Silodyx

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/0049	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	10/10/2022		SmPC, Labelling 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).

IG/1490	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	21/03/2022	n/a		
IG/1489	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	21/03/2022	n/a		
IG/1434	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	22/09/2021	n/a		
N/0045	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/06/2021		PL	
WS/2003	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	09/04/2021	n/a		
N/0044	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/04/2021		PL	
PSUSA/2701/ 202001	Periodic Safety Update EU Single assessment - silodosin	04/09/2020	n/a		PRAC Recommendation - maintenance

WS/1885/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.a.3.b.6 - Changes in the composition (excipients) of the finished product - Other excipients - Replacement of a single excipient with a comparable excipient with the same functional characteristics and at a similar level B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	03/09/2020	n/a		
IG/1284/G	This was an application for a group of variations. B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability -	21/08/2020	n/a		

	Updated certificate from an already approved manufacturer B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material) B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material)				
IG/1228	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	30/04/2020	n/a		
WS/1659/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.2.e - Changes in the manufacturing process of	30/01/2020	n/a		

	the AS - Minor change to the restricted part of an ASMF B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF				
PSUSA/2701/201901	Periodic Safety Update EU Single assessment - silodosin	05/09/2019	n/a		PRAC Recommendation - maintenance
IG/1113	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	31/07/2019	n/a		
WS/1610/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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 C.I.11.a - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of wording agreed by the competent authority	20/06/2019	17/07/2020	SmPC, Annex II, Labelling and PL	
IG/0992/G	This was an application for a group of variations.	16/10/2018	n/a		

	B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer				
PSUSA/2701/201801	Periodic Safety Update EU Single assessment - silodosin	06/09/2018	n/a		PRAC Recommendation - maintenance
IG/0929	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	27/04/2018	n/a		
N/0030	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/04/2018	17/07/2020	Labelling	
WS/1228/G	This was an application for a group of variations following a worksharing procedure according to	28/09/2017	n/a		

	Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF 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				
PSUSA/2701/ 201701	Periodic Safety Update EU Single assessment - silodosin	01/09/2017	n/a		PRAC Recommendation - maintenance
IG/0825/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	10/08/2017	n/a		

	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				
WS/0997/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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.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.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF	29/09/2016	n/a		

	B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF				
WS/0999/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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 B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF	29/09/2016	n/a		
PSUSA/2701/201601	Periodic Safety Update EU Single assessment - silodosin	02/09/2016	n/a		PRAC Recommendation - maintenance
IG/0700/G	This was an application for a group of variations. B.III.1.b.2 - Submission of a new/updated or	18/07/2016	n/a		

	deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer				
WS/0857/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a	21/01/2016	n/a		

	re-test period/storage period supported by real time data				
WS/0858	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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	21/01/2016	n/a		
PSUSA/2701/ 201501	Periodic Safety Update EU Single assessment - silodosin	10/09/2015	n/a		PRAC Recommendation - maintenance
IG/0571/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer	26/06/2015	n/a		

WS/0672/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of section 5.1 of the SmPC in order to add efficacy and safety information from a European Phase IV open label clinical study undertaken in patients with benign prostate hyperplasia. The RMP has been updated accordingly. In addition, the MAH took the opportunity to update the RMP with changes requested by the PRAC in the recent renewal and PSUR procedures. A revised RMP version 11.2 was agreed during the procedure. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.11.a - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of wording agreed by the competent authority	26/02/2015	24/02/2016	SmPC	A phase IV study was conducted to evaluate the effectiveness and safety of silodosin in the treatment of lower urinary tract symptoms in patients with benign prostatic hyperplasia when used in real life situations. The results suggest that silodosin is effective in real-life situations. The results of this study have been included in section 5.1 of the SmPC. In this Phase IV clinical trial, with a mean baseline IPSS total score of 18.9 points, 77.1 % were responders to silodosin (as assessed by a change from baseline in the IPSS total score of at least 25 %). Approximately half of the patients reported an improvement in the most bothersome symptoms complained at baseline by the patients (i.e. nocturia, frequency, decreased stream, urgency, terminal dribbling and incomplete emptying), as assessed by the ICS-male questionnaire.
R/0016	Renewal of the marketing authorisation.	24/07/2014	18/09/2014	SmPC, Annex II 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 Silodyx continues to be adequately and sufficiently demonstrated and therefore considered that the benefit risk profile of Silodyx continues to be favourable in the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). The CHMP recommends the

					renewal of the Marketing Authorisation with unlimited validity.
PSUV/0017	Periodic Safety Update	11/09/2014	n/a		PRAC Recommendation - maintenance
WS/0466/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. To include a new manufacturer and to increase the batch size. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site 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 B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold	18/12/2013	18/09/2014	Annex II and PL	

	compared to the originally approved batch size				
IG/0374	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	26/11/2013	n/a		
PSUV/0013	Periodic Safety Update	19/09/2013	13/11/2013	SmPC and PL	Please refer to Silodyx-H-C-1209-PSUV-0013 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation.
IG/0344	B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer	27/09/2013	n/a		
IG/0316	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	08/07/2013	n/a		
N/0010	Update of the local representative's contact details for Italy in the package leaflet. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/01/2013	13/11/2013	PL	
IB/0009	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)	04/01/2013	13/11/2013	SmPC	
WS/0197	This was an application for a variation following a worksharing procedure according to Article 20 of	15/03/2012	20/04/2012	SmPC, Annex II, Labelling	Following the assessment of the latest PSUR of silodosin, a review of the spontaneously received reports, clinical trial

	Commission Regulation (EC) No 1234/2008. The variation relates to an update of section 4.8 (Undesirable Effects) of the SmPC (Summary of Product Characteristics) and section 4 (Possible Side Effects) of the Package Leaflet (PL) to include the adverse drug reactions 'tachycardia, palpitations, allergic-type reactions such as skin rash, pruritus, urticaria and drug eruption, as well as abnormal liver functions tests (LFTs)' following the assessment of the latest PSUR. In addition, minor changes have been made in accordance with the QRD template and for consistency throughout the product information. C.I.3.b - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under Article 45/46, or amendments to reflect a Core SPC - Change(s) with new additional data submitted by the MAH			and PL	data and literature supported the possibility that some events could be due to silodosin. 'Tachychardia, allegic-type reactions, such as skin rash, pruritus, urticaria and drug erruption, abnormal results of liver function tests' with a 'uncommon' incidence and 'palpitations' with a 'rare' was therefore added to the silodosin product information.
WS/0177/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. To add a new manufacturer of the starting material. Minor changes in the manufacturing process of the active substance. B.I.a.1.z - Change in the manufacturer of AS or of a	15/03/2012	15/03/2012		

	starting material/reagent/intermediate for AS - Other variation B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF				
WS/0176	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. To add a new manufacturer of the starting material. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	15/03/2012	15/03/2012		
IG/0144/G	This was an application for a group of variations. B.III.1.b.2 - Submission of a new or updated Ph. Eur. TSE Certificate of suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.3 - Submission of a new or updated Ph. Eur. TSE Certificate of suitability - Updated certificate from an already approved manufacturer	09/03/2012	n/a		
N/0004	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/07/2011	n/a	Labelling and PL	Update of the Portuguese local representative's contact details. The MAH also took the opportunity to make minor linguistic amendments in the Romanian, Portuguese, German and Slovakian product information in annexes IIIA and IIIB.

N/0003	Update of the contact details of the local repsentatives in Belgium, Greece, Luxembourg and the Netherlands. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/10/2010	n/a	PL	
IB/0002	Addition of new pharmacovigilance database. C.I.9.d - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the safety database	23/08/2010	n/a	Annex II	
N/0001	The Marketing Authorisation Holder updated the list of Local Representatives for Portugal and France. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	10/06/2010	n/a	PL	