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Date: 12 September 2017

CHMP Chairman
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Subject: Withdrawal of Tigecycline Accord, tigecycline, 50mg/vial, Powder for solution for infusion - **EMEA/H/C/004419**

Dear *CHMP Chairman*,

For the withdrawal of initial marketing authorisation application

I would like to inform you that, at this point of time, *Accord Healthcare Limited, UK* has taken the decision to withdraw the application for Marketing Authorisation of Tigecycline Accord, tigecycline, 50mg/vial, Powder for solution for infusion which was intended to be used for

In adults and in children from the age of eight years for the treatment of the following infections:
• Complicated skin and soft tissue infections (cSSTI), excluding diabetic foot infections
• Complicated intra-abdominal infections (cIAI)Tigecycline Accord should be used only in situations where other alternative antibiotics are not suitable.

This withdrawal is based on the following reasons:

- *Company's marketing strategy*
- Other*: Drug substance manufacturing sites have been inspected by EU inspectorates and as a result of this inspection, Statements of GMP Non-Compliance have been issued published on EudraGMDP.*

As confirmed with agency we are already in planning to develop the product using alternative drug substance source.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the European Medicines Agency website.

Yours sincerely,

VP – Regulatory Affairs
Accord Healthcare Limited, UK