EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pioglitazone 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/0025	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	04/11/2021		PL	
IA/0024	A.7 - Administrative change - Deletion of manufacturing sites	01/02/2021	21/06/2021	Annex II and PL	
WS/1791	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. The RMP was updated to the RMP template rev 2 as per GVP module V	11/06/2020	21/06/2021	Annex II	

[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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

	rev 2, and the existing additional risk minimisation measures (educational pack for the healthcare professionals containing a prescriber guide) were removed both from the RMP and their key elements from the Annex IID of the PI, in line with the originator product for pioglitazone. In addition, standard wording was reinstated for the PSUR submission requirement with a reference to the updates included in the EURD list. C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required				
IAIN/0022	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	11/12/2017	28/11/2018	Annex II and PL	
IB/0021/G	This was an application for a group of variations. B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.f.1.e - Stability of FP - Change to an approved stability protocol	26/07/2017	n/a		
IA/0019	A.7 - Administrative change - Deletion of manufacturing sites	05/04/2017	n/a		
N/0020	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/03/2017	28/11/2018	PL	

R/0016	Renewal of the marketing authorisation.	15/12/2016	17/02/2017		Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Pioglitazone Teva in the approved indications remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IA/0018	B.II.a.3.b.1 - Changes in the composition (excipients) of the finished product - Other excipients - Any minor adjustment of the quantitative composition of the finished product with respect to excipients	02/02/2017	n/a		
IB/0017	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	10/10/2016	14/11/2016	SmPC and PL	
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	20/07/2016	14/11/2016	SmPC, Annex II, Labelling and PL	
IA/0014/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) A.7 - Administrative change - Deletion of manufacturing sites	29/06/2016	n/a		
IA/0013	A.7 - Administrative change - Deletion of manufacturing sites	25/04/2016	14/11/2016	Annex II and PL	

IAIN/0012	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	27/11/2015	14/11/2016	Annex II and PL	
T/0011	Transfer of Marketing Authorisation	22/12/2014	30/01/2015	SmPC, Labelling and PL	
IB/0010	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	27/10/2014	n/a		
IAIN/0009/G	This was an application for a group of variations. B.III.2.a.1 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - AS B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	26/09/2014	n/a		
IB/0008	B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation	19/09/2014	n/a		
IB/0007	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	29/07/2014	n/a		
IB/0006/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	25/11/2013	16/12/2014	SmPC, Annex II, Labelling and PL	

	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/0005	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	21/05/2013	n/a		
IA/0004/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	10/04/2013	n/a		
IAIN/0003	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	15/06/2012	n/a		
IB/0002	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	14/06/2012	n/a		
IB/0001	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	14/06/2012	n/a		