EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



# Lamivudine / Zidovudine 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 |
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| IB/0028 | 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 | 21/03/2022 | | 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).

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| IB/0027 | 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 | 15/12/2021 | | SmPC and PL | |
| IB/0026 | 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 | 22/09/2021 | | SmPC and PL | |
| IB/0024 | 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 | 06/07/2021 | 29/09/2021 | SmPC and PL | |
| IA/0025/G | This was an application for a group of variations.<br><br>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<br>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 | 22/06/2021 | n/a | | |

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| | from an already approved manufacturer | | | | |
| IA/0023 | A.7 - Administrative change - Deletion of manufacturing sites | 15/01/2021 | 29/09/2021 | Annex II and PL | |
| IB/0022 | C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation | 05/10/2020 | 29/09/2021 | SmPC and PL | |
| IA/0021 | A.7 - Administrative change - Deletion of manufacturing sites | 29/11/2019 | n/a | | |
| IAIN/0020/G | This was an application for a group of variations.<br><br>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure<br>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) | 04/03/2019 | n/a | | |
| IB/0019 | 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 | 04/02/2019 | n/a | | |
| IB/0018 | C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation | 18/12/2018 | 28/03/2019 | SmPC | |
| IA/0017/G | This was an application for a group of variations. | 05/09/2018 | n/a | | |

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| | 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<br>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 | | | | |
| IB/0016 | 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 | 20/04/2018 | 28/03/2019 | SmPC and PL | |
| IB/0015/G | This was an application for a group of variations.<br><br>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<br>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<br>C.I.2.a - Change in the SPC, Labelling or PL of a | 10/08/2016 | 08/12/2016 | SmPC, Labelling and PL | |

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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 is required to be submitted by the MAH | | | | |
| IA/0014 | A.7 - Administrative change - Deletion of manufacturing sites | 29/03/2016 | 08/12/2016 | Annex II and PL | |
| II/0012/G | This was an application for a group of variations.<br><br>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<br>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<br>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)<br>B.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation | 17/03/2016 | n/a | | |
| IB/0013 | 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 | 22/12/2015 | 08/12/2016 | SmPC | |

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| | product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH | | | | |
| R/0010 | Renewal of the marketing authorisation. | 24/09/2015 | 19/11/2015 | SmPC and PL | Based on the review of the available information the CHMP is of the opinion that the quality, the safety and the efficacy of this medicinal product continues to be adequately and sufficiently demonstrated and therefore considers that the benefit/risk profile of Lamivudine/Zidovudine Teva continues to be favourable. The CHMP was of the opinion that the renewal should be grated with unlimited validity. |
| IB/0011 | 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 | 14/07/2015 | 19/11/2015 | SmPC and PL | |
| T/0009 | Transfer of Marketing Authorisation | 07/10/2014 | 11/11/2014 | | Transfer of Marketing Authorisation fom Teva Pharma B.V. (Utrecht) and Teva B.V (Haarlem). |
| IB/0008/G | This was an application for a group of variations.<br><br>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<br>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following | 12/03/2014 | 11/11/2014 | SmPC, Annex II, Labelling and PL | |

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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 | | | | |
| IAIN/0007 | C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation | 22/05/2013 | n/a | | |
| N/0005 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 08/05/2013 | 11/11/2014 | PL | |
| IA/0006 | A.7 - Administrative change - Deletion of manufacturing sites | 29/04/2013 | n/a | | |
| IB/0004/G | This was an application for a group of variations.<br><br>B.II.b.3.a - Change in the manufacturing process of the finished product - Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions<br>B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products | 16/01/2013 | n/a | | |
| IAIN/0003/G | This was an application for a group of variations.<br><br>A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release | 24/10/2012 | 31/10/2012 | Annex II and PL | |

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| | 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)<br>B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing | | | | |
| IB/0002/G | This was an application for a group of variations.<br><br>Update of sections 4.4, 4.5, 4.6, 5.1 and 5.3 of the SmPC to fulfil the commitments related to all antiretroviral agents containing lamivudine based on clinical experience gained on the use of lamivudine during pregnancy and on new information available on interactions. Section 4.5 was updated in line with the latest HIV guideline. The PL was updated accordingly.<br>Section 4.8 of the SmPC has been amended with the addition of the new adverse event "angioedema" and the calculation of its frequency (rare). PL was modified accordingly.<br>NB - Some changes to the Combivir text as part of variation applications II-59 and II-60 are product specific and N/A for Lamivudine/Zidovudine Teva.<br>Additionally the following changes have been made to the Product Information for Lamivudine/Zidovudine Teva:<br>" Marketing Authorisation numbers included<br>" Date of first authorisation has been added<br>" Updated the PL in order to reflect the | 15/09/2011 | n/a | SmPC and PL | |

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| | wording provided by the innovator, following update N/0058 for Combivir "Minor change in labelling or package leaflet not connected with the SmPC (Art. 61.3 Notification)."<br>" Updated the contact details of the local representative of the MAH for Malta<br><br>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<br>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 | | | | |