



COMMONWEALTH OF AUSTRALIA

Department of Health  
Therapeutic Goods Administration

***THERAPEUTIC GOODS ACT 1989***

Section 14 and 14A Notice

On 4 February 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 iNova Pharmaceuticals Australia Pty Ltd, gave consent to the importation and supply of

- imiquimod (ALDARA) 50 mg/g cream pump (AUST R 191815)

that does 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 old logo and sponsor address are included on the packaging.

The consent is effective from the date of this letter until batches GPK085D and GPK085E are exhausted.

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

1. The packaging to which this consent applies is that provided with the application letter (titled 'proposed') and the assurances provided in the email dated 4 February 2015.
2. Arrangements are in place that any correspondence concerning the products will be promptly referred from the old address to the new address (L10, 12 Help St Chatswood NSW 2067).
3. No other changes have been made to the product.