



COMMONWEALTH OF AUSTRALIA

Department of Health
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

DESIGNATION OF SELEXIPAG 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 selexipag as an orphan drug on 25 September 2014 for the treatment of pulmonary arterial hypertension.

The dose form of selexipag for this indication is tablet.

The sponsor of selexipag is Actelion Pharmaceuticals Australia Pty Ltd.

(Signed by)

Dr Anthony Gill
Delegate of the Secretary

25 September 2014