EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Nevirapine 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
N/0024	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/12/2021		PL	
IA/0023	A.7 - Administrative change - Deletion of manufacturing sites	02/02/2021	29/09/2021	Annex II 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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IB/0022	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	05/10/2020	29/09/2021	SmPC, Annex II, Labelling and PL	
IA/0021	A.7 - Administrative change - Deletion of manufacturing sites	12/06/2019	n/a		
IB/0020	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	29/03/2019	n/a		
IB/0019	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	21/02/2019	n/a		
IAIN/0018	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	24/10/2018	17/10/2019	SmPC	
IA/0017	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	28/06/2018	n/a		
IA/0016	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	23/06/2017	n/a		
IAIN/0015	B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer	12/06/2017	n/a		

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	22/08/2016	24/03/2017	SmPC, Labelling and PL	
N/0012	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	27/04/2016	24/03/2017	PL	
IA/0013	A.7 - Administrative change - Deletion of manufacturing sites	25/04/2016	24/03/2017	Annex II and PL	
T/0011	Transfer of Marketing Authorisation fom Teva Pharma B.V. (Utrecht) and Teva B.V (Haarlem). Transfer of Marketing Authorisation	07/10/2014	22/10/2014	SmPC, Labelling and PL	
R/0010	Renewal of the marketing authorisation.	26/06/2014	26/08/2014	SmPC, Annex II and PL	
IB/0009/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	03/04/2014	26/08/2014	SmPC, Labelling and PL	

	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 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 product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				
IAIN/0008	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)	10/01/2014	n/a		
IB/0007/G	This was an application for a group of variations. To include information on a class labelling for all antiretrovirals to revise section 4.4 and section 4.8 of the SmPC to include information regarding Autoimmune Disorders under Immune Reactivation Syndrome. The changes have also been reflected in the PL." The MAH also wishes to revise section 4.4 and 4.5 of the SmPC and section 2 of the PIL to include Granulocytopenia in line with the originator	11/10/2013	20/02/2014	SmPC, Annex II, Labelling and PL	

	product (IB-103 submission). Furthermore, the MAH has also updated section 2 of the PIL to include statements on Prednisone and contraception, again in line with the innovator product (R-106 submission). Additionally, the Annexes were updated to comply with the QRD template (version 9, 03/2013), again strictly in line with the reference product. In addition, the MAH would like to take this opportunity to update the contact details for the national representatives in the PIL for DE, EE, FI, IE, IS, IT, LV and UK. Furthermore the local representative for Croatia was added to all annexes. Also alignment of annexes to the originator were included in this grouping. 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 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 product - Implementation of change(s) for which NO new additional data is required to be submitted by				

	the MAH C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation				
IAIN/0006	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	04/06/2013	n/a		
IB/0005/G	This was an application for a group of variations. 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 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	21/02/2013	20/02/2014	SmPC, Labelling and PL	
IB/0003	Update of section 4.8 of the SmPC and section 4 of the PL in order to include the adverse drug reactions ("Blood pressure increased" and "Blood phosphorus decreased") and updated frequencies/frequency categories. Furthermore the MAH also made minor amendments to the SmPC to bring the texts in line with those of the innovator. The MAH has also taken this opportunity to update some details in the local contact list in the PL. In addition, a correction has been made to the SK Annex. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following	07/10/2011	25/05/2012	SmPC and PL	

	assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH				
IA/0004	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)	14/09/2011	n/a		
IB/0002	To update sections 4.4 and 4.6 of the SmPC, and section 2 of the PL in order to give a better characterisation of the patient groups that are at greater risk of developing hepatotoxicity following evaluation of an analysis made by an expert panel. In addition, the MAH has also made minor amendments to the SmPC, labelling and PL to bring them in line with the reference product (sections 2, 4.2, 4.8, 4.9, 5.1, 5.2, 5.3). The MAH has taken this opportunity to include the new EMA acronym and new EMA web site address and to update the local contact list in the PL. Annex IIB has also been updated to remove the version number of the DDPS according to the procedural announcement from October 2010. 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	07/01/2011	n/a	SmPC, Labelling and PL	

IA/0001	To replace a manufacturing site regarding secondary packaging activities for the finished product (EU/1/09/598/001-4). IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site	15/12/2009	n/a		