

Initial Submission Kisqali (200 mg)

Reg No. 1C 15019/61 (NC)

Approval date 23 Apr 2018

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15076/62 (N)	MiV-PA 2 Change of product labeling (in accordance to country specific labeling requirement)	23 May 2019	Patient Information Leaflet	
15105/61(N)	MaV-1 : Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	1 Nov 2018	Patient Information Leaflet, Package insert and Summary of Product Characteristics	