

Initial Submission INVEGA TRINZA

Reg No. 1C 53/60 (NC)

Approval date 3 Aug 2017

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15085/62 (N)	Non-AVG	24 Apr 2019		
15090/61 (N)	MaV-2 Change of content of product labeling	1 Mar 2019	Patient Information Leaflet	
15014/61 (N)	Non-AVG	26 Jun 2018		
15147/61 (N)	MiV-PA2 Change of product labeling (in accordance to country specific labeling requirement)	3 Dec 2018	Patient Information Leaflet, Package insert and Summary of Product Characteristics	
15026/61 (N)	MiV-PA8 Change of the specification of drug substance	15 Aug 2018		