

Initial Submission GENVOYA

Reg No. 2C 15013/61 (NC)

Approval date 28 Mar 2018

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15168/61 (N)	MIV-N6 Change of the name and/or address (for example: postal code, street name) of a manufacturer of the drug substance	19 Dec 2018		
15115/61(N)	MaV-1 Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	6 Dec 2018	Patient information Leaflet	