

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15084/62 (N)	MaV 6 Change of the specification drug substance and/or drug product [where European Pharmacopoeial Certificate of Suitability (CEP) is not available]	15 Oct 2019		
15190/62 (NC)	MiV-PA 2 Change of product labeling (in accordance to country specific labeling requirement)	27 Sep 2019	Patient Information Leaflet	
15085/62 (N)	Non-AVG	24 Apr 2019		
15090/61 (N)	MaV-2 Change of content of product labeling	1 Mar 2019	Patient Information Leaflet	
15014/61 (N)	Non-AVG	26 Jun 2018		
15147/61 (N)	MiV-PA2 Change of product	3 Dec 2018	Patient Information	

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	labeling (in accordance to country specific labeling requirement)		Leaflet, Package insert and Summary of Product Characteristics	
15026/61 (N)	MIV-PA8 Change of the specification of drug substance	15 Aug 2018		