EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Ribavirin BioPartners

Procedural steps taken and scientific information after the authorisation

No	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
IB/0003/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	21/11/2012	n/a	SPC, PL	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.
IB/0002/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,	19/11/2010	n/a	SPC, Labelling, PL	To update the Product Information in line with the innovator. Changes made include the following: To update of SmPC with the results of the long term follow-up study (P01906) conducted in paediatric patients. The PL has been updated accordingly To include information pertaining to the therapeutic indication of

[1] Notifications are issued for type I variations (unless part of a group or a worksharing application). Opinions are issued for all other procedures.
[2] No Commission Decision is issued for type IA and type IB variations or for type II variations and annual re-assessments that do not affect the annexes.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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	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, 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.6.b - Change(s) to therapeutic indication(s) - Deletion of a therapeutic indication				combination therapy with peginterferon alfa-2b and ribavirin to include treatment of paediatric population based on results of Study P02538. To update the SmPC sections 4.4 and 4.5 with statements on the potential drug interaction with azathioprine. Furthermore, the side effect diabetes has been deleted from the PL as diabetes mellitus is already listed under uncommon side effects. EMEA has been changed to European Medicines Agency in annex II. To update the SmPC section 4.5 with a statement on co-administration of abacavir and Ribavirin. Additionally, corrections have been made to the SmPC, and PL. Changes have also been made to the annexes to comply with QRD guidance. To update the SmPC section 4.8 and PL section 4 to remove the adverse event Raynaud's disease To remove information on the patented indication of ribavirin used for the treatment of chronic hepatitis C as part of a combination regimen with peginterferon alfa-2b and also to remove information on the patented indication of ribavirin for the treatment of chronic hepatitis C as part of a combination regimen with interferon alfa-2b for naïve patients with genotype 1.