

Initial Submission PARSABIV

Reg No. 1C 15086/61 (NC)

Approval date 24 Dec 2018

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15178/62 (N)	MiV-PA 2 Change of product labeling (in accordance to country specific labeling requirement)	19 Mar 20	PIL User testing	
15009/62 (N)	MaV-15 Extension of shelf-life of the drug product MiV-PA10 Change of shelf-life or retest period for drug substance	4 Mar 19		
15116/62 (NC)	MiV-PA 2 Change of product labeling (in accordance to country specific labeling requirement)		Patient information leaflet	