

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15290/62 (N)	<b>MiV-PA 5</b> : Change of batch size of drug substance [where European Pharmacopoeial Certificate of Suitability (CEP) is not available]	19 Mar 20	Batch size of drug substance	
15120/62 (N)	<b>MiV-PA 28</b> Change in primary packaging material for non-sterile product a) Qualitative and quantitative composition and/or b) Type of container and/or c) Inclusion of primary packaging material <b>Mav-15</b> Extension of shelf-life of the drug product	17 Sep 2019		
15053/60 (N)	<b>MiV-N4</b> : Change of the name or address (for example: postal code, street name) of the manufacturer of drug product	13 Dec 2017	Label and Patient Information Leaflet	