

Initial Submission DARZALEX (Cilag site)

Reg No. 1C 30/59 (NBC)

Approval date 3 Aug 2017

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15036/60 (NB)	<b>MaV 15</b> Extension of shelf-life of the drug product <b>MiV-PA 10</b> Change of shelf-life or re-test period for drug substance <b>Non-AVG</b>	28 May 2018		
15091/61 (N)	<b>MaV 2</b> Change of content of product labeling	6 Oct 2018	Patient information leaflet	
15177/61 (NB)	<b>MiV-PA 9</b> Change of the test procedure of non-compendial drug substance <b>MiV-N7</b> Withdrawal/deletion of the alternative manufacturer(s) (for drug substance and/or drug product and/or packager)	10 Jan 2019		