[redacted]

Date: 22-02-2022

Subject: Withdrawal of Dimherity, Dimethyl Fumarate, 120 and 240 mg, Gastro-resistant Capsules, hard - **EMA/H/C/006042**

[redacted]

For the withdrawal of initial marketing authorisation application

I would like to inform you that, at this point of time, Sandoz GmbH has taken the decision to withdraw the application for Marketing Authorisation of Dimherity, Dimethyl Fumarate, 120 and 240 mg, Gastro-resistant capsules, hard, which was intended to be used for the treatment of adult patients with relapsing remitting multiple sclerosis.

This withdrawal is based on commercial reasons.

This withdrawal has no consequences on ongoing clinical trials or compassionate use programs, since none of these are running.
This application is a duplicate application for which the original application is still in place.

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]