



COMMONWEALTH OF AUSTRALIA

Department of Health
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

DESIGNATION OF SUSOCTOCOG 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 susoctocog alfa as an orphan drug on 3 July 2014 for the treatment and prevention of serious bleeding episodes in patients with acquired haemophilia A.

The dose form of susoctocog alfa for this indication is powder for injection.

The sponsor of susoctocog alfa is Baxter Healthcare Pty Ltd.

(Signed By)

Dr Anthony Gill
Delegate of the Secretary

2 September 2014