



COMMONWEALTH OF AUSTRALIA

Department of Health
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

DESIGNATION OF ELTROMBOPAG (REVOLADE) 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 eltrombopag (REVOLADE) as an orphan drug on 15 July 2014 for the treatment of cytopenias in patients with severe aplastic anemia who have had insufficient response to immunosuppressive therapy.

The dose form of eltrombopag (REVOLADE) for this indication is tablets.

The sponsor of eltrombopag (REVOLADE) is GlaxoSmithKline Australia Pty Ltd.

(Signed by)

Dr Anthony Gill
Delegate of the Secretary

15 July 2014