Sildenafil 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/0041	C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	01/07/2022		SmPC and PL	To update section 4.5 of the SmPC to add a warning about the increase in hypotension observed with concomitant use of sildenafil and sacubitril/valsartan. The Package leaflet is updated accordingly.

[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).

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N/0040	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/09/2021		PL	
IA/0039	A.7 - Administrative change - Deletion of manufacturing sites	18/01/2021	29/09/2021	Annex II and PL	
IAIN/0038	B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)	19/11/2020	n/a		
IB/0037	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	01/10/2020	29/09/2021	SmPC, Annex II, Labelling and PL	
N/0036	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/08/2019	29/09/2021	Labelling and PL	
IAIN/0035	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	24/05/2018	n/a		
IA/0034/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	22/05/2017	n/a		

IB/0033/G	This was an application for a group of variations. 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 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	17/06/2016	n/a		
IA/0032	A.7 - Administrative change - Deletion of manufacturing sites	25/04/2016	06/04/2017	Annex II and PL	
IB/0031	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	09/12/2015	07/01/2016	SmPC and PL	
IAIN/0029	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	24/09/2015	n/a		
T/0028	Transfer of Marketing Authorisation	17/02/2015	10/03/2015	SmPC, Labelling and PL	
IA/0027	A.7 - Administrative change - Deletion of manufacturing sites	28/11/2014	10/03/2015	Annex II and	

				PL	
IB/0026	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	22/10/2014	n/a		
R/0025	Renewal of the marketing authorisation.	24/07/2014	09/09/2014	SmPC and PL	Based on the CHMP review of the available information and on the basis of a re-evaluation of the benefit risk balance, the CHMP is of the opinion that the quality, safety and efficacy of Sildenafil teva continues to be adequately and sufficiently demonstrated and therefore considered that the benefit risk profile of Sildenafil teva continues to be favourable in the treatment of adult men with erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for Sildenafil teva to be effective, sexual stimulation is required. The CHMP recommended the renewal of the Marketing Authorisation with unlimited validity.
IB/0024/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.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.b.2.a - Change in test procedure for AS or	25/03/2014	n/a		

	starting material/reagent/intermediate - Minor changes to an approved test procedure 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 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 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				
IB/0021/G	This was an application for a group of variations. 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 B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement	06/12/2013	n/a		

	or addition) for the AS or a starting material/intermediate				
II/0017	Redefinition of the starting material of the active substance. B.I.a.2.b - Changes in the manufacturing process of the AS - Substantial change to the manufacturing process of the AS which may have a significant impact on the quality, safety or efficacy of the medicinal product	21/11/2013	n/a		
IB/0022/G	This was an application for a group of variations. B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	07/11/2013	n/a		
IB/0023/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a	23/10/2013	31/01/2014	SmPC, Annex II, Labelling and PL	1. Harmonisation of the PI in line with the Originator product and update to the latest QRD template. Also, inclusion of an additional local representative for the new

	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 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				member State Croatia, in the package leaflet. 2. Update of Section 4.4 of the SmPC to revise the information on acute NAION based on new data coming from the clinical study A1481259 according to the Originator. The package leaflet was amended accordingly.
IAIN/0020	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	23/05/2013	n/a		
IB/0019	B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation	20/03/2013	n/a		
IB/0018	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	13/03/2013	31/01/2014	SmPC, Annex II and PL	Implementation of changes approved in the reference product - update of section 4.8 to add 'Penile haemorrhage, Haematospermia, and Haematuria' with an uncommon frequency and deletion of the footnote referring to ear disorders as requested by CHMP. The Package Leaflet was updated accordingly. The MAH also took the opportunity to update Annex II according to the latest QRD template and to update the list of local representatives for Iceland, Ireland, Estonia, Norway and Finland.
IB/0014/G	This was an application for a group of variations. B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any	20/02/2013	n/a		

	manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products B.II.b.3.a - Change in the manufacturing process of the finished product - Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products B.II.b.2.a - Change to batch release arrangements and quality control testing of the FP - Replacement or addition of a site where batch control/testing takes place				
IB/0016/G	This was an application for a group of variations. B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	08/02/2013	31/01/2014	SmPC, Labelling and PL	
IA/0015	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	20/12/2012	n/a		
IA/0012/G	This was an application for a group of variations.	20/12/2012	n/a		

	A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites				
IB/0011/G	This was an application for a group of variations. B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter	26/10/2012	n/a		
IAIN/0010/G	This was an application for a group of variations. B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing A.7 - Administrative change - Deletion of	01/06/2012	10/09/2012	Annex II and PL	

	manufacturing sites				
IB/0008/G	This was an application for a group of variations. B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.III.2.a.1 - Change of specification('s) of a former non Pharmacopoeial substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - AS 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.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.c.3.b - Change in test procedure for the immediate packaging of the AS - Other changes to a test procedure (including replacement or addition) 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	04/04/2012	n/a		

	data				
IA/0009/G	This was an application for a group of variations. 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) 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)	12/03/2012	n/a		
IA/0007/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 responsible for batch release B.II.a.2.a - Change in the shape or dimensions of the pharmaceutical form - Immediate release tablets, capsules, suppositories and pessaries B.II.a.3.a.1 - Changes in the composition (excipients) of the finished product - Changes in components of the flavouring or colouring system - Addition , deletion or replacement	28/10/2010	n/a	SmPC, Annex II and PL	
IB/0006	Update of section 4.8 of the Summary of Product Characteristics to include severe cutaneous adverse drug reactions, i.e. Stevens Johnson syndrome and Toxic epidermal necrolysis. The Package Leaflet is amended accordingly.	20/10/2010	n/a	SmPC and PL	

	In addition, the MAH made minor linguistic amendments throughout the PIs (including the list of local representatives). 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				
IA/0005	B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)	29/09/2010	n/a	SmPC, Labelling and PL	
II/0002	To add an additional active substance manufacturer. Quality changes	24/06/2010	30/06/2010		
II/0003	- addition of a site as a finished product manufacturer, primary and secondary packaging site, quality control and batch release site, - change in manufacturing process for the finished product as a consequence of technology transfer, - change in batch sizes for all strengths as a consequence of technology transfer - addition of alternative immediate packaging for the finished product. Quality changes	18/03/2010	22/04/2010	Annex II and PL	
IB/0004	To change in the composition of the immediate packaging material for Sidenafil Teva finished	04/02/2010	n/a		

	product (EMEA/H/C/001073/0000/001-018) adding Foil Al-Silver Plain and PVC Film Clear Al foil T 200/25/60. IB_29_b_Change in qual./quant. composition of immediate packaging - all other pharm. forms IB_30_b_Change in supplier of packaging components - replacement/addition				
IA/0001	To replace the manufacturing site responsible for secondary packaging IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site	08/01/2010	n/a		