EMA/166003/2021

Ribavirin Teva Pharma BV

Procedural steps taken and scientific information after the authorisation

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Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
IA/0023	A.7 - Administrative change - Deletion of manufacturing sites	18/02/2021		Annex II and PL	
IB/0022/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 product following	21/12/2020	22/01/2021	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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	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 A.6 - Administrative change - Change in ATC Code/ATC Vet Code				
IA/0021	B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold	18/08/2017	n/a		
IA/0020	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	26/10/2016	n/a		
IB/0018	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	25/10/2016	14/11/2016	SmPC, Labelling and PL	
IA/0019/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.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	15/09/2016	n/a		

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IA/0017	A.7 - Administrative change - Deletion of manufacturing sites	25/04/2016	14/11/2016	Annex II and PL	
PSUSA/10007 /201407	Periodic Safety Update EU Single assessment - ribavirin (oral formulations)	12/02/2015	n/a		PRAC Recommendation - maintenance
T/0015	Transfer of Marketing Authorisation	14/10/2014	13/11/2014	SmPC, Labelling and PL	
PSUSA/10007 /201307	Periodic Safety Update EU Single assessment - ribavirin (oral formulations)	20/02/2014	28/04/2014	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10007/201307.
IB/0014	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	11/03/2014	13/11/2014	SmPC and PL	To update sections 4.1, 4.4, 4.8 and 5.1 of the SmPC with long-term follow-up safety data on the durability of virologic response and growth amongst paediatric patients from study P02538 and study P01906 and update section 4 of the PL accordingly as approved for the reference product. Furthermore, some (minor) changes to sections 4.3 and 4.5 of the SmPC are updated. Additionally and in line with the innovator's texts, section 5.2 has been updated to reflect the different sub-headings indicated in the current version of the QRD template, subsequently the contents of this section have been placed under the appropriate sub-headings. The information under "Biotransformation" is currently approved for Ribavirin Teva; it is therefore not considered new information. In addition the following changes are implemented: • Section 4.2 of the SmPC – the subheadings are aligned

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					with the current QRD template (version 9) • update to the contact details of the local representatives in Hungary and Malta Also, for clarification purposes, where the local representative is located outside the country for which they are responsible, the name of the country has been included in the PL. The following were affected; Κύπρος (Cyprus), Island and Luxembourg. Finally, the MAH would also like to take the opportunity to propose some additional amendments in the translated texts in some languages. These amendments are minor and have been introduced in the translated PI texts purely due to readability and compliance with the innovator text and QRD.
R/0012	Renewal of the marketing authorisation.	24/10/2013	16/01/2014	SmPC, Annex II, Labelling and PL	Based on the review of the available information and on the basis of a re-evaluation of the benefit-risk balance, the CHMP is of the opinion that the quality, safety and efficacy of this medicinal product continues to be adequately and sufficiently demonstrated and therefore considered that the benefit-risk profile of Ribavirin Teva Pharma BV continues to be favourable. The product information was brought in line with the reference product. The CHMP is of the opinion that the renewal can be granted with unlimited validity.
IAIN/0011/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	26/07/2013	16/01/2014	Annex II and PL	

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	and quality control testing of the FP - Not including batch control/testing A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites B.III.1.a.1 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer				
II/0010	Submission of a repeat bioequivalence study performed in response to the article 20 CHMP referral opinion in order to lift the suspension of the marketing authorisation. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	25/04/2013	17/07/2013		Please refer to the assessment report H-1064-II-10
A20/0007	Pursuant to Article 20 of Regulation (EC) No. 726/2004, the European Commission requested the CHMP to re-evaluate the benefit-risk balance of Ribavirin Teva Pharma B.V. in light of newly available data on the deficiencies in conduct of bio-analytical studies performed by the Cetero Research facilities in Houston (Texas, USA) and to give its opinion on whether the marketing authorisation in the approved indication should be maintained, varied, suspended or revoked.	20/09/2012	06/12/2012		Please refer to the assessment report: EMEA/H/C/001064/A-20/0007.

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IB/0008/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 are 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 product - Implementation of change(s) for which NO new additional data are 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 product - Implementation of change(s) for which NO new additional data are submitted by the MAH	21/11/2012	16/01/2014	SmPC and PL	To update the SmPC section 4.4 and the PL with a statement on the potential drug interaction with azathioprine. Furthermore to remove the rarely reported side effect diabetes from the PL as diabetes mellitus is already listed under the uncommon side effects. To update section 4.4 of the SmPC with recommendations in patients with psychiatric disorders and substance abuse/use. To remove from the SmPC section 4.6 the requirement of double contraceptive measures for a treated woman and male patients, and to revise SmPC section 5.2 to reflect the results of the pharmacokinetic study related to transfer in seminal fluid. In addition, please note that the MAH has taken this opportunity to update the contact details of the local representatives in Czech Republic, Germany, Estonia, Ireland, Iceland, Italy, Malta, Norway, Austria, Slovenia, Finland and UK.
WS/0081	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. To update the product information for Ribavirin Teva and Ribavirin Teva Pharma B.V. to be in line with the product innovator Rebetol. The update pertains to variation IB-54 of Rebetol and concern the removal of the adverse reaction "Raynaud's disease" from section 4.8 of the SPC. The PL is updated	20/01/2011	21/02/2011	SmPC and PL	The summary of the above mentioned changes will be found in the EPAR (module 8B) of Rebetol.

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	accordingly. In addition updates to the Local representative details for AT, BE, CZ, DE, ES, LU and SI are included. For Ribavirin Teva Pharma B.V. a typographical correction is made in the product information. 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				
IB/0004	B.II.a.3.b.1 - Changes in the composition (excipients) of the finished product - Other excipients - Any minor adjustment of the quantitative composition of the finished product with respect to excipients	04/10/2010	n/a		
WS/0004	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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	21/07/2010	27/07/2010	SmPC and PL	
IA/0003	IA_12_a_Change in spec. of active subst./agent used in manuf. of active subst. - tightening of spec.	12/01/2010	n/a		

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IA/0002	IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site	20/10/2009	n/a		
II/0001	Extension of Indication	24/09/2009	19/10/2009	SmPC and PL	

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