15 October 2020
EMA/CHMP/537033/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Recarbrio

imipenem / cilastatin / relebactam

On 15 October 2020, 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 Recarbrio. The marketing authorisation holder for this medicinal product is Merck Sharp & Dohme B.V.

The CHMP adopted new indications as follows:

- Treatment of hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP), in adults.
- Treatment of bacteraemia that occurs in association with, or is suspected to be associated with HAP or VAP, in adults.

For information, the full indications for Recarbrio will be as follows[2]:

Recarbrio is indicated for:

- **Treatment of hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP), in adults (see sections 4.4 and 5.1).**
- **Treatment of bacteraemia that occurs in association with, or is suspected to be associated with HAP or VAP, in adults.**
- Treatment of infections due to aerobic Gram-negative organisms in adults with limited treatment options (see sections 4.2, 4.4, and 5.1).

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

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**

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