17 September 2020
EMA/CHMP/380902/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Zavicefta

ceftazidime / avibactam

On 17 September 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 an extension to the existing indication as follows:[2]

> Zavicefta is indicated **in adults and** ~~, infants (aged 3 months and older),~~**children aged 3 months and older** ~~and adolescents~~ for the treatment of the following infections ~~in adults~~ (see sections 4.4 and 5.1):
>
> - Complicated intra-abdominal infection (cIAI) ~~(in combination with metronidazole)~~
> - Complicated urinary tract infection (cUTI), including pyelonephritis
>
> ~~Zavicefta is indicated in adults for the treatment of the following infections:~~
>
> - Hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP) ~~(see sections 4.4 and 5.1)~~
>
> 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**s and children aged 3 months and older** ~~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

[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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the marketing authorisation has been granted by the European Commission.