Aripiprazole Sandoz

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/0031	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/09/2024		PL	
IB/0030	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement	31/07/2024	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).

	or addition) for the AS or a starting material/intermediate				
PSUSA/234/202307	Periodic Safety Update EU Single assessment - aripiprazole	07/03/2024	n/a		PRAC Recommendation - maintenance
N/0029	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/12/2023		PL	
IA/0027	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)	14/09/2023	n/a		
IB/0026	B.II.z - Quality change - Finished product - Other variation	22/12/2022	n/a		
IA/0025	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	31/10/2022	n/a		
IB/0023	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	01/09/2022	12/10/2022	SmPC and PL	To update SmPC section 4.8 by adding "blood prolactin decreased" in the tabulated lists of adverse reactions.
IB/0022/G	This was an application for a group of variations. B.II.b.5.z - Change to in-process tests or limits	13/06/2022	n/a		

	applied during the manufacture of the finished product - Other variation B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation				
IA/0021	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	17/03/2022	n/a		
IA/0020	A.7 - Administrative change - Deletion of manufacturing sites	12/11/2021	n/a		
IB/0018/G	This was an application for a group of variations. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation 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	26/10/2021	12/10/2022	SmPC and PL	
IA/0019/G	This was an application for a group of variations.	20/10/2021	n/a		

	B.II.e.2.c - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.2.c - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information				
IA/0017	A.7 - Administrative change - Deletion of manufacturing sites	22/07/2021	n/a		
PSUSA/234/202007	Periodic Safety Update EU Single assessment - aripiprazole	11/02/2021	n/a		PRAC Recommendation - maintenance
IA/0016	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	23/10/2020	n/a		
R/0014	Renewal of the marketing authorisation.	30/04/2020	26/06/2020	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Aripiprazole Sandoz in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/234/2	Periodic Safety Update EU Single assessment -	27/02/2020	28/04/2020	SmPC and PL	Refer to Scientific conclusions and grounds recommending

01907	aripiprazole				the variation to terms of the Marketing Authorisation(s)' for PSUSA/234/201907.
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	12/12/2019	n/a		
PSUSA/234/201807	Periodic Safety Update EU Single assessment - aripiprazole	28/02/2019	29/04/2019	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/234/201807.
IB/0011	B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test	30/10/2018	n/a		
IB/0009	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	15/02/2018	16/03/2018	SmPC, Labelling and PL	
PSUSA/234/201707	Periodic Safety Update EU Single assessment - aripiprazole	08/02/2018	n/a		PRAC Recommendation - maintenance
IAIN/0007	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	13/09/2017	n/a		
IB/0005	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing	11/04/2017	16/03/2018	Annex II	

	authorisation, including the RMP - Other variation				
PSUSA/234/201607	Periodic Safety Update EU Single assessment - aripiprazole	09/02/2017	n/a		PRAC Recommendation - maintenance
IB/0004	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	09/12/2016	16/02/2017	SmPC and PL	
IB/0002	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	04/07/2016	16/02/2017	SmPC, Labelling and PL	
IB/0001/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	17/03/2016	16/02/2017	SmPC, Labelling and PL	

	the MAH				