Pioglitazone Accord

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/0027	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	27/06/2023	n/a		
IB/0026	B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	19/12/2022	n/a		

[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).

IB/0025	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	25/10/2022	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.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure 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 B.III.1.a.4 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Deletion of certificates (in case multiple certificates exist per material)	20/09/2022	n/a		
IA/0023	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	23/06/2022	n/a		

IA/0022	A.7 - Administrative change - Deletion of manufacturing sites	11/01/2022	23/01/2023	Annex II and PL	
II/0020	Update of the Risk Management Plan (RMP) for the removal of safety concerns and additional risk minimisation measures (ARRM) as per summary of RMP of Glidipion (pioglitazone; published on 20-Jul-2020), and content adapted to the new GVP Module V (Rev.2). Product information Annex II is amended accordingly. 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	26/11/2020	09/12/2021	Annex II	n/a
IAIN/0021	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	25/11/2020	09/12/2021	Annex II and PL	
IAIN/0018/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.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site	25/02/2019	n/a		

	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place				
T/0017	Transfer of Marketing Authorisation	28/01/2019	14/02/2019	SmPC, Labelling and PL	
IAIN/0016	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	27/09/2018	14/02/2019	Annex II and PL	
II/0015/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.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site 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 B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.z - Change in the manufacturing process of	19/04/2018	n/a		

	the finished or intermediate product - Other variation 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.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range				
IB/0014	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	05/04/2017	n/a		
R/0011	Renewal of the marketing authorisation.	13/10/2016	05/12/2016		Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Pioglitazone Accord in the approved indications remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IAIN/0013/G	This was an application for a group of variations. 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 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	27/10/2016	n/a		

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 the MAH	28/06/2016	05/12/2016	SmPC and PL	
IAIN/0010	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)	15/01/2016	n/a		
IA/0008	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	02/12/2014	n/a		
IB/0007	To update the section 2, 4.1, 4.2, 4.3, 4.4, 4.6, 4.7, 4.8, 5.1, 5.3, 6.6 of SmPC, Annex II and Annex IIIB section 1, 2, 3, 4, 5, 6, in line with originator product information and to add indication no longer under patent. Furthermore, annexes were brought in line with the latest QRD template version. All changes made are in order to harmonise text with the originator.	10/10/2014	07/11/2014	SmPC, Annex II 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				
IB/0006	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	12/12/2013	07/11/2014	SmPC and PL	
IB/0005	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	12/11/2013	20/12/2013	SmPC, Annex II, Labelling and PL	
IAIN/0004	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	30/08/2013	n/a		
IAIN/0003	A.1 - Administrative change - Change in the name and/or address of the MAH	22/01/2013	20/12/2013	SmPC, Labelling and PL	
N/0002	Minor change in labelling or package leaflet not	18/06/2012	20/12/2013	PL	

	connected with the SPC (Art. 61.3 Notification)				
IB/0001	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	12/06/2012	n/a		