

Initial Submission ENTYVIO 300 mg

Reg No. 1C 41/60 (NBC)

Approval date 22 Nov 2017

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15065/61 (NB)	Non-AVG	15 Jan 2018 24 /18	Labeling	
15129/61 (NB)	Non-AVG	4 Dec 2018		
15130/61 (NB)	Non-AVG	13 Nov 2018	Patient information leaflet	