25 June 2020
EMA/CHMP/312635/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Zavicefta

ceftazidime / avibactam

On 25 June 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 Zavicefta. The marketing authorisation holder for this medicinal product is Pfizer Ireland Pharmaceuticals.

The CHMP adopted a new indication as follows:

"Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above".

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

Zavicefta is indicated for the treatment of the following infections in adults (see sections 4.4 and 5.1):

- *Complicated intra-abdominal infection (cIAI)*
- *Complicated urinary tract infection (cUTI), including pyelonephritis*
- *Hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP)*

Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.

Zavicefta is also indicated for the treatment of infections due to aerobic Gram-negative organisms in adult patients 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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