

Initial Submission Stelara

Reg No. 1C 17/57 (NBC)

Approval date 24 Jun 14

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
i15072/61 (NB)	MiV-PA2 Change of product labeling (in accordance to country specific labeling requirement)	1 May 18	Summary of Product Characteristics	
i15074/61 (NB)	AVG, MaV-9 Major change in the manufacturing process for the drug product	29 Jan 19		
i15075/61 (NB)	Non-AVG	22 Oct 18		
i15086/61 (NB)	MaV-15 Extension of shelf-life of the drug product	17 Jan 19		
i15098/61(NB)	MiV-PA2 Change of product labeling (in accordance to country specific labeling requirement)	9 Oct 18	Label Patient information leaflet Summary of Product Characteristics	
i15101/61(NB)	MiV-PA2 Change of product labeling (in accordance to country specific labeling requirement)	30 Oct 18	Patient information leaflet Summary of Product Characteristics	
i15107/61(NB)	Non-AVG	28 Jan 19		
i15157/61(NB)	MiV-N6 Change of the name and/or address (for example: postal code, street name) of a manufacturer of the drug substance 39	7 Dec 18		