

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15120/62 (N)	MiV-PA 28 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 Mav-15 Extension of shelf-life of the drug product	17 Sep 2019		
15053/60 (N)	MiV-N4 : 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	