

Initial Submission Imbruvica (Cilag site)

Reg No. 1C 73/60 (NC)

Approval date 2 Nov 2017

Variation submission

| Application number | Scope   | Approval date | Product Information affected | Summary |
|--------------------|---|---------------|------------------------------|---------|
| 15099/62 (N)       | <b>MaV 1</b> : Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product | 25 Jun 2019   | PIL, SmPC                    |         |
| 15082/62 (N)       | <b>Non AVG</b>  | 24 Apr 2019   | PIL                          |         |
| 15145/61 (N)       | <b>MaV 2</b> : Change of content of product labeling  | 8 Feb 2019    | PIL, Labeling                |         |
| 15140/61 (N)       | <b>MaV 1</b> : Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product | 11 Mar 2019   | PIL                          |         |
| 15109/61 (N)       | <b>Non AVG</b>  | 14 Feb 2019   |                              |         |
| 15050/60 (N)       | <b>MaV 1</b> : Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product | 13 Jul 2018   | PIL, SmPC                    |         |