

## Mhyosphere PCV ID

### Procedural steps taken and scientific information after the authorisation

| Application number | Scope  | Opinion/ Notification<br><sup>1</sup> issued on | Commission Decision Issued / amended on | Product Information affected <sup>2</sup> | Summary <sup>3</sup>                                     |
|--------------------|--|---|---|---|--|
| II/0001/G          | <p>This was an application for a group of variations.</p> <p>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS</p> <p>B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process</p> <p>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</p> <p>B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range</p> <p>B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process</p> | 09/12/2021                                      |   | SPC and PL                                | Quality-related changes and consequent update of the PI. |

<sup>1</sup> Notifications are issued for type I variations (unless part of a group including a type II variation or higher procedure or a worksharing application). Opinions are issued for all other procedures.

<sup>2</sup> SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

<sup>3</sup> Since October 2019 summary information is no longer published for variations that do not impact upon the product information