Repaglinide Teva

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/0015	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	13/12/2021		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).

IA/0014	A.7 - Administrative change - Deletion of manufacturing sites	16/02/2021		Annex II and PL	
IAIN/0013/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.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	22/01/2020	n/a		
IAIN/0012	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	14/09/2016	28/04/2017	Annex II and PL	
IB/0011/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference	25/05/2016	28/04/2017	SmPC, Annex II, Labelling and PL	

	product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				
IAIN/0010/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 B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)	12/11/2015	n/a		
T/0009	Transfer of Marketing Authorisation from Teva Pharma B.V. (Utrecht) to Teva B.V. (Haarlem). Transfer of Marketing Authorisation	03/11/2014	21/11/2014	SmPC, Labelling and PL	
R/0008	Renewal of the marketing authorisation.	25/04/2014	19/06/2014		This is a renewal of the Marketing Authorisation for a generic product. During the renewal period no significant information has arisen that alters the overall assessment of the benefit/risk balance of Repaglinide Teva. The CHMP recommends that the renewal be granted with unlimited validity.
IA/0007	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 currently approved batch size	25/02/2013	n/a		

IAIN/0006/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 of the finished product, including quality control sites (excluding manufacturer for batch release) B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing	14/12/2012	18/12/2013	Annex II and PL	
IB/0005	Updated section 4.5 of the SmPC in order to include a new drug-drug interaction with deferasirox. Section 2 of the Package Leaflet has been updated accordingly. The Product Information has also been updated in line with the latest QRD template (version 8). The MAH also took this opportunity to update some of the contact details for local representatives in the Package Leaflet (Estonia, Finland, Germany, Iceland, Ireland, Norway and Romania). C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH	28/06/2012	29/10/2012	SmPC, Annex II, Labelling and PL	
IA/0004	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	24/04/2012	n/a		

IA/0003/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 of the finished product, including quality control sites (excluding manufacturer for batch release) B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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 batch release arrangements and quality control testing of the FP - Replacement or addition of a site where batch control/testing takes place B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing B.II.b.3.a - Change in the manufacturing process of the finished product - Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions	02/08/2011	n/a	Annex II and PL	
N/0002	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/03/2011	n/a	Annex II and PL	
IA/0001	To replace a secondary packaging site for Repaglinide Teva finished product.	18/12/2009	n/a		

	IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site				