## COMMONWEALTH OF AUSTRALIA

## Department of Health Therapeutic Goods Administration

## *THERAPEUTIC GOODS ACT 1989*

Sections 14 and 14A Notice

On 11 December 2015, a delegate of the Secretary of the Department of Health, on the application of Biogen Australia Pty Ltd, consented under sections 14 and 14A of the *Therapeutic Goods Act 1989* (the Act) to the importation and supply of

* dimethyl fumarate (TECFIDERA) 120 mg modified release capsules blister packs [AUST R 197118]
* dimethyl fumarate (TECFIDERA) 240 mg modified release capsules blister packs [AUST R 197119]

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| --- | --- | --- |
| AUST R  | Product | Batches |
| 197118 | dimethyl fumarate (TECFIDERA) 120 mg modified release capsules blister pack | ANZDELS601ANZEELS400ANZEHLS100ANZEILSH00 |
| 197119 | dimethyl fumarate (TECFIDERA) 240 mg modified release capsules blister packs | ANZEELSB00ANZEFLSB00ANZEFLSB01ANZEJLS300ANZEGLS601ANZEGLS600ANZEILS700ANZEJLS400 |

that do not conform with the requirements of the paragraph 3(2)(l) of the *Therapeutic Goods Order No. 69 – General requirements for labels for medicines*, in that he carton label of the products include the sponsor’s old address and/or name.

The consent is effective from the 11 December 2015 until the nominated batches are exhausted or have expired.

The consent is subject to the following conditions:

1. The carton labels to which this consent applies are those approved for use currently.