Mylan
Seeing is believing

08 January 2016

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

Subject: Withdrawal of Aripiprazole Mylan 5 mg, 10 mg, 15 mg and 30 mg Tablets and Aripiprazole Mylan 10 mg and 15 mg Orodispersible Tablets - **EMEA/H/C/004236**

Dear Dr Salmonson,

I would like to inform you that, at this point of time, *Mylan SAS* has taken the decision to withdraw the application for Marketing Authorisation of *Aripiprazole Mylan 5 mg, 10 mg, 15 mg and 30 mg Tablets and Aripiprazole Mylan 10 mg and 15 mg Orodispersible Tablets*, which was intended to be used for following:

- Treatment of schizophrenia in adults and in adolescents aged 15 years and older.
- Treatment of moderate to severe manic episodes in Bipolar I Disorder and for the prevention of a new manic episode in adults who experienced predominantly manic episodes and whose manic episodes responded to aripiprazole treatment.
- Treatment up to 12 weeks of moderate to severe manic episodes in Bipolar I Disorder in adolescents aged 13 years and older.

This withdrawal is based on the following reason:

- ***identification of manufacturing issues requiring reformulation***

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]

Generics [UK] Ltd t/a Mylan · Building 4 · Trident Place · Mosquito Way · Hatfield · Hertfordshire · AL10 9UL
Tel No. +44 (0)1707 853000 · Fax No. +44 (0)1707 261803
Registered Office: Station Close · Potters Bar · Herts · EN6 1TL · Registered in England - No. 1558756