Pramipexole Teva

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
IB/0057	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	29/08/2024		SmPC and PL	

[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).

IB/0056	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	10/04/2024	19/04/2024	SmPC and PL	
IAIN/0055	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	24/07/2023	n/a		
IG/1508	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)	23/05/2022	n/a		
IA/0053	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	23/11/2021	n/a		
IB/0052	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	05/11/2021	13/12/2021	PL	
IA/0050	A.7 - Administrative change - Deletion of manufacturing sites	22/12/2020	13/12/2021	Annex II and PL	

IB/0049	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	04/06/2020	26/06/2020	SmPC, Annex II, Labelling and PL	
IA/0048	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	10/01/2020	n/a		
IA/0047/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	31/10/2019	n/a		
N/0046	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/08/2019	03/09/2019	PL	
IA/0045/G	This was an application for a group of variations. B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure B.II.f.1.e - Stability of FP - Change to an approved stability protocol	20/06/2019	n/a		

IB/0044	B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	29/01/2019	n/a		
IB/0043	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	14/09/2018	03/09/2019	SmPC, Labelling and PL	
IAIN/0042/G	This was an application for a group of variations. B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	14/12/2017	30/04/2018	SmPC, Annex II and PL	
IA/0041	B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure	29/11/2017	n/a		
IB/0040	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	30/05/2017	30/04/2018	SmPC and PL	

IA/0039	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)	20/09/2016	n/a		
IAIN/0038/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	20/09/2016	16/12/2016	Annex II and PL	
IB/0037	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	17/08/2016	16/12/2016	SmPC, Labelling and PL	
IA/0036	B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	25/02/2016	n/a		
IB/0034/G	This was an application for a group of variations. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	12/01/2016	n/a		

	B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation				
IAIN/0035/G	This was an application for a group of variations. B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.e.2.b - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.e.2.b - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.e.2.c - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.2.c - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete	22/12/2015	16/12/2016	Annex II and PL	

	parameter) B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products				
IA/0033/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	27/05/2015	n/a		
T/0032	Transfer of Marketing Authorisation	09/01/2015	27/01/2015	SmPC, Labelling and PL	
IB/0030	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	24/09/2014	n/a		
IAIN/0031	B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer	19/09/2014	n/a		
IB/0029	B.II.c.2.d - Change in test procedure for an excipient	30/07/2014	n/a		

	- Other changes to a test procedure (including replacement or addition)				
IB/0028	Update of SmPC sections 4.4 and 4.8 to include mania and delirium as adverse drug reactions and to add a new warning to inform healthcare professionals about the possibility of these events to occur under pramipexole treatment as well as the need for monitoring patients and dose adjustment. The Package Leaflet is updated accordingly. In addition, the contact details of LV, MT, LU, IS, CY and HU representatives have been updated. Furthermore, minor editorial corrections have been implemented in DA SmPC and ES SmPC and package leaflet. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	02/06/2014	27/01/2015	SmPC and PL	
R/0027	Renewal of the marketing authorisation.	27/06/2013	26/08/2013	SmPC, Annex II, Labelling and PL	The CHMP reviewed the available data on the safety and efficacy of pramipexole, including all variations introduced since the marketing authorisation was granted, and based on these data considered that the risk-benefit balance of Pramipexole Teva in the treatment of the signs and symptoms of idiopathic Parkinson's disease, alone (without levodopa) or in combination with levodopa, i.e. over the course of the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and

					fluctuations of the therapeutic effect occur (end of dose or "on off" fluctuations) remains favourable. The CHMP recommended the renewal of the Marketing Authorisation with unlimited validity.
II/0023	Change to the specification of hardness of the 0.088 mg tablets, and of hardness and thickness of the 0.35 mg tablets. B.II.b.5.e - Change to in-process tests or limits applied during the manufacture of the finished product - Widening of the approved IPC limits, which may have a significant effect on overall quality of the finished product	21/03/2013	21/03/2013		
IB/0026/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH	04/03/2013	26/08/2013	SmPC, Annex II, Labelling and PL	1. EMEA/H/C/xxxx/WS/0311: Update of section 4.8 of the SmPC in order to include inappropriate antidiuretic hormone secretion as an adverse drug reaction based on post-marketing data. Furthermore, the PI was brought in line with the latest QRD template version 8.0. 2. EMEA/H/C/xxxx/WS/0326: Update of sections 4.4 and 4.8 of the SmPC in order to update the safety information by implementing class labelling for the risk of impulse control disorders. 3. EMEA/H/C/xxxx/WS/0128: Section 4.8 of the SmPC has been updated based on new data to include 'cardiac failure' as a new side effect, and information has been added to section 4.8 about the estimation of frequencies for listed side effects observed post-marketing. The Package Leaflets were updated in accordance with the above.

					In addition, the list of local representatives has been updated.
IA/0024	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 currently approved batch size	14/02/2013	n/a		
IAIN/0022/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site A.5.b - Administrative change - Change in the name and/or address of a manufacturer of the finished product, including quality control sites (excluding manufacturer for batch release)	07/12/2012	n/a		
IA/0021/G	This was an application for a group of variations. B.II.e.3.b - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition) B.II.e.3.b - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition) B.II.e.3.b - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition)	23/11/2012	n/a		

	B.II.e.2.a - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits				
IA/0020	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	23/11/2012	n/a		
IA/0019	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	23/11/2012	n/a		
IAIN/0018/G	This was an application for a group of variations. B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.III.2.a.1 - Change of specification('s) of a former	13/11/2012	n/a		

	non Pharmacopoeial substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - AS				
IB/0016	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	10/05/2012	n/a		
IB/0015	B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	08/05/2012	n/a		
IA/0014/G	This was an application for a group of variations. B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	16/03/2012	n/a		
IB/0013	B.II.a.3.z - Changes in the composition (excipients) of the finished product - Other variation	07/12/2011	n/a		

IA/0012/G	This was an application for a group of variations. B.II.a.3.b.1 - Changes in the composition (excipients) of the finished product - Other excipients - Any minor adjustment of the quantitative composition of the finished product with respect to excipients B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the currently approved batch size	28/10/2011	n/a		
IA/0011	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	24/08/2011	n/a		
IB/0010/G	This was an application for a group of variations. Variation type IB, C.I.3.a Update of the SPC section 4.5 to include the results of an in depth evaluation of h0CT2 inhibitors (implementation of agreed wording of FUMs for Sifrol amd Mirapexin) and SPC section 4.8 to include new side effects and revise frequency categories on assessment of PSUR 13. The Package Leaflet has been updated accordingly. Variation type IB, C.I.3.a Update of Section 5.3 of SPC to include non-clinical information concerning delayed sexual development observed in rats as agreed in the assessment of FUMs for Sifrol / Mirapexin.	28/01/2011	n/a	SmPC, Annex II and PL	Sections 4.2, 4.5, 4.6, 4.8 and 5.3 of the SPC of Pramipexole Teva were updated to align it with that of the reference medicinal product. Sections 2 and 4 of the Package leaflet were updated accordingly. This followed changes to the SPC of the reference medicinal product (Sifrol) via the following procedures: EMEA/H/C/133/WS/0041/G and EMEA/H/C/133/WS/0061. In addition, Annex II was updated to reflect the revised template for the description of the DDPS and the list of local representatives in the Package Leaflet was updated.

	In addition, minor typographical errors in the Annexes have been amended for PT, LV and CS languages and updates to the local representatives list in the PIL is also being made. Annexes I-III have been updated accordingly. As previously agreed, Annex II.B have also been updated in line with the October and November CHMP procedural announcement. C.I.3.a - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under A 45/46, or amendments to reflect a Core SPC - Changes with NO new additional data are submitted by the MAH C.I.3.a - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under A 45/46, or amendments to reflect a Core SPC - Changes with NO new additional data are submitted by the MAH				
IA/0008/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	09/12/2010	09/12/2010	SmPC, Labelling and PL	

	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 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				
N/0009	The Marketing Authorisation Holder (MAH) took the opportunity to update details of local representatives in Annex IIIB. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	26/11/2010	n/a	PL	

IB/0006	B.II.a.2.a - Change in the shape or dimensions of the pharmaceutical form - Immediate release tablets, capsules, suppositories and pessaries	19/10/2010	n/a	SmPC and PL	
IB/0005	B.II.a.1.a - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings	19/10/2010	n/a	SmPC and PL	
IA/0007	A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release	13/09/2010	n/a	Annex II and PL	
IA/0004	IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site	14/10/2009	n/a		
II/0003	Update, in line with the reference medicinal product of section 4.8 of the Summary of Product Characteristics to include the terms "dyspnoea" and "pneumonia". The Package Leaflet is being updated accordingly. In addition, the list of local representatives was added to the Package Leaflet. Update of Summary of Product Characteristics and Package Leaflet	23/07/2009	20/08/2009	SmPC and PL	Section 4.8 of the SPC of Pramipexole Teva was updated to align it with that of the reference medicinal product. This followed changes to the SPC of the reference medicinal products via the following procedure: EMEA/H/C/133/II/52 (Sifrol).
II/0001	Update of Summary of Product Characteristics and Package Leaflet	23/04/2009	20/05/2009	SmPC and PL	
IA/0002	IA_08_b_01_Change in BR/QC testing - repl./add. manuf. responsible for BR - not incl. BC/testing	15/05/2009	n/a	Annex II and PL	