



Prevexxion RN+HVT+IBD

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued / amended on	Product Information affected ²	Summary ³
IG/1450	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	20/12/2021		Labelling and PL	The Agency accepted the variation to change the name of the solvent, and to update the labelling and package leaflet for the solvent.
WS/2107	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.e.6.a - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that affects the product information	07/10/2021		SPC	The Agency accepted the variation to replace the over-pouch protecting the primary packaging of the diluent and to decrease its shelf-life from 36 to 24 months.
IG/1337	C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure	10/02/2021	n/a		n/a
IB/0001	B.I.a.3.e - Change in batch size (including batch size ranges) of AS or intermediate - The scale for a biological/immunological AS is increased/decreased without process change (e.g. duplication of line)	22/10/2020	n/a		n/a

¹ 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.

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

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

