Mylan

27 May 2016

Dr Tomas Salmonson
CHMP Chairman
European Medicines Agency
30 Churchill Place
Canary Wharf
London
E14 5EU
United Kingdom

Subject: Withdrawal of Alendronic Acid/Colecalciferol Mylan 70 mg/2,800 IU, 70 mg/5,600 IN Tablets, MYLAN SAS - SAINT PRIEST - **EMEA/H/C/004172**

Dear Dr Salmonson,

I would like to inform you that, at this point of time, Mylan SAS has taken the decision to fully withdraw the application for Marketing Authorisation of Alendronic Acid/Colecalciferol Mylan, EMEA/H/C/004172, which was intended to be used for following:

- the treatment of postmenopausal osteoporosis in women at risk of vitamin D insufficiency, reducing the risk of vertebral and hip fractures.

This request is based on the following reason:

- **the time required to generate the supporting data makes this product unviable.**

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.

On behalf of the MAH,

Yours sincerely,

[redacted]