## COMMONWEALTH OF AUSTRALIA

## Department of Health Therapeutic Goods Administration

## *THERAPEUTIC GOODS ACT 1989*

Section 14 and 14A Notice

On 29 June 2015, the delegate of the Secretary of the Department of Health for the purposes of subsection 14 and 14A of the ***Therapeutic Goods Act 1989***(“the Act”), on the application of Biogen Australia Pty Ltd , gave consent to the importation and supply of

* dimethyl fumarate (TECFIDERA) capsules 120 mg and 240 mg in blister packs [AUST R 197118 & 197119] Batches **ANZDELS601, ANZEELS400 & ANZEHLS100 (120 mg capsules) and ANZDKLSH00, ANZDKLSH01, ANZEDLSH00, ANZEELSB00, ANZEFLSB00, ANZEFLSB01, ANZEGLS600, ANZEILS700 & ANZEJLS400 (240 mg capsules)**

that do not conform with the requirements of paragraph 3(2)(l) of the ***Therapeutic Goods Order No. 69- General requirements for labels for medicines***, in that the sponsor name on the label is not that currently registered (no change in address details).

The consent is effective from 29 June 2015 until the exhaustion of supply of the above-nominated batches of the products.

The delegate of the Secretary, under subsection 15(1) of the Act, made the consent subject to the following conditions:

1. The labels to which this consent applies are those currently approved for the products.