

Initial Submission Harvoni

Reg No. 2C 44/59 (NC)

Approval date 23 Sep 2016

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15025/60 (N)	MiV-PA 2 Change of product labeling (in accordance to country specific labeling requirement)	20 Feb 2018		
15009/61 (N)	MaV-1 Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	19 Dec 2018	Patient information leaflet	
15114/61(N)	MaV-15 Extension of shelf-life of the drug product	27 Dec 2018		