



COMMONWEALTH OF AUSTRALIA

Department of Health
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

DESIGNATION OF PEGASPARGASE (ONCASPAR) 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 Pegaspargase (ONCASPAR) as an orphan drug on 6 April 2016 for the treatment of patients with Acute Lymphoblastic Leukaemia.

The dose form of Pegaspargase (ONCASPAR) for this indication is solution for injection.

The sponsor of Pegaspargase (ONCASPAR) is Baxalta Australia Pty Ltd.

(Signed by)

Dr Anthony Gill
Delegate of the Secretary

6 April 2016