



COMMONWEALTH OF AUSTRALIA

Department of Health
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

Sections 14 and 14A Notice

On 11 January 2016, a delegate of the Secretary of the Department of Health, on the application of Otsuka Australia Pharmaceutical Pty Ltd, consented under sections 14 and 14A of the *Therapeutic Goods Act 1989* (the Act) to the importation and supply of

- tolvaptan (SAMSCA) 15 mg tablet blister pack [AUST R 176602]

that do not conform with the requirements of paragraph 3(2)(l) of the *Therapeutic Goods Order No. 69* (TGO 69), *General requirements for labels for medicines*, in that the sponsor stated on the labels is not the current Australian sponsor.

The consent is effective from 11 January 2016 until June 2017.

The consent is subject to the following conditions:

1. The labels to which this consent applies are those previously approved for the former sponsor Aspen and currently subject to a s14 consent to supply/import (PM-2013-02578-1-5), which are over-stickered with the relevant warning statements, storage conditions, previous sponsor's details and the AUST R number;
2. A 'Dear Pharmacist' letter identical to that provided to the Therapeutic Goods Administration on 08 January 2016 advising them to instruct patients to keep the blisters in the cartons so that Australian contact details are retained, must be provided with each of the affected batches; and
3. Arrangements are in place with the former sponsor Aspen for the referral of any queries or complaints concerning the products to Otsuka Australia Pharmaceutical Pty Ltd.