Granupas

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
R/0026	Renewal of the marketing authorisation.	18/10/2018	18/12/2018	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 Granupas in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
T/0025	Transfer of Marketing Authorisation	21/05/2018	29/06/2018	SmPC, 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).

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PSUSA/10171 /201710	Periodic Safety Update EU Single assessment - para-aminosalicyic acid (centrally authorised product)	17/05/2018	n/a		PRAC Recommendation - maintenance
II/0024	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	26/04/2018	n/a		
PSUSA/10171 /201704	Periodic Safety Update EU Single assessment - para-aminosalicyic acid (centrally authorised product)	26/10/2017	n/a		PRAC Recommendation - maintenance
IB/0022/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 B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	26/07/2017	n/a		
PSUSA/10171 /201610	Periodic Safety Update EU Single assessment - para-aminosalicyic acid (centrally authorised product)	05/05/2017	n/a		PRAC Recommendation - maintenance
N/0020	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/04/2017	25/07/2017	PL	
PSUSA/10171 /201604	Periodic Safety Update EU Single assessment - para-aminosalicyic acid (centrally authorised product)	27/10/2016	n/a		PRAC Recommendation - maintenance

IB/0018	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	01/08/2016	n/a		
PSUSA/10171 /201510	Periodic Safety Update EU Single assessment - para-aminosalicyic acid (centrally authorised product)	26/05/2016	22/07/2016	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10171/201510.
II/0014	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	21/07/2016	25/07/2017	SmPC, Labelling and PL	
II/0013	Update of section 5.3 of the SmPC with data from an in vivo genotoxicity study (micronucleus test). C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	26/05/2016	22/07/2016	SmPC	An in vivo genotoxicity study (micronucleus test) has been conducted with para-aminosalicylic acid. Results indicate that para-aminosalicylic acid was considered not to have produced any clastogenic effect in mice treated at non-toxic dose levels (examined 24 hours after 2 daily administrations of 312.5 to 1250 mg/kg).
PSUSA/10171 /201504	Periodic Safety Update EU Single assessment - para-aminosalicyic acid (centrally authorised product)	06/11/2015	n/a		PRAC Recommendation - maintenance
IA/0011/G	This was an application for a group of variations. 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.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the	23/06/2015	n/a		

	Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material				
IG/0560	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/10171 /201410	Periodic Safety Update EU Single assessment - para-aminosalicyic acid (centrally authorised product)	10/04/2015	n/a		PRAC Recommendation - maintenance
IG/0509	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	28/11/2014	n/a		
IA/0006	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	25/06/2014	n/a		
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/06/2014	13/05/2015	PL	
IB/0004	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	10/06/2014	n/a		
IB/0002	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)	10/06/2014	13/05/2015	SmPC	

IAIN/0005	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	15/05/2014	13/05/2015	SmPC, Annex II, Labelling and PL	
IAIN/0003	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	15/05/2014	13/05/2015	Annex II and PL	
IAIN/0001	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	15/05/2014	n/a		