

ANNEX 4

Psychiatric Adverse Events including Cumulative review of spontaneous reports of suicidal and self- injurious behaviour

1.0 Overview of Reports of Psychiatric Adverse Events associated with Atomoxetine

Up to the 22 September 2005 the MAH has received a total of 6,751 reports involving 10,988 psychiatric reactions. Of these reports 2,383 were from healthcare professionals (hcps).

The reactions where more than 50 reports have been received are provided in the table below. As can be seen from this table the most commonly reported reactions (all reports or hcps reports only) include insomnia, abnormal behaviour, aggression mood swings, irritability and agitation.