

Initial Submission Pertagen

Reg No. 2A 2/59(NBC)

Approval date 30 Sep 2016

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15002/60 (NB)	<b>MaV-7</b> Change of batch size of sterile drug product	16 Oct 2017		
15005/60 (NB)	<b>MiV-PA27</b> Change in the test procedure of the drug product (including replacement or addition of a test procedure)	23 Aug 2017		
15011/60 (N)	<b>MaV-15</b> Extension of shelf-life of the drug product	30 Mar 2018		
15023/60 (N)	<b>Non-AVG</b>	3 Jan 2018		
15029/60 (NB)	<b>Non-AVG</b>	26 Jun 2018		
15058/60 (NB)	<b>MiV-PA9</b> Change of the test procedure of non-compendial drug substance <b>Non-AVG</b>	29 Jun 2018		