Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Act 1989
Therapeutic Goods Regulations 1990

DESIGNATION OF ANAKINRA (KINERET) AS AN ORPHAN DRUG

I, Dr Anthony Gill, Delegate of the Secretary for the purposes of 16J of the Therapeutic Goods Regulations 1990 ("the Regulations"), acting under subregulation 16J(2) of the Regulations, designate Anakinra (KINERET) as an orphan drug on 17th April 2013 for the treatment of Cryopyrin Associated Periodic Syndromes (CAPS) in adults and children including Muckle-Wells Syndrome (MWS), Familial Cold-induced Autoinflammatory Syndrome (FCAS) / Familial Cold Urticaria (FUC), and Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological Cutaneous and Articular syndrome (CINCA).

The dose form of Anakinra (KINERET) for this indication is a solution, pre-filled syringe 100 mg /0.67 mL.

The sponsor of Anakinra (KINERET) is A. Menarini Australia Pty Ltd

(Signed by)

Dr Anthony Gill
Delegate of the Secretary

24th April 2013

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