Initial Submission Prezista 800 mg **Reg No.** 1C 39/59 (NC) **Approval date** 22 Sep 2016

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
i15018/61 (N)	**MiV-PA 2** Change of product labeling (in accordance to country specific labeling requirement)	7 June 2018	Summary of Product Characteristics Patient information leaflet	
i15099/61(N)	**MaV-2** Change of content of product labeling	30 Jan 2019	Patient information leaflet	
i15155/61 (N)	**MiV-PA 2** Change of product labeling (in accordance to country specific labeling requirement)	7 Dec 2018	Labeling	
i15011/62 (N)	**MiV-PA 2** Change of product labeling (in accordance to country specific labeling requirement)	21 May 2019		