# Steglatro

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 |
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| IAIN/0016/G | This was an application for a group of variations.<br><br>B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - | 05/12/2022 | | Annex II and PL | |

[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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| | Not including batch control/testing<br>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site<br>A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release<br>B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site<br>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) | | | | |
| R/0015 | Renewal of the marketing authorisation. | 15/09/2022 | 15/11/2022 | 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 Steglatro in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. |
| PSUSA/10682 /202112 | Periodic Safety Update EU Single assessment - ertugliflozin | 01/09/2022 | n/a | | PRAC Recommendation - maintenance |
| WS/1953 | This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.<br><br>Update of sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC of Steglatro and Segluromet in order to modify the indication, update posology recommendations and include efficacy and safety information based on | 16/09/2021 | 22/10/2021 | SmPC and PL | Please refer to Scientific Discussion Steglatro and Segluromet EMEA/H/C/WS1953 |

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| | final results from the VERTIS CV study (protocol 8835-004/B1521021) listed as a category 3 study in the RMP. This is a multi-centre, multi-national, randomised, double-blind, placebo-controlled study to evaluate the effect of ertugliflozin on cardiovascular risk in adult patients with type 2 diabetes and established atherosclerotic cardiovascular disease. The Package Leaflet is updated accordingly.<br><br>C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one | | | | |
| WS/1825 | This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.<br><br>C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation | 23/07/2020 | 09/07/2021 | SmPC and PL | |
| PSUSA/10682 /201912 | Periodic Safety Update EU Single assessment - ertugliflozin | 09/07/2020 | n/a | | PRAC Recommendation - maintenance |
| IB/0011 | B.I.b.1.h - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition or replacement (excl. Biol. or immunol. substance) of a specification parameter as a result of a safety or quality issue | 16/04/2020 | n/a | | |

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| IG/1211 | 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 | 27/02/2020 | n/a | | |
| PSUSA/10682 /201906 | Periodic Safety Update EU Single assessment - ertugliflozin | 16/01/2020 | n/a | | PRAC Recommendation - maintenance |
| IG/1157 | C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation | 14/11/2019 | 12/05/2020 | SmPC, Annex II, Labelling and PL | |
| PSUSA/10682 /201812 | Periodic Safety Update EU Single assessment - ertugliflozin | 11/07/2019 | n/a | | PRAC Recommendation - maintenance |
| WS/1590 | This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.<br><br>C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation | 23/05/2019 | 12/05/2020 | SmPC and PL | |
| PSUSA/10682 /201806 | Periodic Safety Update EU Single assessment - ertugliflozin | 31/01/2019 | 02/04/2019 | | Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10682/201806. |
| WS/1488 | This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.<br><br>Submission of the final CSR for Study P007/1017 - a Phase 3, randomized, double-blind, placebo- | 14/02/2019 | n/a | | No changes to the product information are warranted at present. The RMP will be updated at the next opportunity. The benefit/risk ration for Steglatro, Steglujan and Segluromet is unchanged. |

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| | controlled, 26-week multicenter study with a 78-week extension to evaluate the efficacy and safety of ertugliflozin in subjects with type 2 Diabetes Mellitus and inadequate glycaemic control on metformin monotherapy - together with the final summarized data of all adjudicated confirmed fractures from the broad pool and pooled 2-year safety data from the 7 completed Phase 3 studies, including both 2-year studies P007/1017 and P002/1013.<br><br>C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority | | | | |
| T/0002 | Transfer of Marketing Authorisation | 12/07/2018 | 28/08/2018 | SmPC, Labelling and PL | |
| IB/0001/G | This was an application for a group of variations.<br><br>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes<br>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes | 26/04/2018 | 28/08/2018 | SmPC, Labelling and PL | |