

Initial Submission AUBAGIO (14 MG)

Reg No. 1C 43/60 (NC)

Approval date 27 Jun 2017

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15160/62 (N)	MaV 2 Change of content of product labeling	11 Sep 2019		
15112/62 (N)	MiV-PA2 Change of product labeling (in accordance to country specific labeling requirement)	5 Jun 2019	Label	
15166/61 (N)	MiV-PA8 Change of the specification of drug substance	26 Feb 2019		
15027/61 (N)	MiV-PA2 Change of product labeling (in accordance to country specific labeling requirement)	11 Sep 2018	Patient information leaflet	