



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Act 1989
Therapeutic Goods Regulations 1990

DESIGNATION OF MERCAPTOPYRINE 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 Mercaptopurine as an orphan drug on the 14 December 2012 for the treatment of Acute Lymphoblastic Leukaemia in Children.

The dose form of Mercaptopurine for this indication is oral suspension.

The sponsor of Mercaptopurine is Ballia Holdings Pty Ltd

(Signed by)

Dr Anthony Gill
Delegate of the Secretary

14 December 2012