

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15070/62 (NB)	non-AVG	18 Jun 2019	Patient information leaflet	
15040/62 (NB)	MaV 1 Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	10 May 2019	Summary of Product Characteristics	
15078/62 (NB)	non-AVG	24 Apr 2019	Patient information leaflet	
15177/61 (NB)	MiV-PA 9 Change of the test procedure of non-compendial drug substance MiV-N7 Withdrawal/deletion of the alternative manufacturer(s) (for drug substance and/or drug product and/or packager)	10 Jan 2019		
15172/61 (NB)	MiV-PA 2 Change of product labeling (in accordance to	8 Jan 2019	Patient Information Leaflet and Summary of Product Characteristics	

	country specific labeling requirement)			
15091/61 (N)	MaV 2 Change of content of product labeling	6 Oct 2018	Patient information leaflet	
15001/61 (NB)	MaV-1 Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	10 Sep 2018		
15020/61 (NB)	non-AVG	10 Sep 2018		
15036/60 (NB)	MaV 15 Extension of shelf-life of the drug product MiV-PA 10 Change of shelf-life or re-test period for drug substance Non-AVG	28 May 2018		