

**Initial Submission** Hemlibra (Solution for injection 30 mg/ml)

**Reg No.** 1C 15037/61 (NBC)

**Approval date** 6 Jul 2018

Variation submission

| <b>Application number</b> | <b>Scope</b>  | <b>Approval date</b> | <b>Product Information affected</b>                                | <b>Summary</b> |
|---------------------------|---|----------------------|--|----------------|
| 15141/61 (N)              | <b>MaV-1</b> Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product | 27 May 2019          | Patient Information Leaflet and Summary of Product Characteristics |                |