

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15171/62 (N)	<b>MiV-PA 2</b> Change of product labeling (in accordance to country specific labeling requirement)	5 Sep 19	PIL	
15167/61 (N)	<b>MaV 6</b> Change of the specification drug substance and/or drug product [where European Pharmacopoeial Certificate of Suitability (CEP) is not available]	23 Aug 2019		
15099/62 (N)	<b>MaV 1</b> : Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	25 Jun 2019	PIL, SmPC	

Application number	Scope	Approval date	Product Information affected	Summary
15140/61 (N)	<b>MaV 1</b> : Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	11 Mar 2019	PIL	
15082/62 (N)	<b>Non AVG</b>	24 Apr 2019	PIL	
15109/61 (N)	<b>Non AVG</b>	14 Feb 2019		
15145/61 (N)	<b>MaV 2</b> : Change of content of product labeling	8 Feb 2019	PIL, Labeling	
15050/60 (N)	<b>MaV 1</b> : Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	13 Jul 2018	PIL, SmPC	