9 November 2017
EMA/CHMP/452568/2017
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (post authorisation)**

# Genvoya

## elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide

On 9 November 2017, 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 International Ltd.

The CHMP adopted an extension to the existing indication as follows[2]:

"Genvoya is indicated for the treatment of ~~adults and adolescents (aged 12 years and older with body weight at least 35 kg) infected with~~ human immunodeficiency virus-1 (HIV-1) **infection** without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir, **as follows:** ~~(see sections 4.2 and 5.1).~~

- **In adults and adolescents 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 ~~resistance or~~ toxicities.**

**See sections 4.2, 4.4 and 5.1."**

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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