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Apotex recalls injection on behalf of Hospira

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Singapore: Apotex has voluntarily recalled 15 lots of piperacillin and tazobactam for injection, 40.5 grams, on behalf of manufacturer Hospira (NDC number 60505-0773-00), which was meant to be supplied to hospitals in the US. Apotex is the US distributor of the product and is conducting the recall at the request and on behalf of Hospira, which is investigating to determine the root cause.

Hospira feels that the impacted lots of piperacillin and tazobactam may show precipitation or crystallization in intravenous (IV) bag or IV line after reconstitution.
Hospira has stated that administration of precipitated Piperacillin or Tazobactam may result in local reactions such as phlebitis, renal impairment, end-organ embolism and ischemia, and/or vasculitis.

In addition, the precipitation of the drug may not allow delivering a needed therapeutic dose of piperacillin and tazobactam, thus resulting in inadequate treatment of the targeted infection. This could result in adverse health consequences that could range from transient and minor impairment or complaints to permanent impairment of a body function or permanent damage to a body structure. Hospira has not received any reports of adverse events related to this recall.

The product is indicated for the treatment of patients with moderate to severe infections caused by piperacillin-resistant, piperacillin/tazobactam-susceptible, Ã?Æ?Ã Â¸-lactamase producing strains of the designated microorganisms in the specified conditions such as, appendicitis, uncomplicated and complicated skin and skin structures infections, postpartum endometritis or pelvic inflammatory disease, community acquired pneumonia and nosocomial pneumonia.