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Dear Health Care Provider:

This is to inform you of a voluntary global product recall of **ZERBAXA® (ceftolozane and tazobactam powder for injection) 1.5 g/vial (1 g/0.5 g) 10 x 20 mL vials**. Please refer to the Health Canada website for details on the recall: https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/74593r-eng.php. The three batches subject to this recall represent all batches within expiry on the Canadian market. Due to a recent manufacturing issue identified during the routine testing of ZERBAXA®, manufacturing of the product has been temporarily stopped.

As a result, this voluntary recall is being conducted because of potential compromised sterility. Some recently manufactured batches of ZERBAXA® were found to be contaminated with *Ralstonia pickettii* on release sterility testing and were not released. The three batches on the Canadian market met specifications at release; however, they were manufactured at the same facility using the same equipment that was used to manufacture the contaminated batches. The recalled batches of ZERBAXA® are considered at low risk to contain viable microorganisms (*Ralstonia pickettii*, a potential opportunistic pathogen) in sufficient quantities to cause serious adverse health consequences because these batches passed sterility testing at release. Therefore, the potential safety risk remains and is greatest for immunocompromised and critically ill patients. The adverse health consequences can include colonization of an indwelling IV catheter, bacteremia, septicemia and infection at a secondary site (e.g. endocarditis).

In Canada, the risk associated with this recall is Type I. Type I recalls are defined as situations in which there is a reasonable probability that the use of, or exposure to, a product will cause serious adverse health consequences or death. Please note that potential situations of compromised sterility in sterile injectables are handled as Type I recalls.

ZERBAXA® is indicated for the treatment of the following infections in adults: complicated intra-abdominal infections, complicated urinary tract infections including acute pyelonephritis, nosocomial pneumonia, including ventilator-associated pneumonia.

Accordingly, Merck recommends that health care providers should immediately discontinue use of ZERBAXA® in their patients and follow up with those patients for whom the product is being administered in a setting outside of the hospital or clinic. Health care providers should consider an alternative treatment plan in consultation with Infectious Disease specialists as needed. When culture and susceptibility information are available, they should be considered in selecting

or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

We 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. Please refer to the Drug Shortages Canada database for information regarding the availability of ZERBAXA® at https://www.drugshortagescanada.ca

To report an adverse event or should you require any medical information on this recall, please contact Merck Canada Medical Information Centre preferably by email at medinfocanada@merck.com and provide your name, your phone number and the details of your inquiry. You may also contact the Medical Information Centre by calling at 1-800-567-2594, ext. 2.

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax.

This recall is being conducted with the knowledge of Health Canada. We appreciate your immediate attention, and sincerely regret any inconvenience caused by this action.

Regards,

Gretty Deutsch, M.D.
Executive Director, Medical & Scientific Affairs
Merck Canada Inc.

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