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h-3899-steps after_en

Aripiprazole Zentiva

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or	Commission Decision IssuedA Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g.	Product Information affectedSmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).	Summary

		extension application or a worksharing application). Opinions are issued for all other procedures. **issued on**	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. **/ amended on**		
IB/0019/G	This was an application for a group of variations.	23/11/2023		Annex II and	

	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.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.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing 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 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.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation			PL	
IA/0017	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder	12/10/2022	n/a		

	or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient				
IB/0016	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	10/08/2022	24/07/2023	SmPC, Annex II, Labelling and PL	Section 4.8 of the SmPC has been updated to add "blood prolactine decreased" in the tabulated list of all adverse reactions in line with the text of reference product. The PL has been updated accordingly.
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	10/02/2021	04/06/2021	SmPC, Annex II, Labelling and PL	
IB/0014/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF	23/07/2020	n/a		
IB/0013	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	04/06/2020	04/06/2021	SmPC and PL	

	new additional data is required to be submitted by the MAH				
R/0012	Renewal of the marketing authorisation.	26/03/2020	02/06/2020	SmPC, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Aripiprazole Zentiva in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
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	05/06/2019	02/06/2020	SmPC, Labelling and PL	
IG/1029	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)	18/12/2018	n/a		
IB/0009	B.II.c.3.z - Change in source of an excipient or reagent with TSE risk - Other variation	14/03/2018	n/a		
IB/0008	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	06/02/2018	21/03/2018	SmPC and PL	

IA/0007	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	08/12/2017	n/a		
IB/0006	B.II.z - Quality change - Finished product - Other variation	30/10/2017	n/a		
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	18/04/2017	21/03/2018	Annex II	
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	13/02/2017	SmPC and Labelling	
IB/0003	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	01/07/2016	13/02/2017	SmPC and PL	
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	17/03/2016	13/02/2017	SmPC, Annex II 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 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				
IA/0001	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)	24/02/2016	n/a		