

Initial Submission Kisqali (200 mg)

Reg No. 1C 15019/61 (NC)

Approval date 1 Nov 2018

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
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	
15007/62 (NB)	MiV-PA2 Change of product labeling (in accordance to country specific labeling requirement)	23 Jan 2019	Label	
15048/60(NB)	MiV-PA35 Change of storage conditions of the drug product (Increasing from the current approved storage	13 Jan 2018	Patient Information Leaflet, Package insert and Summary of Product Characteristics	

	condition)			
15158/61 (NB)	นอกเหนือ AVG	30 Nov 2018		
15104/61 (NB)	MaV-2 Change of content of product labeling	8 Nov 2018	Label	