as follows:~~
>
> - ~~In adults and adolescents paediatric patients aged from 12 years and with body weight at least 35 kg~~
> - ~~In children aged from 6 years and with body weight at least 25 kg for whom alternative regimens are unsuitable due to toxicities.~~

The CHMP also recommended the addition of a new strength as follows: 90 mg/90 mg/120 mg/6 mg film-coated tablets.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in **bold**, removed text as strikethrough.

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