

Initial Submission DARZALEX (Vetter) Reg No. 1C 31/60 (NBC) Approval date 3 Aug 2017

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15020/61 (NB)	Non-AVG	10 Sep 2018		
15037/60 (NB)	MaV-15 Extension of shelf-life of the drug product MiV-PA10 Change of shelf-life or retest period for drug substance Non-AVG	28 May 2018		
15001/61 (NB)	MaV-1 Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	10 Sep 2018	Patient information leaflet Summary of Product Characteristics	
15091/61 (NB)	MaV-2 Change of content of product labeling	10 Jun 2019	Patient information leaflet	
15176/61 (NB)	MiV-PA2 Change of product labeling (in accordance to country specific labeling requirement)	8 Jan 2019	Patient information leaflet Summary of Product Characteristics	
15178/61 (NB)	MiV-PA9 Change of the test procedure of non-compendial drug substance MiV-N7 Withdrawal/deletion of the alternative manufacturer(s) (for drug substance and/or drug product and/or packager)	8 Jan 2019		

