Spectrila

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/0034/G	This was an application for a group of variations. B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation B.II.g.4.b - Changes to an approved change management protocol - Minor changes that do not	20/06/2023	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).

	change the strategy defined in the protocol				
II/0032/G	This was an application for a group of variations. C.I.4: Update of sections 4.4 and 4.6 of the SmPC in order to include the recommendations from the SWP regarding genotoxic medicinal products and contraception duration period; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI. C.I.6.b: Deletion of the indication lymphoblastic lymphoma (LBL) in section 5.3 of the SmPC, as Spectrila is not approved for LBL. C.I.6.b - Change(s) to therapeutic indication(s) - Deletion of a therapeutic indication C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	09/03/2023		SmPC and PL	SmPC new text For more information, please refer to the Summary of Product Characteristics.
IB/0033/G	This was an application for a group of variations. B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation	08/12/2022	n/a		

II/0029	B.I.e.2 - Introduction of a post approval change management protocol related to the AS	08/12/2022	n/a		
II/0031	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	01/09/2022	n/a		
IB/0030	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	26/04/2022	n/a		
II/0026	B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS	24/03/2022	n/a		
IB/0028	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	06/01/2022	n/a		
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)	19/11/2021	n/a		
II/0025	B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a	02/09/2021	n/a		

	biological AS				
PSUSA/10445 /202101	Periodic Safety Update EU Single assessment - asparaginase (centrally authorised product)	02/09/2021	n/a		PRAC Recommendation - maintenance
IA/0023/G	This was an application for a group of variations. B.III.2.a.2 - 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 - Excipient/AS starting material A.7 - Administrative change - Deletion of manufacturing sites	07/01/2021	n/a		
II/0021/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 B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol	10/12/2020	n/a		

	product and any of the test methods at the site is a biol/immunol method B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation				
IA/0022	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	30/11/2020	n/a		
R/0018	Renewal of the marketing authorisation.	23/07/2020	24/09/2020	SmPC, Labelling and PL	
PSUSA/10445 /202001	Periodic Safety Update EU Single assessment - asparaginase (centrally authorised product)	04/09/2020	n/a		PRAC Recommendation - maintenance
IB/0020	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	15/07/2020	n/a		
II/0017	Update of the Risk Management Plan (version 12) for Spectrila in accordance with GVP Module V Rev 2 including the implementation of the new RMP template and the new definition of safety concerns. The QPPV and the Milestones / Timelines for the clinical study MC-Spectrila.1/ALL were updated in accordance to the newly applied DLP for this Risk Management Plan.	14/05/2020	n/a		

	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				
II/0015/G	This was an application for a group of variations. B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits 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 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.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.e.1.z - Change in immediate packaging of the finished product - Other variation	05/03/2020	n/a		

IA/0016	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	18/12/2019	n/a		
PSUSA/10445 /201901	Periodic Safety Update EU Single assessment - asparaginase (centrally authorised product)	11/07/2019	n/a		PRAC Recommendation - maintenance
IB/0014	B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	05/06/2019	n/a		
PSUSA/10445 /201807	Periodic Safety Update EU Single assessment - asparaginase (centrally authorised product)	28/02/2019	26/04/2019	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10445/201807.
IB/0012/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.1.f - Change in the manufacturer of AS or of a	04/01/2019	n/a		

	starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place				
IB/0009	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	13/08/2018	n/a		
PSUSA/10445 /201801	Periodic Safety Update EU Single assessment - asparaginase (centrally authorised product)	12/07/2018	n/a		PRAC Recommendation - maintenance
IB/0008	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	18/06/2018	26/04/2019	SmPC and Labelling	
PSUSA/10445 /201707	Periodic Safety Update EU Single assessment - asparaginase (centrally authorised product)	08/02/2018	n/a		PRAC Recommendation - maintenance
IA/0006	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the	19/12/2017	n/a		

	finished product, including quality control sites (excluding manufacturer for batch release)				
PSUSA/10445 /201701	Periodic Safety Update EU Single assessment - asparaginase (centrally authorised product)	01/09/2017	n/a		PRAC Recommendation - maintenance
IB/0003	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	20/07/2017	29/06/2018	SmPC	
PSUSA/10445 /201607	Periodic Safety Update EU Single assessment - asparaginase (centrally authorised product)	09/02/2017	n/a		PRAC Recommendation - maintenance