Nucala

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
IB/0016/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new	14/09/2018		Annex II	

[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).

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	in-process test and limits B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product				
II/0013/G	This was an application for a group of variations. Type II-C.I.6-Extension of Indication to include children and adolescents aged 6 to 17 years for Nucala; as a consequence, Sections 4.1, 4.2, 4.5, 4.8, 5.1, 5.2 and 6.6 of the SmPC and the Package Leaflet are updated accordingly. In addition, Section 4.4 of the SmPC and package leaflet are updated in order to reflect that the name and batch number of the administered product should be clearly recorded in the patient file. Type IB-B.II.d.2.z- Change to the justification of specifications for the finished product to include a dose dependent calculation in support of the approved specifications. To change the dose dependent controls for raw material clearance and exposure. Type IB B.I.b.2.z –Change to the justification of specifications for the active substance to include a dose dependent calculation in support of the approved specifications. To change the dose dependent controls for raw material clearance and exposure. In addition, editorial changes are introduced in section P.5.5 of Module 3. B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation B.II.d.2.z - Change in test procedure for the finished	26/07/2018	27/08/2018	SmPC and PL	Nucala is indicated as an add-on treatment for severe refractory eosinophilic asthma in adults, adolescents and children aged 6 years and older. Adults and adolescents aged 12 years and older: The recommended dose of mepolizumab is 100 mg administered subcutaneously once every 4 weeks. Children aged 6 to 11 years old: The recommended dose of mepolizumab is 40 mg administered subcutaneously once every 4 weeks. The posology of Nucala in children and adolescents aged between 6 to 17 years old with severe refractory eosinophilic asthma has been determined by limited efficacy, pharmacokinetic and pharmacodynamic studies and supported by modelling and simulation data.

	product - Other variation C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
IB/0015/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 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)	01/06/2018	27/08/2018	SmPC	
PSUSA/10456 /201709	Periodic Safety Update EU Single assessment - mepolizumab	12/04/2018	n/a		PRAC Recommendation - maintenance
II/0012	B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product	01/02/2018	n/a		
II/0011	B.I.e.2 - Introduction of a post approval change management protocol related to the AS	25/01/2018	n/a		
PSUSA/10456 /201703	Periodic Safety Update EU Single assessment - mepolizumab	26/10/2017	n/a		PRAC Recommendation - maintenance

II/0007	B.I.e.2 - Introduction of a post approval change management protocol related to the AS	22/06/2017	n/a		
PSUSA/10456 /201609	Periodic Safety Update EU Single assessment - mepolizumab	06/04/2017	n/a		PRAC Recommendation - maintenance
IA/0009/G	This was an application for a group of variations. 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.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	17/03/2017	n/a		
IB/0008	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)	28/02/2017	19/02/2018	SmPC	
II/0005	Update of sections 4.4 and 4.8 of the SmPC in order to include “anaphylaxis” as an adverse reaction. The Package Leaflet is updated accordingly. Minor amendments to section 6.6 of the SmPC and to the Instructions for use and handling, reconstitution, and administration for the HCP are also introduced. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local	27/10/2016	16/02/2017	SmPC, Labelling and PL	

	representatives in the Package Leaflet and to bring the PI (Product Information) in line with the latest QRD template version 10. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
PSUSA/10456 /201603	Periodic Safety Update EU Single assessment - mepolizumab	29/09/2016	n/a		PRAC Recommendation - maintenance
IB/0004	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	26/08/2016	n/a		
IAIN/0002	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	02/06/2016	n/a		
IA/0001	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	25/02/2016	16/02/2017	SmPC	