Mylan

March 8th 2010

To Eric ABADIE
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Subject: Withdrawal of Docetaxel Mylan 10 mg/ml, powder and solvent for solution for infusion - EMEA/H/C/1193

Dear Dr ABADIE,

I would like to inform you that, at this point of time, Mylan S.A.S have taken the decision to withdraw the application for Marketing Authorisation of Docetaxel Mylan 10 mg/ml, powder and solvent for solution for infusion, which was intended to be used for breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma, and head and neck cancer.

This withdrawal is based on the following reason:

- the CHMP considers that the data provided do not allow the committee to conclude on a positive benefit risk balance.

At present time, there is no on-going clinical trial with Docetaxel Mylan 10 mg/ml, powder and solvent for solution for infusion.

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 EMEA website.

Yours sincerely,

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