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
X/0039/G	This was an application for a group of variations. Extension application to introduce a new pharmaceutical form associated with new strength (8 mg/ml prolonged-release granules for oral suspension), grouped with a type II variation	27/06/2024	22/08/2024	SmPC, Labelling and PL	Please refer to Scientific Discussion "Betmiga EMEA/H/C/002388/X/0039/G".

[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).

	(C.I.6.a) to include treatment of neurogenic detrusor overactivity (NDO) in pediatric patients aged 3 to less than 18 years. The RMP (version 9.2) is updated in accordance. Furthermore, the PI is brought in line with the latest QRD template version 10.4. Annex I_2.(c) Change or addition of a new strength/potency Annex I_2.(d) Change or addition of a new pharmaceutical form C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
IAIN/0048	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	16/04/2024	22/08/2024	Annex II and PL	
IA/0047	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	03/11/2023	n/a		
IB/0046	B.III.2.a.1 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - AS	13/06/2023	n/a		
IA/0045/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name	01/02/2023	n/a		

	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 A.7 - Administrative change - Deletion of manufacturing sites				
IB/0044/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.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation 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.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	23/11/2022	n/a		
IB/0041	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	09/08/2022	n/a		
IA/0043	B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material	08/07/2022	n/a		

IB/0040	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	06/07/2022	n/a		
IA/0042	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	04/07/2022	n/a		
PSUSA/10031 /202106	Periodic Safety Update EU Single assessment - mirabegron	10/02/2022	n/a		PRAC Recommendation - maintenance
IA/0038	B.II.e.1.b.3 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Deletion of an immediate packaging container without a complete deletion of a strength or pharmaceutical form	26/10/2021	21/09/2022	SmPC, Labelling and PL	
IA/0036	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	05/10/2021	n/a		
II/0033	Final study report of the PASS Study 178-CL-114 – An evaluation of Cardiovascular Events in Users of Mirabegron and Other Treatments for Overactive Bladder. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission	29/10/2020	n/a		The MAH submitted with this variation the final results of the Post-Authorisation Safety Study 178-CL-114. This study was conducted to investigate the cardiovascular events of mirabegron (especially in elderly). The results of the study did not find higher risk of MACE, AMI, stroke, CV mortality or all-cause mortality among current users of mirabegron as compared to current users of antimuscarinic

	of studies to the competent authority				medications, and the Committee agreed there was no need to update the product information. RMP, version 8.0 was updated to reflect the completion of the study and to bring it in line with GVP rev.2 template.
N/0034	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/03/2020	21/09/2022	PL	
IB/0035/G	This was an application for a group of variations. B.I.z - Quality change - Active substance - Other variation 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 B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS 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	25/03/2020	n/a		
IA/0032/G	This was an application for a group of variations.	27/09/2019	n/a		

	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.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)				
II/0030	Submission of the final report of the Drug Utilization Study of mirabegron using real-word healthcare databases from the NL, ES, UK and FI (study 178-PV-002), as agreed via MEA 009.2. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	14/06/2019	n/a		
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)' 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 /201706	Periodic Safety Update EU Single assessment - mirabegron	11/01/2018	n/a		PRAC Recommendation - maintenance
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)	28/07/2016	n/a		

	packaging material not in contact with the finished product formulation - Change that does not affect the product information				
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 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	22/03/2016	n/a		
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 location	10/03/2014	n/a		
IAIN/0010/G	This was an application for a group of variations. 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 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 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 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	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	09/12/2013	n/a		

	data				
IB/0008/G	This was an application for a group of variations. 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 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.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling down to 10-fold 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	06/12/2013	n/a		
IAIN/0006/G	This was an application for a group of variations. 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	16/09/2013	n/a		

	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				
IAIN/0005/G	This was an application for a group of variations. 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 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	13/09/2013	n/a		
IAIN/0004/G	This was an application for a group of variations. C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the contact details of the QPPV C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV C.I.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	14/05/2013	n/a		

IAIN/0003	C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV	17/04/2013	n/a		
IAIN/0002/G	This was an application for a group of variations. C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the contact details of the QPPV C.I.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	20/02/2013	n/a		
IAIN/0001/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release	19/02/2013	20/02/2014	SmPC, Annex II, Labelling and PL	