

Initial Submission incrise ellipta

Reg No. 1C 37/60 (NC)

Approval date 25 Jun 2018

Variation submission

| Application number | Scope | Approval date | Product Information affected | Summary |
|--------------------|---|---------------|--|---------|
| 15044/60 (N) | MiV-PA 2 : Change of product labeling (in accordance to country specific labeling requirement) | 24 Apr 2018 | Label | |
| 15034/60 (N) | MiV-PA 2 : Change of product labeling (in accordance to country specific labeling requirement) | 24 Apr 2018 | Patient Information Leaflet and Summary of Product Characteristics | |
| 15035/60 (N) | MiV-PA 10 : Change of shelf-life or retest period for drug substance | 16 Jan 2018 | | |