Medicine	Trade Name	Innovator Sponsor	PI Changes Required	Letter Drafted	Changes discussed with OMA Clinical Evaluation Unit 1?	Date sent to sponsor	Sponsor Response Received	Further correspondence with sponsor?	PI Updated as of
ATYPICAL ANTIPSYCHOTICS									
Amisulpride	Solian	Sanofi-Aventis	PDSEAP Rec 4 (diabetes) Suicide precaution	Yes	Yes, agreed by on 3/5/12	3/05/2012 (posted and faxed)	SRN Submitted to OMA on 1/6/2012	No further action required.	28/06/2012
Aripiprazole	Abilify	Bristol Myers Squibb	PDSEAP Rec 4 (diabetes)	Yes	Yes, agreed by on 3/5/12	3/05/2012 (posted and faxed)	SRN Submitted to OMA on 1/6/2012	No further action required.	12/06/2012
Clozapine	Clozaril	Novartis	PDSEAP Rec 3 (akathisia) Suicide precaution Addition of PE/CVA/bronchospasm and hyponatraemia to AE section	Yes	Yes, agreed by on 3/5/12	3/05/2012 (posted and faxed)	Novartis received on 15/5/2012 requesting an extension until the end of July. Extension granted. See TRIM R12/831810. Response received 3/7/2012, akathisia precaution accepted, suicide precaution partially accepted, PE accepted, CVA/bronchospasm/hypona	Sponsor will be submitting SRN to OMA including akathisia precaution, first sentence of suicide precaution and pulmonary embolism in adverse events section, along with some other safety-related changes not negotiated with OPR. Letter sent to Novartis confirming that their response is acceptable 23/10/2012	26/07/2012
Olanzapine	Zyprexa	Eli Lilly Australia Pty Ltd 112 Wharf Road WEST RYDE NSW 2114 Fax: 02 93254688	PDSEAP Rec 3 (akathisia) Addition of anaemia, hyponatraemia and confusional state to AE section	Yes	Yes, agreed by on 3/5/12	3/05/2012 (posted and faxed)	traemia not accepted.  Response received on 12/7/2012 (letter dated 9/7/2012). The sponsor do not agree with any of our proposed changes.	Response to Eli Lilly sent on 12/10/2012: reiterating original request for akathisia precaution, however inclusion of anaemia/hyponatraemia/confusion al state to AE section no longer required.	13/12/2012

will respond to the TGA by 3/6/2012. Response received 1/6/2012, partially agreeing to akathisia and suicide precaution, but arguing against the inclusion of benign pituitary adenoma in the PI.	
Quetiapine  Seroquel  Astra-Zeneca  PDSEAP Rec 3 (akathisia)  Yes  Yes, agreed by on 3/05/2012 (posted and faxed)  Received submission from sponsor on 24/5/2012, argueing against inclusion of akathisia warning based on previous correspondence with OMA and OPR.  Response sent on 25/10/2012	Seroquel PI Updated 11/02/2013 Seroquel XR  PI last updated 11/02/2013
Sertindole  Serdolect  Lundbeck  PDSEAP Rec 4 (Diabetes)  Yes  Yes, agreed by on 3/5/2012 (posted and faxed)  Received email from sponsor on 28/5/2012, they plan to submit an SRN with some other Pt changes as well, and request a deadline extension until the 15th of June. SRN submitted on 15/6/2012	29/06/2012
SSRIs	

Citalopram	Cipramil	Lundbeck	Addition of sleep disorder and confusion to adverse events section	Yes	Yes, agreed by on 24/5/12	28/5/2012 (posted and faxed)	Email received from sponsor on 25/6/2012 proposing to include the terms 'insomnia', 'abnormal dreams' and 'confusional state' in the post-marketing section of PI, rather than the terms sleep disorder and confusion. Proposed changes approved. Sponsor will submit SRN to OMA.		23/07/2012
Escitalopram	Lexapro	Lundbeck	Addition of psychosis to AE section	Yes	Yes, agreed by on 24/5/12	28/5/2012 (posted and faxed)	Email received from sponsor on 25/6/2012 proposing to include the term 'psychotic disorder' in the post-marketing section of PI, rather than the term 'psychosis'. Proposed changes approved. Sponsor will submit SRN to OMA.	No further action required.	20/07/2012
Paroxetine	Aropax	GSK	PDSEAP Rec 5 (diabetes) Addition of promethazine to interactions section	Yes	Yes, agreed by on 24/5/12	28/5/2012 (posted, unable to get fax to go through)	Email received from sponsor on 26/6/2012 requesting two week extension until 12/7/2012. Extension granted. Response received 16/7/2012 (letter dated 11/7/2012)	OPR response sent 20/8/2012, reiterating original request to include a diabetes precaution and add promethazine to the interactions section. SRN submitted on 5/10/2012	26/04/2013
Fluvoxamine	Luvox	Abbott	Addition of visual disturbance and hepatitis to adverse events section		Yes, agreed by on 24/5/12	28/5/2012 (posted and faxed)	requesting extension until 30/7/2012. Extension granted. Response received on 9/8/2012.	OPR response sent 25/9/2012, reiterating original request (see TRIM R12/1036506 and R12/1041370). Email from sponsor requesting extension until 8/11/2012 - extension granted. Email sent to SIU coordinator on 14/11/2012 confirming that sponsor will submit SRN with PI changes as requested.	Updated 15/01/2013. Mydriasis not added to post-marketing data section. has advised that the PI is acceptable 23/08/2013.
Fluoxetine	Prozac	Eli Lilly Australia Pty Ltd 112 Wharf Road WEST RYDE NSW 2114 Fax: 02 93254688	Addition of confusion to AE section Addition of phenothiazines and antipsychotics to CYP2D6 interactions.	Yes	Yes, agreed by on 24/5/12	28/5/2012 (posted and faxed)	SRN submitted on 4/7/2012	No further action required.	27/06/2012
SNRIs									

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Cymbalta	112 Wharf Road WEST RYDE NSW 2114 Fax: 02 93254688	PDSEAP Rec 1 (bipolar) PDSEAP Rec 2 (MAOIs and serotonin syndrome)	Yes	Yes, agreed by on 24/5/12				23/07/2012
				Check with re any application for extension of indication for zybar, to include depression.				
Avanza	Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670 Fax: 02 9795 9957	Addition of blurred vision and memory impairment to post-marketing section.	Yes	Yes, agreed by on 24/5/12	28/5/2012 (posted and faxed)	12th of July. Extension granted. Response received 16/7/2012 (letter	response is acceptable and no PI update is required at the present	No PI update required
Tolvon	Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670 Fax: 02 9795 9957	PDSEAP Rec 1 (mania)	Yes	Yes, agreed by on 24/5/12	1	Response received 3/7/2012 (letter dated 22/6/2012), sponsor have agreed to mania precaution, but have included additional text regarding close monitoring of patients.	Counter proposal sent to sponsor on 6/7/2012.	23/08/2012
			Type William					
		Avanza Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670 Fax: 02 9795 9957  Tolvon Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670 Fax: 02 9795 9957	Avanza  Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670 Fax: 02 9795 9957  Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670 Fax: 02 9795 9957  Tolvon  Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670 Fax: 02 9795 9957  Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670  PDSEAP Rec 2 (MAOIs and serotonin syndrome)  Addition of blurred vision and memory impairment to post-marketing section.	Avanza Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670  Tolvon Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670  Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670  Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670  PDSEAP Rec 2 (MAOIs and serotonin syndrome)  Addition of blurred vision and memory impairment to post-marketing section.  Yes	112 Wharf Road WEST RYDE NSW 2114 Fax: 02 93254688  Avanza  Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670  Tolvon  Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670  Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670  Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670  Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670  Morth RYDE BC NSW 1670  PDSEAP Rec 1 (mania)  Yes  Yes, agreed by ■ on 24/5/12  Yes, agreed by ■ on 24/5/12	Avanza Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670  Tolvon Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670  Tolvon Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670  Tolvon Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670  Tolvon Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670  Tolvon Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670  Tolvon Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RYDE BC NSW 1670	Avanza Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RVDE BC NSW 1670 Fax: 02 9795 9957  Tolvon Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RVDE BC NSW 1670 Fax: 02 9795 9957  Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RVDE BC NSW 1670 Fax: 02 9795 9957  Tolvon Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RVDE BC NSW 1670 Fax: 02 9795 9957  Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RVDE BC NSW 1670 Fax: 02 9795 9957  Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RVDE BC NSW 1670 Fax: 02 9795 9957  Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RVDE BC NSW 1670 Fax: 02 9795 9957  Merck Sharp & Dohme Australia Pty Ltd Locked Bag 2234 NORTH RVDE BC NSW 1670 Fax: 02 9795 9957	## PDSEAP Rec 2 (MAOLs and serotonin syndrome)  ## PDSEAP Rec 2 (MaOLs and se

Ananfranil	Clomipramine	Novartis	PDSEAP Rec 1 (mania)	Yes	Yes, agreed by on 29/10/2012	7/11/2012 (posted and faxed)		7/12/2012
Imipramine	Tofranil	Link Medical	PDSEAP Rec 1 (mania)	Yes	Yes, agreed by on 29/10/2012	7/11/2012 (posted and faxed)		5/12/2012
Nortriptyline	Allegron	Aspen	PDSEAP Rec 1 (mania)	Yes	Yes, agreed by on 29/10/2012	7/11/2012 (posted and faxed)		7/12/2012
Trimipramine	Surmontil	Aspen	PDSEAP Rec 1 (mania)	Yes	Yes, agreed by on 29/10/2012	7/11/2012 (posted and faxed)		28/11/2012
Dothiepine	Prothiaden	Abbott	No PI update required (already has PDSEAP rec 1)	N/A				
Amitriptyline	Endep	Alphapharm	PDSEAP Rec 1 (mania)	Yes	Yes, agreed by on 29/10/2012	7/11/2012 (posted and faxed)		10/12/2012
MAOIs								
Moclobemide	Aurorix	Meda Valeant	PDSEAP Rec 1 (mania)	Yes	Yes, agreed by <b>150</b> on 29/10/2012	7/11/2012 (posted and faxed)		7/01/2013
Phenelzine	Nardil	Link Medical	Already has PDSEAP rec 1 precaution. Requires contraindication for concomitant use with SSRI/SNRI/TCAs and update of precautions section with further info re serotonin syndrome	Yes	Yes, agreed by on 29/10/2012	7/11/2012 (posted and faxed)		05/12/2012.
Tranylcypromine	Parnate	Goldshield Healthcare	No PI update required (already has PDSEAP rec 1)	N/A				
Melatonergic								
Agonist Agomelatine	Valdoxan	Servier	PDSEAP Rec 1 (mania)	Yes	Yes, agreed by on 29/10/2012	7/11/2012 (posted and faxed)	Letter received from sponsor dated 16/11/2012, requesting to include PI update as part of minor cat 1 application currently in progress with OMA, rather than submitting separate SRN. Discussed with approval given to include as part of current cat 1 application.	This change is being included in PM-2012-03723-1-1. (OPR corro has been attached to Module 1 of application data). Check once approved.