Peyona

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/0025	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/12/2021		PL	
IB/0024	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	10/08/2021	n/a		

[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/482/202007	Periodic Safety Update EU Single assessment - caffeine (apnea)	11/02/2021	n/a		PRAC Recommendation - maintenance
IB/0023	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	27/10/2020		SmPC, Annex II and PL	
N/0021	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/11/2018		PL	
PSUSA/10615/201707	Periodic Safety Update EU Single assessment - caffeine (apnea, centrally authorised product only)	08/03/2018	n/a		PRAC Recommendation - maintenance
IAIN/0019	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	21/09/2017	19/04/2018	Annex II and PL	
IB/0018	B.II.e.5.z - Change in pack size of the finished product - Other variation	27/07/2017	n/a		
IB/0017	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	19/04/2017	19/04/2018	Annex II, Labelling and PL	
IA/0016	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	23/11/2016	n/a		
II/0013	Update of the statement regarding hepatic and renal impairment patients in sections 4.2 and 4.4, and section 4.8 of the SmPC to reflect the results of an	26/02/2015	24/02/2016	SmPC and PL	

	European Non-Interventional Post-Authorisation Study to assess drug utilisation and safety of caffeine citrate in the treatment of premature infants affected by apnoea. This study addresses a post-authorisation measure in the RMP. Section 4 of the package leaflet is updated accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
PSUSA/482/201407	Periodic Safety Update EU Single assessment - caffeine (apnea)	04/12/2014	n/a		PRAC Recommendation - maintenance
R/0011	Renewal of the marketing authorisation.	18/12/2013	03/03/2014	SmPC, Annex II, Labelling and PL	Base on the review of the available information the CHMP is of the opinion that the quality, the safety and the efficacy of this medicinal product continues to be adequately and sufficiently demonstrated and therefore considers that the benefit/risk profile of Peyona continues to be favourable. The CHMP was of the opinion that the renewal could be granted with unlimited validity.
PSUV/0012	Periodic Safety Update	09/01/2014	n/a		PRAC Recommendation - maintenance
N/0010	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/08/2013	03/03/2014	PL	
IAIN/0009	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	13/02/2013	n/a		
IAIN/0008	C.I.9.i - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) to a	13/04/2012	n/a		

	DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH				
IAIN/0007/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.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	24/02/2012	n/a		
N/0006	Update of the list of local representatives contact details in the package leaflet. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/01/2012	31/05/2012	PL	
IA/0005	A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release	19/10/2011	31/05/2012	Annex II and PL	
IA/0004/G	This was an application for a group of variations. C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s)	25/11/2010	n/a	Annex II	

	to the DDPS that does not impact on the operation of the pharmacovigilance system 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				
IA/0003	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	24/11/2010	n/a	SmPC, Annex II, Labelling and PL	
II/0002	Addition of a new presentation of 1 ml ampoule 20 mg/ml. B.II.e.5.c - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, and biological/immunological multidose parenteral medicinal products	22/04/2010	04/06/2010	SmPC, Labelling and PL	
IA/0001	To update the European Pharmacopeia Certificate of Suitability (R1-CEP 1998-022-Rev 02) B.III.1.a.2 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	16/02/2010	n/a		