

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 [REDACTED] 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 [REDACTED] 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 [REDACTED] on 3/5/12	3/05/2012 (posted and faxed)	Email from [REDACTED] at 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/hyponatraemia not accepted.	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 [REDACTED] on 3/5/12	3/05/2012 (posted and faxed)	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/confusional state to AE section no longer required.	13/12/2012

Ananfranil	Clomipramine	Novartis	PDSEAP Rec 1 (mania)	Yes	Yes, agreed by [REDACTED] 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 [REDACTED] on 29/10/2012	7/11/2012 (posted and faxed)			5/12/2012
Nortriptyline	Allegron	Aspen	PDSEAP Rec 1 (mania)	Yes	Yes, agreed by [REDACTED] on 29/10/2012	7/11/2012 (posted and faxed)			7/12/2012
Trimipramine	Surmontil	Aspen	PDSEAP Rec 1 (mania)	Yes	Yes, agreed by [REDACTED] 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 [REDACTED] 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 [REDACTED] 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 [REDACTED] on 29/10/2012	7/11/2012 (posted and faxed)			05/12/2012.
Tranlycypromine	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 [REDACTED] 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 [REDACTED], 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.