



COMMONWEALTH OF AUSTRALIA

Department of Health
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

DESIGNATION OF SEBELIPASE ALFA 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 SEBELIPASE ALFA as an orphan drug on 14 November 2015 for the treatment of lysosomal acid lipase (LAL) deficiency.

The dose form of SEBELIPASE ALFA for this indication is solution for injection.

The sponsor of SEBELIPASE ALFA is Alexion Pharmaceuticals Australasia Pty Ltd.

(Signed by)

Dr Anthony Gill
Delegate of the Secretary

14 November 2015