Sun Pharmaceutical Industries Europe BV
Polarisavenue 87
2132 JH Hoofddorp - The Netherlands
Tel: +31 (0)23 568 55 01
Fax: +31 (0)23 568 55 05

[redacted]
European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

[redacted]

Hoofddorp, 7 June 2016

Subject: Withdrawal of
Docetaxel SUN 20 mg/1 ml concentrate for solution for infusion
Docetaxel SUN 80 mg/4 ml concentrate for solution for infusion
Docetaxel SUN 160 mg/8 ml concentrate for solution for infusion
[redacted]
Procedure number: EMEA/H/C/4086/0000

Dear [redacted]

I would like to inform you that, at this point of time, Sun Pharmaceutical Industries Europe B.V. has taken the decision to withdraw the application for Marketing Authorisation of

Docetaxel SUN 20 mg/1 ml, 80 mg/4 ml, 160 mg/8 ml concentrate for solution for infusion, docetaxel anhydrous, Sun Pharmaceutical Industries Europe B.V.

This withdrawal is based on the following reason:
Sun Pharmaceutical Industries Europe B.V. has decided to discontinue this application on commercial grounds.

At the present time, there are no ongoing clinical trials with Docetaxel SUN 20 mg/1 ml, 80 mg/4 ml, 160 mg/8 ml concentrate for solution for infusion.

There are therapeutic alternatives for Docetaxel SUN 20 mg/1 ml, 80 mg/4 ml, 160 mg/8 ml concentrate for solution for infusion, as it is one of many generics.

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

I agree for this letter to be published on the EMA website.
I assume to have informed you sufficiently, however if not, please do not hesitate to contact me in case of additional questions.

Yours sincerely,

[redacted]
Sun Pharmaceutical Industries Europe B.V.