PecFent

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/0061	Transfer of Marketing Authorisation	19/04/2024	16/05/2024	SmPC, Labelling and PL	
PSUSA/1369/ 202304	Periodic Safety Update EU Single assessment - fentanyl (transmucosal route of administration)	25/01/2024	25/03/2024	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for

[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).

					PSUSA/1369/202304.
IA/0058	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	03/05/2023	n/a		
IB/0057	B.II.e.1.a.2 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Semi-solid and non-sterile liquid pharmaceutical forms	17/04/2023	n/a		
II/0054	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 by new additional data to be submitted by the MAH where significant assessment is required	29/09/2022	23/08/2023	Annex II	
IB/0056	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	21/04/2022	15/07/2022	SmPC, Labelling and PL	
IB/0055	C.I.1.b - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a Union referral procedure - The product is not covered by the defined scope of the procedure but the change(s) implements the outcome of the procedure and no new additional data is required to be submitted by the MAH	25/02/2022	15/07/2022	Labelling	
IB/0053/G	This was an application for a group of variations.	22/07/2021	15/07/2022	SmPC,	

	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.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			Labelling and PL	
PSUSA/1369/202004	Periodic Safety Update EU Single assessment - fentanyl (transmucosal route of administration)	28/01/2021	31/03/2021	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/1369/202004.
IB/0052	B.II.z - Quality change - Finished product - Other variation	04/11/2020	n/a		
IB/0050	B.I.z - Quality change - Active substance - Other variation	12/06/2020	n/a		
IB/0049	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	25/06/2019	18/06/2020	SmPC and PL	
N/0048	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/01/2019	18/06/2020	Labelling and PL	
IAIN/0047/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites	27/09/2018	n/a		

	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)				
T/0046	Transfer of Marketing Authorisation	02/07/2018	19/07/2018	SmPC, Labelling and PL	
PSUSA/1369/201704	Periodic Safety Update EU Single assessment - fentanyl (transmucosal route of administration)	22/02/2018	08/05/2018	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/1369/201704.
IAIN/0045	A.1 - Administrative change - Change in the name and/or address of the MAH	18/01/2018	08/05/2018	SmPC, Labelling and PL	
IA/0041/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 B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter B.II.d.2.b - Change in test procedure for the finished product - Deletion of a test procedure if an alternative method is already authorised	27/04/2017	n/a		
N/0042	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/04/2017	02/06/2017	Labelling and PL	
N/0040	Minor change in labelling or package leaflet not	24/11/2016	02/06/2017	PL	

	connected with the SPC (Art. 61.3 Notification)				
N/0039	Update to Section 4 of the package leaflet to add side effects in line with those already listed in the SmPC. In addition, the MAH has updated the package leaflet with revised contact details of the local representatives for Belgium, Bulgaria, Denmark, Germany, Finland, France, the Netherlands, Norway and Sweden. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	15/08/2016	02/06/2017	PL	
IA/0038/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 A.7 - Administrative change - Deletion of manufacturing sites B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information 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	28/06/2016	n/a		
IB/0037/G	This was an application for a group of variations.	16/06/2016	02/06/2017	SmPC, Labelling and	

	B.II.e.5.d - Change in pack size of the finished product - Change in the fill weight/fill volume of nonparenteral multi-dose (or single-dose, partial use) products B.II.e.6.a - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that affects the product information B.II.e.6.a - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that affects the product information 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.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation			PL	
IAIN/0036	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		
N/0035	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/11/2015	02/06/2017	PL	
IAIN/0034	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		

R/0032	Renewal of the marketing authorisation.	21/05/2015	17/07/2015	SmPC, Labelling and PL	Based on the review of data on quality, safety and efficacy, including all variations introduced since the marketing authorisation was granted, the CHMP considered that the benefit-risk balance of Pecfent in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IAIN/0033	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	20/05/2015	n/a		
PSUSA/1369/ 201404	Periodic Safety Update EU Single assessment - fentanyl (transmucosal route of administration)	18/12/2014	30/03/2015	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/1369/201404.
II/0031	Submission of the final Study report for the PecFent French Drug Utilisation Study (DUS) CP064/1 dated 1st October 2014. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	26/03/2015	n/a		
IAIN/0030	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	09/10/2014	n/a		
IB/0029	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	04/09/2014	n/a		

IB/0027	To add adverse event reporting details to section 4.8 of the SmPC and section 4 of the PL following the QRD template version 9. In addition, minor text errors and minor grammatical errors were amended. Finally the contact details of the local representative for Croatia were updated. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	02/06/2014	30/03/2015	SmPC, Annex II, Labelling and PL	
PSUSA/1369/ 201304	Periodic Safety Update EU Single assessment - fentanyl (transmucosal route of administration)	19/12/2013	28/02/2014	SmPC and PL	Refer to the Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation for PSUSA/1369.
IB/0026	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	08/01/2014	n/a		
IA/0025	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	22/11/2013	n/a		
IB/0024	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	21/11/2013	n/a		
IA/0022	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	31/10/2013	n/a		

	of the Ph. Eur. or national pharmacopoeia of a Member State				
IA/0020	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	16/10/2013	n/a		
IA/0021	B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	11/10/2013	n/a		
IB/0018/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.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site	03/10/2013	n/a		
IAIN/0017	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)	13/09/2013	n/a		
IA/0016/G	This was an application for a group of variations. B.II.b.2.a - Change to batch release arrangements and quality control testing of the FP - Replacement	11/01/2013	n/a		

	or addition of a site where batch control/testing takes place B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure				
IB/0014	B.II.f.1.b.2 - Stability of FP - Extension of the shelf life of the finished product - After first opening (supported by real time data)	25/10/2012	31/10/2012	SmPC, Labelling and PL	
A20/0013	Pursuant to Article 20 of Regulation (EC) No 726/2004, the European Commission requested the opinion of the CHMP further to the concerns raised during a Good Clinical Practice inspection on the conduct of bio-analytical studies by the Cetero Research facilities (Houston, USA), to assess the impact thereof on the risk-benefit balance of PecFent and to give its opinion whether the marketing authorisation of this product should be maintained, varied, suspended or withdrawn.	19/07/2012	24/09/2012		Please refer to the assessment report : EMEA/H/C/1164/A-20/0013
IB/0012	B.II.e.1.a.2 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Semi-solid and non-sterile liquid pharmaceutical forms	29/06/2012	n/a		
N/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/06/2012	24/09/2012	Labelling	The Marketing Authorisation Holder (MAH) took the opportunity to update Annex IIIA following feedback from healthcare professionals.

II/0008	to widen the release specification for the excipient propylparahydroxybenzoate. B.II.c.1.d - Change in the specification parameters and/or limits of an excipient - Change outside the approved specifications limits range	24/05/2012	24/05/2012		
IAIN/0010	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	24/04/2012	n/a		
IA/0009	C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system	17/02/2012	n/a		
IB/0006/G	This was an application for a group of variations. B.II.e.1.b.1 - Change in immediate packaging of the finished product - Type of container - Solid, semi-solid and non-sterile liquid pharmaceutical forms B.II.e.2.a - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products	01/02/2012	n/a		
IAIN/0007/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the	10/01/2012	n/a		

	QPPV C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the contact details of the QPPV C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV C.I.9.d - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the safety database C.I.9.e - Changes to an existing pharmacovigilance system as described in the DDPS - Changes in the major contractual arrangements with other persons or organisations involved in the fulfilment of pharmacovigilance obligations and described in the DD C.I.9.g - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the site undertaking pharmacovigilance activities C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system				
II/0005	to change the description of the features of the bottle after the end of normal use and change the precautions for disposal in sections 4.2, 6.5 and 6.6 of the SmPC and sections 3, 5 and 6 of Patient Leaflet. C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-	20/10/2011	22/11/2011	SmPC and PL	

	clinical, clinical or pharmacovigilance data				
IA/0004/G	This was an application for a group of variations. C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV C.I.9.d - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the safety database C.I.9.e - Changes to an existing pharmacovigilance system as described in the DDPS - Changes in the major contractual arrangements with other persons or organisations involved in the fulfilment of pharmacovigilance obligations and described in the DD C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system	03/05/2011	n/a	Annex II	
N/0003	The Marketing Authorisation Holder (MAH) took the opportunity to update details of the local representatives in Annex IIIB. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/12/2010	n/a	PL	
IB/0002	To extend the shelf-life of the finished product from 24 to 36 months. B.II.f.1.b.1 - Stability of FP - Extension of the shelf	29/11/2010	n/a	SmPC	

	life of the finished product - As packaged for sale (supported by real time data)				
IB/0001/G	This was an application for a group of variations. To add a new pack size of 12 bottles for the 100 and 400 µg strengths (EU/1/10/644/005-006). 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	29/11/2010	29/11/2010	SmPC, Labelling and PL	