Trevicta

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
WS/2405	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance	25/05/2023		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).

	data				
IG/1499	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	21/03/2022	n/a		
PSUSA/2266/202106	Periodic Safety Update EU Single assessment - paliperidone	10/02/2022	n/a		PRAC Recommendation - maintenance
IB/0028	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	08/11/2021	n/a		
WS/1877	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	09/04/2021	29/04/2022	SmPC and PL	
IG/1257	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	21/07/2020	n/a		
WS/1833/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.	25/06/2020	n/a		

	B.I.b.z - Change in control of the AS - Other variation B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits				
R/0022	Renewal of the marketing authorisation.	19/09/2019	14/11/2019	SmPC	
WS/1638	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.c.z - Container closure system of the AS - Other variation	11/07/2019	n/a		
IB/0019/G	This was an application for a group of variations. B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	07/03/2019	n/a		
IB/0016/G	This was an application for a group of variations. B.I.z - Quality change - Active substance - Other variation B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	07/03/2019	n/a		

IG/1075/G	This was an application for a group of variations. 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 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	28/02/2019	n/a		
IA/0020/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the 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	27/02/2019	n/a		
PSUSA/2266/ 201806	Periodic Safety Update EU Single assessment - paliperidone	14/02/2019	n/a		PRAC Recommendation - maintenance
IA/0018/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	06/02/2019	n/a		

	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				
IA/0017	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)	06/02/2019	n/a		
WS/1417/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 sections 4.4 and 4.5 of the SmPC in order to add information regarding concomitant use of paliperidone and risperidone with psychostimulants (in line with the CMDh recommendations for risperidone) and of section 4.8 of the SmPC to add catatonia as a new side-effect categorised as 'Rare'. The Package Leaflet is updated accordingly. The MAH took also the occasion to include editorial changes in the PI and to update the local representative for Ireland in the Package leaflet for Trevicta, Invega and Xeplion and Bulgaria for Risperidal Consta. The	13/09/2018	12/12/2018	SmPC, Labelling and PL	Caution is warranted in patients receiving both, psychostimulants (e.g., methylphenidate) and paliperidone concomitantly, as extrapyramidal symptoms could emerge when adjusting one or both medications. Gradual withdrawal of stimulant treatment is recommended. Catatonia has been introduced in the list of adverse drug reaction with a rare frequency.

	MAH also implemented the weekdays in section 5 of the annex IIIA for invega OPA blister according to the QRD guidance. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
WS/1359	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of section 4.8 of the SmPC in order to include somnambulism and sleep-related eating disorder under a rare and not known frequency, respectively, after post marketing reports analysis. The Package Leaflet is updated accordingly. In addition, for INVEGA/XEPLION/TREVICTA minor editorial changes have been introduced and the details of the local representatives in Portugal, Belgium Iceland, Slovenia, Netherlands and Luxembourg are updated in the Package Leaflet. An update is also proposed to the INVEGA Package Leaflet in section 2 to add a standard statement concerning sodium content according to the Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'. Updated wording to align to the Excipients Guideline	31/05/2018	12/12/2018	SmPC and PL	

	is also proposed for Risperdal Oral, together with removing the brand name (West Medimop) for the vial adaptors for Risperdal Consta. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
II/0011	Update of section 4.8 of the SmPC in order to update the safety information after assessment of study R092670-SCA-3004 (A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of Paliperidone Palmitate Evaluating Time to Relapse in Subjects With Schizoaffective Disorder). The Package Leaflet has been updated accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	14/09/2017	12/12/2018	SmPC and PL	There were no new adverse drug reactions following the assessment of study R092670-SCA-3004; only changes to frequencies of existing ADRs have been identified. For more information please refer to the Summary of Product Characteristics.
IB/0009	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	17/09/2016	14/09/2017	SmPC	
X/0007/G	This was an application for a group of variations. Annex I_2.(c) Change or addition of a new strength/potency A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or	01/04/2016	26/05/2016	SmPC, Annex II, Labelling and PL	Please refer to Scientific Discussion Trevicta-H-4066-X-0007-G-AR.

	modification of an approved one C.I.7.b - Deletion of - a strength C.I.7.b - Deletion of - a strength C.I.7.b - Deletion of - a strength C.I.7.b - Deletion of - a strength C.I.7.b - Deletion of - a strength C.I.7.b - Deletion of - a strength				
PSUSA/2266/201506	Periodic Safety Update EU Single assessment - paliperidone	14/01/2016	n/a		PRAC Recommendation - maintenance
WS/0760	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of sections 4.4 and 4.8 of the SmPC in order to add a warning and update the safety information based on post-marketing experience on occurrence of hypersensitivity reactions in patients who have previously tolerated oral risperidone or paliperidone. The Package Leaflet is updated accordingly. In addition, the Worksharing applicant (WSA) took the opportunity to introduce minor editorial changes and to update the list of local representatives for Belgium and Luxemburg in the Package Leaflet. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	16/07/2015	13/04/2016	SmPC and PL	Anaphylactic reactions in patients who have previously tolerated oral risperidone or oral paliperidone have been rarely reported during post marketing experience. If hypersensitivity reactions occur, discontinue use of paliperidone; initiate general supportive measures as clinically appropriate and monitor the patient until signs and symptoms resolve.
IG/0582/G	This was an application for a group of variations.	01/07/2015	n/a		

	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 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				
WS/0700	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	25/06/2015	13/04/2016	SmPC and PL	
IG/0549	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	29/04/2015	n/a		
IB/0003	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	27/04/2015	13/04/2016	SmPC	
IG/0531	B.II.b.1.a - Replacement or addition of a	05/03/2015	n/a		

	manufacturing site for the FP - Secondary packaging site				