Lamivudine 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/0025/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	10/10/2022	15/11/2022	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).

	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				
IG/1508	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)	23/05/2022	n/a		
IB/0023/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	22/12/2021	15/11/2022	SmPC and PL	

	product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				
N/0022	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/10/2021	15/11/2022	PL	
IA/0021/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	06/07/2021	n/a		
IA/0020	A.7 - Administrative change - Deletion of manufacturing sites	09/02/2021	04/06/2021	Annex II and PL	
IB/0019	B.II.e.1.b.1 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms	03/06/2020	04/06/2021	SmPC, Labelling and PL	
IA/0018	A.7 - Administrative change - Deletion of manufacturing sites	11/12/2019	n/a		
IAIN/0017	B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the	11/02/2019	n/a		

	relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)				
IA/0016/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	24/10/2018	n/a		
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	18/05/2018	11/04/2019	SmPC and PL	
IB/0014	C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	03/08/2016	23/02/2017	SmPC, Annex II, Labelling and PL	
IA/0013	A.7 - Administrative change - Deletion of manufacturing sites	29/03/2016	23/02/2017	Annex II and PL	
II/0012/G	This was an application for a group of variations.	17/03/2016	n/a		

	B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation 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) B.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation				
T/0011	Transfer of Marketing Authorisation	05/11/2014	16/12/2014	SmPC, Labelling and PL	
R/0009	Renewal of the marketing authorisation.	24/07/2014	09/09/2014	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 Lamivudine Teva continues to be favourable. The CHMP is of the opinion that the renewal can be granted with unlimited validity.
IAIN/0010	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 including batch control/testing	09/06/2014	09/09/2014	Annex II and PL	
IB/0008	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	10/02/2014	09/09/2014	SmPC, Annex II, Labelling and PL	
IAIN/0007	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	31/05/2013	n/a		
IAIN/0006/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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	13/04/2012	31/05/2012	Annex II and PL	

IB/0005/G	This was an application for a group of variations. Lamivudine Teva PI is being updated to reflect changes introduced during Zeffix renewal. The MAH also takes this opportunity to correct the text in sections 4.4 and 5.1 of the SmPC and section 1, 2 and 3 of the PL of Lamivudine Teva to bring it in line with the reference. These additional changes have been highlighted in yellow in the present & proposed table for better clarification. Sections 4.2, 4.4, 4.6 and 5.1 of the SmPC were updated as a response to the commitments made by the MAH as part of Zeffix licence renewal. The PL was revised accordingly. Major changes affected section 4.1 and 4.2 in light of the emergence of new data, which have questioned the appropriateness of lamivudine as first line therapy for CHB due to its high risk of resistance. As a consequence the indication was restricted and the availability of other antiviral agents with a better resistance profile highlighted. The need for combination therapy in patients with decompensated liver disease was also introduced. Section 4.6 was updated to reflect the complexity of the benefit/risk assessment of lamivudine treatment in breast feeding mothers. Section 5.1 was updated to include new data on the frequency of meergence of YMDD variant HBV and its impact on the treatment response. Minor changes affected section 4.4 and 4.5.	11/11/2011	31/05/2012	SmPC, Annex II and PL	

	Furthermore the complete indication concerning decompensated liver disease was removed from the PI for Lamivudine Teva The MAH requested to update sections 4.4 of the SmPC to improve clarity around the current text on exacerbation of hepatitis, inline with other nucleoside agents for CHB, and section 4.8 has been updated with regards to the frequency category of ADR based on the SmPC Guideline rev.2 in accordance with the originator. The PL has been revised accordingly. Section 4.4 of the SmPC has been amended to improve clarity around the text on exacerbation of hepatitis, in line with other nucleoside agents for CHB. The approved text " differentiate information rela 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 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				
II/0003/G	This was an application for a group of variations.	17/02/2011	02/03/2011		

	To register an additional manufacturing process and to change the test procedure for the active substance lamivudine. B.I.a.2.b - Changes in the manufacturing process of the AS - Substantial change to the manufacturing process of the AS which may have a significant impact on the quality, safety or efficacy of the medicinal product B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate				
IA/0001	IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site	22/12/2009	n/a		