EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Rienso

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
PSUV/0015	Periodic Safety Update	22/01/2015	19/03/2015	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUV/0015.
IA/0017	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	20/11/2014	n/a		
IAIN/0016	A.1 - Administrative change - Change in the name	24/10/2014	19/03/2015	SmPC,	

[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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	and/or address of the MAH			Labelling and PL	
PSUV/0014	Periodic Safety Update	24/07/2014	18/09/2014	SmPC, Annex II, Labelling and PL	Please refer to Rienso PSUV-14 Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation.
IG/0401	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	11/02/2014	n/a		
IB/0012	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	17/01/2014	29/01/2014	SmPC and PL	
PSUV/0011	Periodic Safety Update	09/01/2014	n/a		PRAC Recommendation - maintenance
IB/0010	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	05/11/2013	29/01/2014	SmPC and PL	
IA/0009	A.7 - Administrative change - Deletion of manufacturing sites	05/08/2013	n/a		
IB/0007	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	31/07/2013	n/a		
T/0006	Transfer of Marketing Authorisation	28/05/2013	11/06/2013	SmPC, Labelling and	Transfer of the Marketing Authorisation from Takeda Global Research and Development Centre (Europe) to Takeda

				PL	Pharma A/S.
IAIN/0005	A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release	16/04/2013	11/06/2013	Annex II and PL	
IG/0285	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	08/04/2013	n/a		
IG/0231	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	16/11/2012	n/a		
N/0002	The Marketing Authorisation Holder (MAH) took the opportunity to update the details of local representatives in the package leaflet. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/08/2012	n/a	PL	
IAIN/0001/G	This was an application for a group of variations. B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes	31/07/2012	n/a	SmPC, Labelling and PL	