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GOVERNMENT NOTICES

COMMONWEALTH OF AUSTRALIA

Department of Health
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

Section 14 and 14A Notice

On November 26 2014, 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"), by application of A Menarini Australia Pty Ltd, gave consent to the importation and supply of:

- anakinra (KINERET) 100 mg/0.67 mL solution for injection prefilled syringe [AUST R 82872] that does not conform with the requirements of the *Therapeutic Goods Order No. 69- General requirements for labels for medicines* in that the product has United Kingdom (UK) packaging.

The consent is effective from November 26 2014 until further notice.

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

1. Supply is restricted to the Product in UK packaging as provided to the Therapeutic Goods Administration in the original application.
2. A sticker containing Australian sponsor details and ARTG number will be placed on the packaging.
3. An Australian CMI will be supplied with each box as detailed in the Company's application.
4. A letter will be sent with the product to hospitals explaining the altered packaging of anakinra (KINERET) 100 mg/0.67 mL solution for injection prefilled syringe as detailed in the Company's application and previous correspondence.
5. The sponsor must inform the Therapeutic Goods Administration at least once every 12 months of the numbers of patients treated with the Product in the previous 12 month period. This information should be submitted to biological.medicines@tga.gov.au unless you have reached agreement with the Therapeutic Goods Administration for an alternative.
6. The consent is granted unless patient numbers exceed 100 per calendar year, or if the medicine is listed on the PBS for indications other than the orphan indication cryopyrin-associated periodic syndromes (CAPS). The sponsor must inform the Therapeutic Goods Administration in writing as soon as possible if any of these changes occurs.

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