Vizarsin

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
N/0036	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/02/2023		PL	
IB/0035	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	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

[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).

	assessment done under A 45/46 - Other variation				updated accordingly.
N/0034	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	06/01/2022		PL	
IAIN/0033	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	01/02/2021	24/01/2022	SmPC, Labelling and PL	
IB/0032/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 C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	06/11/2020	24/01/2022	SmPC, Annex II, Labelling and PL	
IA/0031	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	27/02/2020	n/a		
II/0029	B.I.a.1.b - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a manufacturer of the AS supported by an ASMF	12/09/2019	n/a		
IA/0030	B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change	30/10/2018	n/a		

	to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State				
IB/0028	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	06/12/2017	31/01/2019	SmPC	
N/0027	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/07/2017	31/01/2019	Labelling and PL	
IB/0026/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	17/05/2016	28/04/2017	SmPC, Labelling and PL	
N/0025	Amendment of section 5 of the carton label text for the trilingual version in accordance with the assessment of EMEA/H/C/001076/IB/024. In addition, linguistic changes have also been made in section 5 of the trilingual carton label in order to adjust the translation fully in accordance with the approved English version for the following languages: BG, DE, FR, HU, IT and NL. And one additional linguistic correction has been made to the	01/03/2016	28/04/2017	Labelling	

	German PI in section 5 of the blister label to revise the translation of the instructions for the separation of the unit-dose blister for a better description. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)				
IB/0024	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	08/01/2016	22/02/2016	SmPC, Annex II, Labelling and PL	
IA/0023	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	02/12/2015	n/a		
IB/0021	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	15/10/2015	n/a		
IAIN/0022	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	06/10/2015	n/a		
IA/0020	A.7 - Administrative change - Deletion of manufacturing sites	06/10/2015	n/a		

IB/0019/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 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 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	16/07/2014	28/07/2015	SmPC and PL	
R/0018	Renewal of the marketing authorisation.	20/03/2014	16/05/2014	SmPC, Annex II, Labelling 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 Vizarsin continues to be adequately and sufficiently demonstrated and therefore considered that the benefit risk profile of Vizarsin 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

					Vizarsin to be effective, sexual stimulation is required.
IB/0017	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	26/11/2013	20/12/2013	SmPC	
IB/0016/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 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	10/10/2013	20/12/2013	SmPC and PL	1. Harmonisation of the PI in line with the Originator product and update to the latest QRD template. The MAH also took the opportunity to make linguistic corrections in some of the languages. 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.
N/0015	Update of the list of local representatives contact details and addition of a local representative of the MAH for Croatia in the package leaflets. The MAH also corrected the pictograms for orodispersable tablets in the Labelling and in the Package Leaflet. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/07/2013	20/12/2013	Labelling and PL	Update of the list of local representatives contact details and addition of a local representative of the MAH for Croatia in the package leaflets. The MAH also corrected the pictograms for orodispersable tablets in the Labelling and in the Package Leaflet.
IB/0014/G	This was an application for a group of variations.	15/05/2013	n/a		

	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 B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation				
IB/0013	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	14/03/2013	20/12/2013	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 the list of local representatives for PL, PT and ES and to update Annex II according to the latest QRD template.
IB/0012	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	18/12/2012	20/12/2013	SmPC, Labelling and PL	
X/0006	Annex I_1.(a) Replacement of a chemical AS by diff. salt/ester complex/derivative, with the same therapeutic moiety Annex I_2.(d) Change or addition of a new pharmaceutical form	15/03/2012	15/05/2012	SmPC, Labelling and PL	See Assessment Report EMEA/H/C/001076/X/06
N/0010	Update of the Spanish local representative's contact details. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	28/11/2011	15/03/2012	PL	Update of the Spanish local representative's contact details.

IB/0009	B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF	22/11/2011	n/a		
IA/0008/G	This was an application for a group of variations. 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.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold	27/10/2011	n/a		
IB/0007	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	25/08/2011	n/a	SmPC and PL	- to extend the shelf life of the finished product from 24 to 36 months - the MAH took the opportunity to correct editorial changes to the product information in Czech, Finnish and French
IA/0005	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	28/01/2011	n/a		
IA/0004	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	15/12/2010	n/a		

IB/0003	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. In addition, the web address of the EMA has been updated in Section 10 of the SmPC and in the PL. These changes were made to bring Vizarsin's product information in line with the reference medicinal product Viagra. Furthermore the MAH has updated the contact details of the local representatives in Spain, Latvia, Lithuania, Spain, Austria, Poland and the United Kingdom. In addition minor linguistic changes were introduced in the Latvian SmPC to align with the originator. In addition the MAH took this opportunity to make minor linguistic changes to the Danish and Norwegian annexes. 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	23/08/2010	n/a	SmPC and PL	
IA/0002	IA_09_Deletion of manufacturing site	23/11/2009	n/a		
IA/0001	IA_07_a_Replacement/add. of manufacturing site:	10/11/2009	n/a		

	Secondary packaging site				