Abilify Maintena

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/0042	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	13/10/2021		SmPC, Labelling and PL	
II/0040	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission	08/07/2021	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).

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	of studies to the competent authority				
IB/0041	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	17/06/2021	n/a		
PSUSA/234/202007	Periodic Safety Update EU Single assessment - aripiprazole	11/02/2021	n/a		PRAC Recommendation - maintenance
IB/0039/G	This was an application for a group of variations. 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 B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products	18/12/2020	n/a		
II/0035	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	17/09/2020	27/10/2020	SmPC, Annex II, Labelling and PL	
II/0037	To update the product information with "DRESS" as new identified ADR in section 4.8 of the SmPC and subsequently in section 4 of the package leaflet	10/09/2020	27/10/2020	SmPC and PL	The product information has been updated to reflect "DRESS" as new identified ADR. Please refer to Scientific Discussion 'Product Name-H-C-002755-II-Var.No 0037'

	according to the current CCDS version. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				For more information, please refer to the Summary of Product Characteristics.
II/0036/G	This was an application for a group of variations. B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes 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	23/07/2020	n/a		
PSUSA/234/201907	Periodic Safety Update EU Single assessment - aripiprazole	27/02/2020	28/04/2020	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/234/201907.
IB/0032/G	This was an application for a group of variations. B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting	21/11/2019	n/a		

	material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) A.7 - Administrative change - Deletion of manufacturing sites B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits 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				
IAIN/0033/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) B.IV.1.a.1 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking	15/10/2019	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.
IA/0031	B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier	10/04/2019	n/a		
IA/0030	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	14/12/2018	n/a		
N/0028	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/12/2018	29/04/2019	PL	
IA/0029/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) B.II.e.7.z. - Change in supplier of packaging components or devices (when mentioned in the dossier) - Other variation	12/12/2018	n/a		
T/0026	Transfer of Marketing Authorisation	14/09/2018	16/10/2018	SmPC, Labelling and PL	
R/0025	Renewal of the marketing authorisation.	28/06/2018	27/08/2018	SmPC, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Abilify Maintena in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.

PSUSA/234/201707	Periodic Safety Update EU Single assessment - aripiprazole	08/02/2018	n/a		PRAC Recommendation - maintenance
II/0023	Update of sections 4.4 and 4.8 of the SmPC with further information about the risk of impulse control disorders, and section 4.8 of the SmPC to include the new ADRs 'impulse control disorders', 'binge eating', 'compulsive shopping' and 'poriomania'. The Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to implement minor editorial changes and align the annexes with the latest QRD template. C.I.3.b - 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 - Change(s) with new additional data submitted by the MAH	26/10/2017	27/08/2018	SmPC, Labelling and PL	Patients can experience increased urges, particularly for gambling, and the inability to control these urges while taking aripiprazole. Other urges, reported, include: increased sexual urges, compulsive shopping, binge or compulsive eating, and other impulsive and compulsive behaviours. It is important for prescribers to ask patients or their caregivers specifically about the development of new or increased gambling urges, sexual urges, compulsive shopping, binge or compulsive eating, or other urges while being treated with aripiprazole. It should be noted that impulse-control symptoms can be associated with the underlying disorder; however, in some cases, urges were reported to have stopped when the dose was reduced or the medication was discontinued. Impulse control disorders may result in harm to the patient and others if not recognised. Consider dose reduction or stopping the medication if a patient develops such urges while taking aripiprazole.
IA/0021/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.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)	03/05/2017	n/a		

PSUSA/234/201607	Periodic Safety Update EU Single assessment - aripiprazole	09/02/2017	n/a		PRAC Recommendation - maintenance
PSUSA/234/201507	Periodic Safety Update EU Single assessment - aripiprazole	25/02/2016	28/04/2016	SmPC and PL	Please refer to Abilify - PSUSA/00000234/201507 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation.
N/0019	Update of the package leaflet with revised contact details of the local representatives for Austria, Belgium, Luxembourg, Croatia and Iceland. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/04/2016	27/08/2018	PL	
II/0018	Update of the SmPC sections 4.4 and 5.1 to reflect data from Clinical Trials 31-12-291 and 31-12-297 in patients with acute episodes of schizophrenia and to warn against use of Abilify Maintena in case of severe attacks requiring immediate symptom control. The Package leaflet is updated accordingly. In addition, the MAH took the opportunity to include information on the effect of Abilify Maintena on prolactin levels in section 5.1 of the SmPC in support of an existing cross-reference from section 4.8, to align the PI with the latest QRD template version 9.1 and to introduce minor editorial changes. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	28/01/2016	28/04/2016	SmPC, Annex II and PL	Section 5.1 of the Abilify Maintena Summary of Product Characteristics (SmPC) was updated to include clinically relevant information for the prescriber in relation to the treatment of acute relapses of schizophrenia based on results from the double-blind, phase 3 trial 31-12-291 and from its 6-month open-label extension (Trial 31-12-297). There was a relevant weight and akathisia increase that was more frequent than when Abilify Maintena was studied for maintenance treatment, which is reflected in the new wording added to SmPC section 5.1. Additionally, a warning statement advising against the use of Abilify Maintena in case of severe attacks requiring immediate symptom control was added to section 4.4 of the SmPC.

IB/0016/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.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	19/06/2015	28/04/2016	SmPC and PL	
PSUSA/234/201407	Periodic Safety Update EU Single assessment - aripiprazole	26/02/2015	24/04/2015	SmPC and PL	Please refer to Abilify and Abilify Maintena PSUSA/0234/201407 EPAR: Scientific conslusions and grounds recommending the variation to the terms of the marketing authorisation
II/0011/G	This was an application for a group of variations. B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing	26/03/2015	28/04/2016	SmPC, Annex II, Labelling and PL	
IAIN/0015/G	This was an application for a group of variations. B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g.	25/03/2015	28/04/2016	SmPC, Labelling and PL	

	tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes				
IB/0014	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	05/02/2015	n/a		
II/0012/G	This was an application for a group of variations. B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.IV.1.a.1 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	22/01/2015	24/04/2015	SmPC, Labelling and PL	
IA/0013	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	19/12/2014	n/a		
IB/0010	C.I.z - Changes (Safety/Efficacy) of Human and	17/12/2014	24/04/2015	SmPC and PL	

	Veterinary Medicinal Products - Other variation				
IAIN/0007	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	17/07/2014	n/a		
N/0005	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	23/06/2014	24/04/2015	Labelling	
IB/0004	The MAH proposes to present all presentations for each strength in one single SmPC and to combine the Package leaflet. In addition, the use of the abbreviation "IM" for "intramuscular" is proposed in the Labelling for the vial. In line with the SmPC, information related to method of administration has been added in the outer carton. An editorial change was also made in section 4.2 of the SmPC with deletion of a bullet point. Furthermore, the use of EN translation of INNs was introduced in the Annexes (powder vial only) for Austria, Belgium Bulgaria, Germany, Greece, Spain, Croatia, Ireland, Iceland, Malta, Netherlands and Norway. The use of Latin translation of INNs was introduced in the Annexes (powder vial only) for Czech Republic, Denmark, Estonia, Finland, Hungary, Italy, Latvia, Lithuania, Poland, Romania, Slovenia, Slovak Republic and Sweden. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	28/03/2014	24/04/2015	SmPC, Labelling and PL	

IA/0003/G	This was an application for a group of variations. 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 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	13/02/2014	n/a		
IA/0001/G	This was an application for a group of variations. 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 B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	10/01/2014	n/a		