

Initial Submission Tonizep FDT5

Reg No. 1A 36/59(NG)

Approval date 6 Oct 2016

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15006/60 (NG)	Non-AVG	8 June 2017		
15124/61 (NG)	Mav-1 Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	29 March 2019		