

Initial Submission LIXIANA 15 mg

Reg No. 1C 104/59 (NC)

Approval date 2 Dec 2016

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15013/60 (N)	MaV-15 Extension of shelf-life of the drug product	17 Nov 2017		
15018/60 (N)	Non-AVG	21 Mar 2018		
15031/60 (N)	MaV-1 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	
15132/61 (N)	MiV-PA 2 Change of product labeling (in accordance to country specific labeling requirement)	7 Nov 2018	Patient information leaflet	
15133/61 (N)	Non-AVG	8 Nov 2018		