

Initial Submission LIXIANA 15 mg  
2016

Reg No. 1C 104/59 (NC)

Approval date 2 Dec

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15154/62 (N)	<b>MiV-PA 2</b> Change of product labeling (in accordance to country specific labeling requirement)	26 Sep 2019		
15133/61 (N)	<b>Non-AVG</b>	8 Nov 2018		
15132/61 (N)	<b>MiV-PA 2</b> Change of product labeling (in accordance to country specific labeling requirement)	7 Nov 2018	Patient information leaflet	
15018/60 (N)	<b>Non-AVG</b>	21 Mar 2018		
15031/60 (N)	<b>MaV-1</b> Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	4 Dec 2017	Patient information leaflet	

15013/60 (N)	<b>MaV-15</b> Extension of shelf-life of the drug product	17 Nov 2017		
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