

Dr. Harald Enzmann
CHMP Chairman
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Date: 08 May 2020

Subject: Withdrawal of Fingolimod Mylan (Fingolimod) 0.5 mg hard capsules – EMEA/H/C/005282

Dear Dr. Enzmann,

We would like to inform you that, at this point of time, *Mylan Ireland Limited*, has taken the decision to withdraw the application for Marketing Authorisation of *Fingolimod Mylan (Fingolimod) 0.5 mg hard capsules*, which was intended to be used for single disease modifying therapy in highly active relapsing remitting multiple sclerosis for the following groups of adult patients and paediatric patients aged 10 years and older.

- Patients with highly active disease despite a full and adequate course of treatment with at least one disease modifying therapy (for exceptions and information about washout periods see sections 4.4 and 5.1).
- or
- Patients with rapidly evolving severe relapsing remitting multiple sclerosis defined by 2 or more disabling relapses in one year and with 1 or more Gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI.

This withdrawal is based on the following reason:

- the CHMP considers that the clinical data provided do not allow the committee to draw conclusions on the bioequivalence of the product and an additional bioequivalence cross-over or parallel design study is required.

The applicant wishes to withdraw the application in order to perform an additional bioequivalence study as requested by the Rapporteur at Day 195 and agreed by the other CHMP members during the Oral explanation hearing on Day 210. It is the applicant's intention to resubmit the application with the new study as requested.

We confirm that this withdrawal has no consequences on on-going clinical trials or compassionate use programmes.



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,

On behalf of the applicant