EMA/180286/2021

Telmisartan 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
IA/0027	A.7 - Administrative change - Deletion of manufacturing sites	09/02/2021		Annex II and PL	
IB/0026	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	14/07/2020		SmPC 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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IA/0025	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	31/07/2019	n/a		
IA/0024/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	03/05/2019	n/a		
N/0022	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/07/2018		Labelling	
IA/0021	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	08/07/2016	n/a		
IA/0020	A.7 - Administrative change - Deletion of manufacturing sites	14/06/2016	n/a		
IA/0019/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)	19/04/2016	20/03/2017	Annex II and PL	

	A.7 - Administrative change - Deletion of manufacturing sites				
T/0017	Transfer of Marketing Authorisation	22/01/2015	10/02/2015	SmPC, Labelling and PL	
R/0016	Renewal of the marketing authorisation.	23/10/2014	19/12/2014	SmPC and PL	Telmisartan Teva 20, 40 & 80 mg tablets contain telmistartan, an orally active and specific angiotensin II receptor (type AT1) antagonist that does not exhibit any partial agonist activity. Telmisartan Teva is indicated in the treatment of essential hypertension in adults and for the reduction of cardiovascular morbidity in adults with manifest atherothrombotic cardiovascular disease (history of coronary heart disease, stroke, or peripheral arterial disease) or type 2 diabetes mellitus with documented target organ damage. Based on the CHMP review of data on quality, safety and efficacy, the CHMP considers that the risk-benefit balance of Telmisartan Teva remains favourable and therefore recommends the renewal of the marketing authorisation under unlimited validity.
A31/0010	On 17 April 2013, further to the emergence of new evidence from the scientific literature on dual RAS blockade therapy and given the seriousness of the identified safety concerns, the Italian Medicines Agency (AIFA) initiated a review under Article 31 of Council Directive 2001/83/EC, requesting the Pharmacovigilance Risk Assessment Committee (PRAC) to issue a recommendation on the benefit-risk of dual RAS blockade therapy through the	22/05/2014	04/09/2014	SmPC and PL	For further information please refer to the Renin-angiotensin-system (RAS)-acting agents Article 31 referral - Assessment report.

	combined use of angiotensin-converting enzyme inhibitors (ACE-inhibitors), angiotensin II receptor blockers (ARBs) or aliskiren and to determine whether any regulatory measures should be taken on the marketing authorisations of the products involved in this procedure.				
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	30/04/2014	04/09/2014	SmPC and PL	
PSUSA/2882/ 201304	Periodic Safety Update EU Single assessment - hydrochlorothiazide / telmisartan, telmisartan	07/11/2013	n/a		PRAC Recommendation - maintenance
IB/0012/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 product - Implementation of change(s) for which NO new additional data is required to be submitted by	09/10/2013	04/09/2014	SmPC, Annex II and PL	

	the MAH				
IA/0013	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	27/09/2013	n/a		
IAIN/0011/G	This was an application for a group of variations. B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier 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)	04/09/2013	n/a		
IAIN/0009	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	28/05/2013	n/a		
IA/0008/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) A.7 - Administrative change - Deletion of manufacturing sites	11/03/2013	n/a		
IB/0007/G	This was an application for a group of variations. Update of section 4.4 of the SmPC to include a	26/07/2012	29/10/2012	SmPC, Labelling and	

	warning for diabetic patients when treated with insulin or oral antidiabetics and to include a warning on RAAS blockage in patients with uncontrolled blood pressure, and update to section 4.8 of the SmPC to include "cough", "somnolence" and "interstitial lung disease" as new ADR and consequential changes to section 4 of the Package Leaflet. These changes are implemented following approval of variation EMEA/H/C/000209/WS/0220 for Micardis. Update of sections 4.1, 4.2, 4.8 and 5.1 of the SmPC and consequently sections 1, 3 and 4 of the Package Leaflet to add indication of cardiovascular prevention in line with the indications registered for the reference product Micardis. This indication was registered for the reference product Micardis via variation EMEA/H/C/000209/II/0073. In addition the MAH has aligned the Annexes with version 8 of the QRD template and updated the list of local representatives in the Package Leaflet for Austria, Estonia, Finland, Germany, Italy, Ireland, Norway and United Kingdom. Furthermore, minor amendments have been introduced in some languages to keep the Product Information in line with the originator product. 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			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				
IB/0005/G	This was an application for a group of variations. B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the currently approved batch size B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.c.2.z - Change in the specification parameters and/or limits of the immediate packaging of the AS - Other variation B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	09/07/2012	n/a		
IAIN/0006/G	This was an application for a group of variations. B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes	09/05/2012	30/08/2012	SmPC, Labelling and PL	

IB/0004/G	This was an application for a group of variations. Update of section 4.8 of the SmPC to include the ADR 'angioedema (also with fatal outcome)', to add further information about 'liver disorder' and to add the ADR 'hypoglycaemia" under post-marketing experience upon request by the CHMP following the assessment of PSUR 9. In addition the SmPC was updated to bring it in line with the latest version of the SmPC guideline. The package Leaflet has been updated accordingly. Furthermore, a typographical error in the post code of the batch release site Teva Sante, France was amended in Annex II and in the PL, and the details of the local representative in Malta have also been updated in the Package Leaflet. Finally, additional amendments to the translated PI texts have been introduced due to readability and in compliance with the innovator's text and the QRD template version 7-3-1. 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	07/09/2011	n/a	SmPC, Annex II and PL	

IA/0003/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.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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)	19/04/2011	n/a		
IA/0001/G	This was an application for a group of variations. B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g.	01/04/2011	01/04/2011	SmPC, Annex II, Labelling and PL	

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IB/0002	B.II.a.3.z - Changes in the composition (excipients) of the finished product - Other variation	18/03/2011	n/a		