



Ribavirin Mylan

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification ¹ issued on	Commission Decision issued / amended on	Product Information affected ³	Summary
N/0030	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/03/2019		PL	
T/0029	Transfer of Marketing Authorisation	25/07/2018	03/08/2018	SmPC, Labelling and PL	
IAIN/0028/G	This was an application for a group of variations.	31/05/2018	n/a		

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).



	<p>A.7 - Administrative change - Deletion of manufacturing sites</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p> <p>B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site</p>				
IA/0027/G	<p>This was an application for a group of variations.</p> <p>A.7 - Administrative change - Deletion of manufacturing sites</p> <p>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure</p> <p>B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer</p> <p>B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer</p> <p>B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer</p> <p>B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New</p>	07/11/2016	n/a		

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	<p>certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer</p> <p>B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer</p> <p>B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer</p> <p>B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer</p> <p>B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer</p> <p>B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer</p>				
IA/0026	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	06/07/2016	n/a		
IB/0025	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar product, 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	28/06/2016	29/07/2016	SmPC, Labelling and PL	

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	MAH				
IA/0024	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	25/05/2016	n/a		
IAIN/0023/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 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	08/12/2015	n/a		
PSUSA/10007 /201407	Periodic Safety Update EU Single assessment - ribavirin (oral formulations)	12/02/2015	n/a		PRAC Recommendation - maintenance
R/0021	Renewal of the marketing authorisation.	18/12/2014	11/02/2015		Based on the CHMP 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 Ribavirin Mylan continues to be adequately and sufficiently demonstrated and therefore considered that the benefit risk profile of Ribavirin Mylan continues to be favourable.
IAIN/0020/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name	22/09/2014	n/a		

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	and/or address of a manufacturer/importer 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.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information				
IB/0019	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)	21/08/2014	11/02/2015	SmPC	
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.
IAIN/0016/G	This was an application for a group of variations. 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.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	12/08/2014	11/02/2015	Annex II and PL	

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	including batch control/testing				
IB/0017	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	11/02/2015	SmPC and PL	To update sections 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 P02598, section 4 of the PL is updated accordingly.
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 are submitted by the MAH	01/08/2013	18/12/2013	SmPC Annex I, Labelling and PL	To bring the annexes in line with the originator and to updated to the latest QRD version. In addition the MAH took this opportunity to update the details of the local representative in DK. The MAH also updated the annexes to include the new Member State Croatia.
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 of the finished product, including quality control sites (excluding manufacturer for batch release) B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	12/04/2013	n/		

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	<p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p> <p>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</p> <p>B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)</p> <p>B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State</p> <p>C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation</p>				
IB/0012/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>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</p> <p>C.I.2.a - Change in the SPC, Labelling or PL of a</p>	11/01/2013	18/12/2013	SmPC and PL	<p>To update the SmPC section 4.4 and 4.5 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.</p> <p>To update section 4.4 of the SmPC with recommendations in patients with psychiatric disorders and substance abuse/use.</p> <p>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</p>

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	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				seminal fluid.
IB/0009/G	<p>This was an application for a group of variations.</p> <p>B.II.e.1.b.1 - Change in immediate packaging of the finished product - Type of container - Solid, semi-solid and non-sterile liquid pharmaceutical forms</p> <p>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes</p> <p>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes</p> <p>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes</p> <p>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes</p> <p>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes</p> <p>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes</p> <p>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes</p>	17/08/2012	29/10/2012	SmPC, Labelling and PL	

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	ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes				
IB/0007	C.I.8.b - Introduction of a new Pharmacovigilance system - which has been assessed by the relevant NCA/EMA for another product of the same MAH	16/01/2012	n/a		
IA/0006/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products	11/05/2011	n/a		
N/0005	The MAH took this opportunity to add the list of local representatives Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/03/2011	n/a	PL	
T/0004	Transfer of Marketing Authorisation	17/12/2010	27/01/2011	SmPC, Labelling and PL	
IA/0003	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	17/12/2010	n/a	SmPC, Labelling and	

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				PL	
IB/0002	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	14/12/2010	n/a	SmPC and PL	The product information has been revised in all languages following a request from the EMA to include safety changes in-line with an adopted variation IB-54 for Rebetol.
IB/0001	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	14/12/2010	n/a	SmPC and Labelling	Update of PI following adoption of innovator product Rebetol II-51 to amend section 4.5 and 4.6 of SmPC. Additional minor spelling errors have been made and the MAH added the marketing authorisation numbers and date of the first marketing authorisation to the PI in all languages

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