Telmisartan Actavis

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
IAIN/0031	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	23/04/2024		Annex II and PL	
N/0029	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	23/10/2023		Labelling and	

[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).

				PL	
IG/1612	A.1 - Administrative change - Change in the name and/or address of the MAH	31/05/2023		SmPC, Labelling and PL	
IB/0027	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	08/11/2022	n/a		
IA/0026	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	23/05/2022	n/a		
IB/0025	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	08/04/2022	n/a		
N/0024	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/09/2021		PL	
IB/0022/G	This was an application for a group of variations. 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	24/02/2021	n/a		

	B.I.b.1.h - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition or replacement (excl. Biol. or immunol. substance) of a specification parameter as a result of a safety or quality issue 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)				
IA/0021	A.7 - Administrative change - Deletion of manufacturing sites	08/12/2020	22/09/2021	Annex II and PL	
IB/0020	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	18/09/2020	22/09/2021	SmPC, Annex II and PL	
IB/0019/G	This was an application for a group of variations. B.I.b.1.h - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition or replacement (excl. Biol. or immunol. substance) of a specification parameter as a result of a safety or quality issue 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	22/07/2020	n/a		
N/0018	Minor change in labelling or package leaflet not	21/08/2018	22/09/2021	PL	

	connected with the SPC (Art. 61.3 Notification)				
N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/03/2018	22/09/2021	Labelling and PL	
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	27/02/2017	n/a		
N/0015	Update of the package leaflet with revised contact details of the local representatives for Belgium, Bulgaria, Germany, Spain, France, Croatia, Luxembourg and the Netherlands. In addition, the MAH took the opportunity to make linguistic and editorial amendments to the French, Estonian, Dutch, Lithuanian, Finnish, Czech, Latvian and Hungarian package leaflets. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	05/07/2016	22/09/2021	PL	
R/0014	Renewal of the marketing authorisation.	23/04/2015	19/06/2015	SmPC, Annex II and PL	Based on the review of data on quality, safety and efficacy, including all variations introduced since the marketing authorisation was granted, the CHMP considered that the benefit-risk balance of Telmisartan Actavis in the approved indications remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IA/0013/G	This was an application for a group of variations.	01/12/2014	n/a		

	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 A.7 - Administrative change - Deletion of manufacturing sites				
IA/0012/G	This was an application for a group of variations. B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	17/11/2014	n/a		
A31/0007	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 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.	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.

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	23/04/2014	04/09/2014	SmPC and PL	
IB/0010/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 the MAH	21/11/2013	04/09/2014	SmPC, Annex II and PL	
PSUSA/2882/ 201304	Periodic Safety Update EU Single assessment - hydrochlorothiazide / telmisartan, telmisartan	07/11/2013	n/a		PRAC Recommendation - maintenance
IB/0008	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	29/07/2013	04/09/2014	SmPC and PL	

IB/0006	Update of SmPC and package leaflet following CHMP adoption on 19 April 2012 of safety variations to the Marketing Authorisations for Micardis, Pritor and Kinzalmono. Amendments in line with the originator, the current QRD template (Version 8, 07/2011; Rev. 1, 10/2011) and minor editorial amendments are proposed in sections 2, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 5.1, 5.2, 6.6 of the SmPC, Annex II, section 6 of the Labelling, and all sections of the Package Leaflet. Additionally, Package Leaflet is updated with the details of local representatives for CZ, PL, EL, NL, SI, CY. Furthermore, corrections in the translations were made for the following countries: DE, EL, FR, IS, MT and SI to be in line with the originator. 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	26/07/2012	04/09/2014	SmPC, Annex II, Labelling and PL	
IB/0005/G	This was an application for a group of variations. 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 B.I.b.1.b - Change in the specification parameters	07/02/2012	n/a		

	and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.III.2.a.1 - Change of specification('s) of a former non Pharmacopoeial substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - AS 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.a.2.z - Changes in the manufacturing process of the AS - Other variation				
IB/0004	B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	02/12/2011	n/a		
IAIN/0003	B.III.1.a.1 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer	17/11/2011	n/a		
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 C.I.2.a - Change in the SPC, Labelling or PL of a	06/10/2011	n/a	SmPC, Annex II, Labelling and PL	

	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				