

Initial Submission Hemlibra (Solution for injection 150 mg/ml)

Reg No. 1C 15038/61 (NBC)

Approval date 6 Jul 2018

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15141/61 (N)	MaV-1 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, Package insert and Summary of Product Characteristics	