MSD
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23rd December 2020

Dear Health Care Provider:

Re: ZERBAXA ceftolozane sulfate/tazobactam sodium 1000 mg/500 mg powder for injection RECALL ACTION

MSD, following consultation with the Therapeutic Goods Administration (TGA), is conducting a recall in Australia of ZERBAXA, batches **S036990 and T025455.**

Due to a recent manufacturing issue identified during the routine testing of ZERBAXA (ceftolozane/tazobactam), manufacturing of the product has been temporarily stopped. The results of sterility tests of seven batches of product were out of specification. 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 *R. Pickettii* is ongoing and the seven batches have not been released to the market.

All product distributed to the Australian market has met the registered specifications for release, including for sterility. However, these batches were manufactured on the same equipment as the affected batches and hence as a precautionary measure, MSD is recalling all batches of ZERBAXA currently within expiry in Australia **(**batches S036990 and T025455**).** This is a recall of ZERBAXA worldwide.

If you have a patient currently being treated with ZERBAXA, please apply clinical discretion regarding continuation of 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 those who are immunosuppressed or are in some other way debilitated.

The available evidence supports the determination that the presence of viable *R. pickettii* in a final filled vial is a sporadic, random defect, and ZERBAXA currently released to the market is at low risk to contain viable *R. pickettii* in sufficient quantities to cause serious adverse health consequences. However, a potential safety risk remains and is greatest in high-risk patients. High-risk patients are immunocompromised and critically ill patients.

Based on the available information at this time, the probability of serious adverse health consequences in patients that have recently received ZERBAXA is

considered extremely remote for the overall population, and remote in high-risk populations.

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.

For questions about this recall or to report any adverse events, please contact:

MSD Medical Information via phone on 1800 818 553

We appreciate your immediate attention, and sincerely regret any inconvenience caused by this action.

Gary Jankelowitz

Australia and New Zealand Medical Director
MSD