**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 |
|---|---|---|---|---|
| 15178/61 (NB) | **MiV-PA9** Change of the test procedure of non-compendial drug substance<br>**MiV-N7** Withdrawal/deletion of the alternative manufacturer(s) (for drug substance and/or drug product and/or packager) | 10 Jan 2019 | | |
| 15176/61 (NB) | **MiV-PA2** Change of product labeling (in accordance to country specific labeling requirement) | 8 Jan 2019 | Patient information leaflet<br>Summary of Product Characteristics | |
| 15091/61 (NB) | **MaV-2** Change of content of product labeling | 6 Oct 2018 | Patient information leaflet | |
| 15020/61 (NB) | **Non-AVG** | 10 Sep 2018 | | |
| 15001/61 (NB) | **MaV-1** Change and/or additional indication/dosing regimen/patient | 10 Sep 2018 | Patient information leaflet<br>Summary of Product Characteristics | |

| Application number | Scope | Approval date | Product Information affected | Summary |
|---|---|---|---|---|
| | population/inclusion of clinical information extending the usage of the product | | | |
| 15037/60 (NB) | **MaV-15** Extension of shelf-life of the drug product<br>**MiV-PA10** Change of shelf-life or retest period for drug substance<br>**Non-AVG** | 28 May 2018 | | |