

Initial Submission GAPENTIN

Reg No. 1A 44/59(NG)

Approval date 13 Dec 2016

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15003/60 (NG)	<b>Non-AVG</b>	5 May 2017		
15071/61 (NG)	<b>MaV-6</b> Change of the specification drug substance and/or drug product [where European Pharmacopoeial Certificate of Suitability (CEP) is not available]	10 May 2018		