



COMMONWEALTH OF AUSTRALIA

Department of Health
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

DESIGNATION OF ICATIBANT (FIRAZYR) 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 Icatibant (FIRAZYR) as an orphan drug on 10 October 2013 for the treatment of angiotensin-converting-enzyme inhibitor (ACE-1) induced angioedema

The dose form of Icatibant (FIRAZYR) for this indication is solution for injection.

The sponsor of Icatibant (FIRAZYR) is Shire Australia Pty Ltd.

(Signed by)

Dr Anthony Gill
Delegate of the Secretary

10 October 2013