Wyeth Europa Limited
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Wyeth

22 April 2008

[redacted]
CHMP Chairperson
C/O The Central Information Group
The European Medicines Agency (EMEA)
7 Westferry Circus
Canary Wharf
London E14 4HB

Dear [redacted]

Re: Tygacil - For the withdrawal of Type II variation application linked to an extension of indication for a medicinal product already authorised in the European Union

Withdrawal of Variation Application EMEA/H/C/644/II/13 for Community Acquired Pneumonia

I would like to inform you that, at this point of time, Wyeth Europa Ltd has taken the decision to withdraw the Type II variation application for a new indication for Tygacil 50mg Powder for Solution for Infusion, adding the indication for Community Acquired Pneumonia.

This withdrawal is based on the following reason:

- The CHMP considers that the data provided do not allow the committee to conclude a positive benefit risk balance in Community Acquired Pneumonia at this time.

There are no consequences of the withdrawal to ongoing clinical trials or to the use of Tygacil in the currently approved indications as detailed in the Summary of Product Characteristics for "Complicated skin and soft tissue infections, and complicated intra-abdominal infections. Consideration should be given to official guidance on the appropriate use of antibacterial agents."

We reserve the right to make further submissions at a future date for Tygacil in this or other therapeutic indication.

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I agree for this letter to be published on the EMEA website.

Yours sincerely,
For and on behalf of Wyeth Europa Limited

[redacted]
Senior Director
Regulatory Affairs Europe

Copies to:
[redacted] Rapporteur
[redacted] EMEA PTL