

## Syvazul BTV

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

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued/ amended on	Product Information affected <sup>2</sup>	Summary <sup>3</sup>
IAIN/0004	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	20/01/2022		PL	The Agency accepted the variation to change the address of the local representative for Greece in the package leaflet.
IAIN/0002	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	30/03/2021		PL	The Agency accepted the variation to change the local representative information for France on the package leaflet.
IAIN/0001	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	02/07/2019	28/08/2020	PL	The Agency accepted the variation to introduce information on the MAH's local representative on the package leaflet.

<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