



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 |
|---------------------|---|--|--|---|-----------------------------------|
| 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 | 15/07/2020 | 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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| | arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place | | | | |
| II/0017 | <p>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.</p> <p>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</p> | 14/05/2020 | n/a | | |
| II/0015/G | <p>This was an application for a group of variations.</p> <p>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</p> <p>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</p> <p>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</p> <p>B.II.b.5.c - Change to in-process tests or limits</p> | 05/03/2020 | n/a | | |

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| | <p>applied during the manufacture of the finished product - Deletion of a non-significant in-process test</p> <p>B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation</p> <p>B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)</p> <p>B.II.e.1.z - Change in immediate packaging of the finished product - Other variation</p> | | | | |
| 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. | 04/01/2019 | n/a | | |

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| | <p>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</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p> | | | | |
| 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 |

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| 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 finished product, including quality control sites (excluding manufacturer for batch release) | 19/12/2017 | n/a | | |
| 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 |