Mylan
Seeing is believing

07 May 2015

Dr. Tomas Salmonson
CHMP Chairman
European Medicines Agency
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Canary Wharf
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E14 5EU
United Kingdom

Cc: [redacted]
Procedure Manager
European Medicines Agency

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Scientific Administrator [redacted]
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Subject: Withdrawal of Aripiprazole Mylan, aripiprazole, 5 mg, 10 mg, 15 mg, 30 mg Tablets and 10 mg, 15 mg Orodispersible Tablets - EMEA/H/C/003926

Dear Dr. Salmonson,

I would like to inform you that, at this point of time, Generics [UK] Limited, has taken the decision to withdraw the application for Marketing Authorisation of Aripiprazole Mylan, aripiprazole, 5 mg, 10 mg, 15 mg, 30 mg Tablets and 10 mg, 15 mg Orodispersible Tablets, which was intended to be used for (i) the treatment of schizophrenia in adults and in adolescents aged 15 years and older, (ii) the 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 and (iii) the 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 reasons:

- *identification of major GCP issues*

New bioequivalence studies using a different Contract Research Organisation have been performed and it is the company's intention to resubmit the application for assessement. We believe the new trial data will be compliant with the good clinical practice requiremements set in Directives 2001/20/EC and 2001/83/EC.

There are no on-going clinical trial with Aripiprazole, nor is there a compassionate use programme.

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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,

[redacted]

[redacted]

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