## Initial Submission Ribomustin 25 MG (ONCOTEC PHARMA PRODUKTON GMBH site)

Reg No. 1C 56/58 (NC)

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15069/61 (N)	<b>MiV-PA2 :</b> Change of product labeling (in accordance to country specific labeling requirement)	18 Apr 2018	PIL	
15041/60 (N)	<b>MaV 1</b> : Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	17 Nov 2017		