# Verzenios

## 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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| PSUSA/10724 /201903 | Periodic Safety Update EU Single assessment - abemaciclib | 31/10/2019 | n/a | | PRAC Recommendation - maintenance |
| II/0003 | Update of section 4.2 of the SmPC in order to add a criterion for discontinuing abemaciclib in the event of specific hepatic changes based on available safety data. Furthermore, section 4.5 of the SmPC is updated in order to update the information on contraceptive methods. In addition, the Marketing | 19/09/2019 | 21/10/2019 | SmPC | Patients should discontinue abemaciclib in case of elevation in AST and/or ALT >3 x ULN with total bilirubin >2 x ULN in the absence of cholestasis.<br>Moreover, the recommendation for use of an additional barrier contraceptive method for women receiving systematically acting hormonal contraceptives was |

[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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| | authorisation holder (MAH) took the opportunity to make editorial changes to section 5.1 of the SmPC and to the list of local representatives in the PL.<br><br>C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation | | | | removed, as women treated with abemaciclib for breast cancer should not be using exogenous oestrogen and progestins. |
| II/0005 | B.II.g.2 - Introduction of a post approval change management protocol related to the finished product | 12/09/2019 | n/a | | |
| IA/0007 | 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 | 14/08/2019 | n/a | | |
| IAIN/0002/G | This was an application for a group of variations.<br><br>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<br>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<br>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<br>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 | 26/11/2018 | 21/10/2019 | SmPC, Labelling and PL | |

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| | the range of the currently approved pack sizes<br>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<br>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 | | | | |
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