

Initial Submission Lipitor (Tablets 80 mg)

Reg No. 1C 11/59 (N)

Approval date 31 Mar 2016

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15007/61 (N)	MaV-1 Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product MaV-2 Change of content of product labeling MiV-PA2 Change of product labeling (in accordance to country specific labeling requirement)	17 Sep 2018	Patient information leaflet Summary of Product Characteristics	
15048/61 (N)	MiV-PA8 Change of the specification of drug substance	31 Oct 2018		
15005/62 (N)	MaV-2 Change of content of product labeling	26 Dec 2018	Label	
15057/61 (N)	MiV-PA24 Change of release and shelf-life specifications of the drug product	6 Jun 2019		
15055/62 (N)	MiV-PA2 Change of product labeling (in accordance to country specific labeling requirement)	21 Mar 2019	Label	
15109/62 (N)	MiV-PA2 Change of product labeling (in accordance to country specific labeling requirement)	24 Jun 2019	Label	

