Neofordex

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
IAIN/0021/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release A.1 - Administrative change - Change in the name	15/05/2023		SmPC, Annex II, 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).

	and/or address of the MAH				
IAIN/0020/G	This was an application for a group of variations. 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 A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.1 - Administrative change - Change in the name and/or address of the MAH	18/01/2023		SmPC, Annex II, Labelling and PL	
II/0017/G	This was an application for a group of variations. C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation 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.3.a - Change in the manufacturing process of	23/06/2022	02/08/2022	SmPC and PL	The SmPC section 3 has been updated with the new appearance of the tablet; The SmPC section 4 has been updated by removing the 20 mg posology; The SmPC section 6.4 has been updated by removing references to halved tablets. The PL has been updated accordingly.

	the finished or intermediate product - Minor change in the manufacturing process B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site 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.7 - Administrative change - Deletion of manufacturing sites 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 originally approved batch size 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.a.1.a - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings 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.a.1.b - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in scoring/break lines intended to divide into equal doses				
PSUSA/10480	Periodic Safety Update EU Single assessment -	05/05/2022	n/a		PRAC Recommendation - maintenance

/202109	dexamethasone (centrally authorised product indicated in symptomatic multiple myeloma)				
R/0016	Renewal of the marketing authorisation.	15/10/2020	09/12/2020	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 Neofordex in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. Changes were made to the PI to bring it in line with the current QRD template, SmPC guideline and other relevant guidelines.
PSUSA/10480 /201909	Periodic Safety Update EU Single assessment - dexamethasone (centrally authorised product indicated in symptomatic multiple myeloma)	30/04/2020	25/06/2020	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10480/201909.
N/0014	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	02/12/2019	25/06/2020	PL	
IG/1165	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	10/11/2019	n/a		
IG/1136/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the	22/08/2019	25/06/2020	Annex II and PL	

	finished product, including quality control sites (excluding manufacturer for batch release) A.7 - Administrative change - Deletion of manufacturing sites B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site				
N/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/07/2019	25/06/2020	PL	
PSUSA/10480 /201809	Periodic Safety Update EU Single assessment - dexamethasone (centrally authorised product indicated in symptomatic multiple myeloma)	26/04/2019	25/06/2019	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10480/201809.
II/0008	Submission of an updated RMP version 4.2 in order to delete the category 3 activity 'Development of a 20mg oral dosage form' and update the due date of the category 3 activity 'removal of the score line for subdivision of the 40mg tablet and consequent deletion of the 20mg posology'. In addition, the MAH implemented the RMP revision 2 format. 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	21/03/2019	n/a		

	where significant assessment is required				
IB/0009	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	05/11/2018	n/a		
IAIN/0007	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	28/05/2018	20/09/2018	Annex II and PL	
PSUSA/10480 /201709	Periodic Safety Update EU Single assessment - dexamethasone (centrally authorised product indicated in symptomatic multiple myeloma)	12/04/2018	n/a		PRAC Recommendation - maintenance
PSUSA/10480 /201703	Periodic Safety Update EU Single assessment - dexamethasone (centrally authorised product indicated in symptomatic multiple myeloma)	28/09/2017	n/a		PRAC Recommendation - maintenance
IB/0005/G	This was an application for a group of variations. 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) 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	16/08/2017	20/09/2018	SmPC, Labelling and PL	
PSUSA/10480 /201609	Periodic Safety Update EU Single assessment - dexamethasone (centrally authorised product	06/04/2017	n/a		PRAC Recommendation - maintenance

	indicated in symptomatic multiple myeloma)				
N/0002	Inclusion of the list of local representatives at the end of the package leaflet. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/06/2016	20/09/2018	PL	
IB/0001	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	11/04/2016	n/a		