Sancuso

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
T/0064	Transfer of Marketing Authorisation	30/10/2024	22/11/2024	SmPC, Labelling and PL	
PSUSA/10101 /202310	Periodic Safety Update EU Single assessment - granisetron (transdermal patch)	13/06/2024	n/a		PRAC Recommendation - maintenance

[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).

IA/0062/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites	14/07/2023	n/a		
II/0061	Update of sections 4.4, 4.6, 4.7, 4.8, 4.10 and 5.3 of the SmPC in order to add 'Serotonin syndrome' and 'Application site Reactions' to the list of adverse drug reactions (ADRs) with frequency unknow; as well as 'Application site Irritation' with frequency 'Uncommon' based on post-marketing data and literature. The MAH also proposes to update sections 4.4 and 4.5 of the SmPC to add drug-drug interaction information with buprenorphine/Opioids and serotonergic medicinal products based on post-marketing data and literature. The Package Leaflet has been updated accordingly. The RMP version 5 has also been submitted. In addition, the MAH took the opportunity to introduce editorial changes in the SmPC. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	09/02/2023	25/01/2024	SmPC and PL	Section 4.4 New information added Gastrointestinal disorders: "Granisenton may mask a progressive ileus and/or gastric distension caused by an underlying condition" Serotonin syndrome: "There have also been reports of possible drug-drug interactions between buprenorphine/Opioids and serotonergic medicinal products leading to serotonin syndrome" Skin Reactions: "In clinical studies with granisetron transdermal patch, application site reactions generally mild in intensity were reported and did not lead to discontinuation of use. If severe reactions, or a generalised skin reaction occur (e.g. allergic rash, including erythematous, macular, papular rash or pruritus), the transdermal patch must be removed". Potential for drug abuse and dependence "Granisetron has no known potential for abuse and dependence" Section 4.7 Text replaced: "The effect of SANCUSO on the ability to drive or operate machinery has not been studied" Section 4.8 Text replaced: Serotonin syndrome was added as ADR with frequency unknown with a description a selected ADR regarding

					reports of serotonin syndrome following concomitant use of 5 HT3 antagonists with Buprenorphine, opiods SSRIs, SNRIs and serotonergic medicinal products. (section 4.5 also updated) Section 5.3 New text added Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. These studies did not reveal any evidence of impaired fertility or harm to the foetus due to granisetron. Fertility was unaffected following granisetron treatment in rat (sentence transferred from 4.6) For more information, please refer to the Summary of Product Characteristics.
PSUSA/10101 /202010	Periodic Safety Update EU Single assessment - granisetron (transdermal patch)	10/06/2021	n/a		PRAC Recommendation - maintenance
II/0058	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	14/01/2021	n/a		
IA/0059/G	This was an application for a group of variations. B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place A.4 - Administrative change - Change in the name	11/12/2020	n/a		

	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				
PSUSA/10101 /201910	Periodic Safety Update EU Single assessment - granisetron (transdermal patch)	14/05/2020	n/a		PRAC Recommendation - maintenance
II/0056/G	This was an application for a group of variations. Update of the SmPC section 5.2. to revise the statement regarding data in paediatric patients. The RMP has also been updated to implement RMP template EMA/PRAC/613102/2015 Rev 2 and includes the addition or deletion of safety concerns (identified risks, potential risks, missing information) not previously assessed or requested by a competent authority. The MAH took the opportunity to update the Pregnancy information in section 4.6 of Annex I to align with the QRD statements as of the QRD product information template v10.1. Minor QRD updates have also been implemented in the annex II in line with version 10.1 of the QRD template. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated	30/04/2020	16/04/2021	SmPC, Annex II, Labelling and PL	

	by new additional data to be submitted by the MAH where significant assessment is required				
PSUSA/10101 /201810	Periodic Safety Update EU Single assessment - granisetron (transdermal patch)	16/05/2019	n/a		PRAC Recommendation - maintenance
N/0055	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/03/2019	16/04/2021	PL	
II/0053/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 B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place 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.5.c - Change to in-process tests or limits	24/01/2019	n/a		

	applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test				
T/0052	Transfer of Marketing Authorisation	02/07/2018	19/07/2018	SmPC, Labelling and PL	
PSUSA/10101 /201710	Periodic Safety Update EU Single assessment - granisetron (transdermal patch)	17/05/2018	n/a		PRAC Recommendation - maintenance
N/0050	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/06/2017	19/07/2018	PL	
PSUSA/10101 /201610	Periodic Safety Update EU Single assessment - granisetron (transdermal patch)	05/05/2017	n/a		PRAC Recommendation - maintenance
IB/0049/G	This was an application for a group of variations. 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 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	21/03/2017	n/a		

	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test				
R/0047	Renewal of the marketing authorisation.	10/11/2016	09/01/2017	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Sancuso in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IAIN/0046	A.1 - Administrative change - Change in the name and/or address of the MAH	02/06/2016	09/01/2017	SmPC, Labelling and PL	
PSUSA/10101 /201510	Periodic Safety Update EU Single assessment - granisetron (transdermal patch)	13/05/2016	n/a		PRAC Recommendation - maintenance
N/0045	Update of the package leaflet with revised contact details of the local representative for Spain. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/02/2016	09/01/2017	PL	
IB/0043/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.z - Change in the manufacturer of AS or of a	03/02/2016	n/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.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 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.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.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.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)				

	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) 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) 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) 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) 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.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.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				
IAIN/0042	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	09/12/2015	n/a		
PSUSA/10101 /201504	Periodic Safety Update EU Single assessment - granisetron (transdermal patch)	06/11/2015	n/a		PRAC Recommendation - maintenance
IAIN/0041	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	24/09/2015	n/a		
N/0039	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/06/2015	25/01/2016	PL	
PSUSA/10101 /201410	Periodic Safety Update EU Single assessment - granisetron (transdermal patch)	07/05/2015	n/a		PRAC Recommendation - maintenance
N/0038	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/02/2015	25/01/2016	PL	
IB/0037/G	This was an application for a group of variations. B.II.e.6.z - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Other variation B.II.b.3.z - Change in the manufacturing process of	29/01/2015	25/01/2016	SmPC and PL	

	the finished or intermediate product - Other variation B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter				
PSUV/0034	Periodic Safety Update	20/11/2014	15/01/2015	SmPC and PL	Please refer to Sancuso PSUV-34 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation.
IB/0035/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.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF 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 B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation 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	13/01/2015	n/a		

	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.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.I.d.1.b.3 - Stability of AS - Change in the storage conditions - Change in storage conditions of the AS				
PSUV/0030	Periodic Safety Update	22/05/2014	18/07/2014	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUV/0030.
IA/0031	A.7 - Administrative change - Deletion of manufacturing sites	11/04/2014	n/a		
IAIN/0029	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	28/11/2013	18/07/2014	SmPC and PL	
N/0028	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	02/08/2013	18/07/2014	PL	
II/0027	Introduction of a site specific alternate process and controls for the manufacture of the finished product.	27/06/2013	n/a		

	B.II.b.3.b - Change in the manufacturing process of the finished product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product				
IB/0026/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 manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products B.II.a.2.z - Change in the shape or dimensions of the pharmaceutical form - Other variation 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 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 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.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other	18/04/2013	n/a		

	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.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				
IB/0022/G	This was an application for a group of variations. B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition) B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)	18/04/2013	n/a		
IB/0024/G	This was an application for a group of variations. B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation	15/03/2013	n/a		

IB/0025/G	This was an application for a group of variations. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	08/03/2013	n/a		
IB/0021/G	This was an application for a group of variations. B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms 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.z - Change in the specification parameters	08/03/2013	n/a		

	and/or limits of the immediate packaging of the finished product - Other variation				
IB/0013	B.II.c.1.f - Change in the specification parameters and/or limits of an excipient - Addition or replacement (excluding biological or immunological product) of a specification parameter as a result of a safety or quality issue	10/01/2013	n/a		
IAIN/0020	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	19/12/2012	n/a		
IB/0019	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	18/12/2012	n/a		
IB/0018	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	17/12/2012	n/a		
IA/0017/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	12/12/2012	n/a		
IB/0002/G	This was an application for a group of variations. B.II.e.6.b - Change in any part of the (primary)	29/11/2012	n/a		

	packaging material not in contact with the finished product formulation - Change that does not affect the product information B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation				
IB/0014	B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)	22/11/2012	n/a		
IB/0012	B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)	22/11/2012	n/a		
IB/0008	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	13/11/2012	n/a		
IB/0007	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	13/11/2012	n/a		
IA/0011	B.II.c.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits	12/11/2012	n/a		
IA/0010	B.II.c.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits	12/11/2012	n/a		

IA/0009	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	12/11/2012	n/a		
IA/0006	B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits	08/11/2012	n/a		
IB/0005/G	This was an application for a group of variations. B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition) B.II.c.z - Change in control of excipients in the Finished Product - Other variation	08/11/2012	n/a		