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GOVERNMENT NOTICES

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]

AUST R	Product	Batches
197118	dimethyl fumarate (TECFIDERA) 120 mg modified release capsules blister pack	ANZDELS601 ANZEELS400 ANZEHLS100 ANZEILSH00
197119	dimethyl fumarate (TECFIDERA) 240 mg modified release capsules blister packs	ANZEELSB00 ANZEFLSB00 ANZEFLSB01 ANZEJLS300 ANZEGLS601 ANZEGLS600 ANZEILS700 ANZEJLS400

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.

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