



Betmiga

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued ² / amended on	Product Information affected ³	Summary
PSUSA/10031 /201806	Periodic Safety Update EU Single assessment - mirabegron	31/01/2019	02/04/2019	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s) ¹ for PSUSA/10031/201806.
IB/0029	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	20/06/2018	n/a		
PSUSA/10031	Periodic Safety Update EU Single assessment -	11/01/2018	n/a		PRAC Recommendation - maintenance

¹ Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.

² A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.

³ SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



/201706	mirabegron				
IA/0028	B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size	12/10/2017	n/a		
R/0026	Renewal of the marketing authorisation.	20/07/2017	18/09/2017	SmPC, Labelling and PL	
PSUSA/10031 /201606	Periodic Safety Update EU Single assessment - mirabegron	12/01/2017	n/a		PRAC Recommendation - maintenance
IB/0025/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size	14/12/2016	n/a		
IA/0023	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	14/09/2016	n/a		
IA/0022	B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	28/07/2016	n/a		

PSUSA/10031 /201512	Periodic Safety Update EU Single assessment - mirabegron	07/07/2016	n/a		PRAC Recommendation - maintenance
IA/0021	B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	25/05/2016	n/a		
IA/0020/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	04/05/2016	n/a		
PSUSA/10031 /201506	Periodic Safety Update EU Single assessment - mirabegron	28/01/2016	31/03/2016	SmPC, Annex II and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10031/201506.
IB/0018	B.II.b.1.e - Replacement or addition of a	22/03/2016	n/a		

	manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products				
PSUSA/10031/201412	Periodic Safety Update EU Single assessment - mirabegron	23/07/2015	14/09/2015	SmPC and PL	Please refer to Betmiga EMEA/H/C/PSUSA/00010031/201412 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
PSUV/0015	Periodic Safety Update	22/01/2015	16/03/2015	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s) for PSUV/0015.
PSUV/0013	Periodic Safety Update	25/09/2014	19/11/2014	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s) for PSUV/0013.
IAIN/0014	B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer	24/06/2014	n/a		
PSUV/0007	Periodic Safety Update	20/02/2014	23/04/2014	SmPC, Annex II and PL	Please refer to Betmiga-2388-PSUV-0033 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation. In addition the MAH took the opportunity to update the list of local representatives in the package leaflet. Furthermore, the PI is being brought in line with the latest QRD template version 9.
IAIN/0012	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF	10/03/2014	n/a		

	location				
IAIN/0010/G	<p>This was an application for a group of variations.</p> <p>B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes</p> <p>B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes</p> <p>B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes</p> <p>B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes</p>	05/02/2014	20/02/2014	SmPC, Labelling and PL	
N/0011		27/01/2014		PL	
IB/0009	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	09/12/2013	n/a		
IB/0008/G	<p>This was an application for a group of variations.</p> <p>B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The</p>	06/12/2013	n/a		

	<p>proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer</p> <p>B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place</p> <p>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS</p> <p>B.I.a.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling down to 10-fold</p> <p>B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS</p>				
IAIN/0006/G	<p>This was an application for a group of variations.</p> <p>C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure</p> <p>C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the PhV system</p>	16/09/2013	n/a		
IAIN/0005/G	<p>This was an application for a group of variations.</p> <p>B.I.a.1.a - Change in the manufacturer of AS or of a</p>	13/09/2013	n/a		

	<p>starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer</p> <p>B.1.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place</p>				
IAIN/0004/G	<p>This was an application for a group of variations.</p> <p>C.1.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the contact details of the QPPV</p> <p>C.1.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV</p> <p>C.1.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system</p>	14/05/2013	n/a		
IAIN/0003	<p>C.1.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV</p>	17/04/2013	n/a		
IAIN/0002/G	<p>This was an application for a group of variations.</p> <p>C.1.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the contact details of the QPPV</p>	20/02/2013	n/a		

	C.1.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system				
IAIN/0001/G	<p>This was an application for a group of variations.</p> <p>A.1 - Administrative change - Change in the name and/or address of the MAH</p> <p>A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release</p>	19/02/2013	20/02/2014	SmPC, Annex II, Labelling and PL	