

Initial Submission TREMFYA

Reg No. 1C 15015/62 (NBC)

Approval date 26 Feb 2019

Register submission

Application number	Scope	Approval date	Product Information affected	Summary
15094/62 (NB)	non-AVG	10 May 2019	Patient information leaflet	
15097/62 (NB)	MiV-PA 2 Change of product labeling (in accordance to country specific labeling requirement)	15 May 2019	Labeling	