Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

SECTION 14 AND 14A NOTICE

On October 23 2012, the delegate of the Secretary of the Department of Health and Ageing for the purposes of subsection 14 and 14A of the *Therapeutic Goods Act 1989* ("the Act") gave his consent to:

(a) the supply of the product vinflunine (as ditartrate) (JAVLOR) 50 mg/2 mL concentrated injection vial [Aust R 166767] by Pierre Fabre Medicament Australia Pty Ltd, North Ryde NSW ("the Company"):

That does not conform with paragraphs 3(2)(e) and 4(7)(c)of Therapeutic Goods Order 69, in that the labels on the cartons and vials are those of the UK product rather than the approved Australian labels.

Pursuant to subsection 15(1) of the Act, the consent given by the delegate of the Secretary as described above is subject to the following conditions:

1. This consent to supply applies for a period of 6 months from October 23 2012.

2. The labels to be used are identical to those submitted in correspondence from the Company dated September 12 2012, viz the UK carton and vial labels, but with an over-sticker containing the Aust R number and the name and address of the Company on the carton label.

3. No other changes have been made to the product vinflunine (as ditartrate) (JAVLOR) 50 mg/2 mL concentrated injection vial [Aust R 166767].

4. Each pack of the product vinflunine (as ditartrate) (JAVLOR) 50 mg/2 mL concentrated injection vial [Aust R 166767] is to be supplied with the Australian product information together with the "Dear Doctor/Pharmacist/Healthcare Professional" letter, the draft of which was provided in correspondence from the Company dated October 19 2012.

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