December, 23rd 2020

GLOBAL RECALL: Zerbaxa (ceftolozane / tazobactam) 1 g/0.5 g powder for concentrate for solution for infusion

Dear Healthcare Professional,

MSD in agreement with the European Medicines Agency and <National Competent Authority> would like to inform you of the following:

Summary

- **Seven batches of Zerbaxa (ceftolozane/tazobactam) failed sterility tests. Five of these batches tested positive for *Ralstonia pickettii* according to the analysis performed by MSD. None of these batches have been released to the market.**
- **All product batches distributed to the market before this incident have met the registered specifications for release, including for sterility.**
- **However, as a precautionary measure, MSD is recalling all Zerbaxa within expiry. This is a voluntary recall at pharmacy level. Pharmacies are requested to quarantine all products immediately for collection by <date>.**
- **Health care professionals should immediately stop using Zerbaxa and consider an alternative treatment for their patients.**

Background on the safety concern

Zerbaxa (ceftolozane/tazobactam) is indicated for the treatment of the following infections in adults: complicated intra-abdominal infections, acute pyelonephritis, complicated urinary tract infections; hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP).

According to the analysis performed by MSD, seven batches of Zerbaxa failed sterility tests and manufacturing of the product has been temporarily stopped. Five of these batches tested positive for *Ralstonia pickettii* and two batches produced turbid results that could not be further identified. The investigation into the source of the contamination is ongoing and the seven batches have not been released to the market. While all product batches distributed to the market has met the registered specifications for release, including for sterility, as a precautionary measure, we are conducting a voluntary Class II (healthcare professional level) global recall of all Zerbaxa within expiry.

Accordingly, MSD hereby informing healthcare professionals (HCPs) to immediately discontinue use of ZERBAXA in their patients. HCPs should consider alternative treatment.

R. pickettii is a strictly aerobic, oxidase positive, non-fermenting, non-motile, non-spore forming, Gram-negative rod. It is commonly found in soil and water. *R. pickettii* is considered to be an opportunistic pathogen, particularly in patients who are immunocompromised or in critically ill patients, as well as neonates.

Regarding the batches of Zerbaxa currently released on the market, there is a potential safety risk to cause adverse health consequences, particularly in high-risk patients (such as immunocompromised and critically ill patients). It should be noticed that at this stage no safety signals in relation with this quality defect have been reported.

Call for reporting

For questions about this recall or to report any adverse events, please contact: Local Medical Information (Designated Point of Contact – DPOC).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

We recognize that ZERBAXA is an important choice for patient care and apologize for the impact of the unavailability of the product. We are committed to doing our utmost to resume supply of ZERBAXA for patients and prescribers around the world as quickly as possible.

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>
Dependent of each country.