



COMMONWEALTH OF AUSTRALIA

Department of Health
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

DESIGNATION OF OBETICHOLIC ACID (NO TRADE NAME) 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 obeticholic acid (no trade name) as an orphan drug on 21 April 2017 for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.

The dose form of obeticholic acid (no trade name) for this indication is tablets.

The sponsor of obeticholic acid (no trade name) is AU Pharma Pty Ltd.

(Signed by)

Dr Anthony Gill
Delegate of the Secretary
21 April 2017