



COMMONWEALTH OF AUSTRALIA

Department of Health
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

DESIGNATION OF DEUTETRABENAZINE 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 Deutetrabenazine as an orphan drug on 9 May 2016 for the treatment of chorea associated with Huntington's disease.

The dose form of Deutetrabenazine for this indication is film-coated tablets.

The sponsor of Deutetrabenazine is Teva Pharma Australia Pty Ltd.

(Signed by)

Dr Anthony Gill
Delegate of the Secretary
9 May 2016