

Steps taken following Prequalification of [MA058 trade name]*

Changes	WHOPAR parts affected	Accepted on
Change in the shelf life of the FPP	4	08 July 2010
Addition of FPP manufacturing site	3	30 March 2012
Change in the name of the FPP supplier	3,4,5	27 December 2016
Change in labelling information to delete the street name of the FPP supplier	5	27 December 2016
Product information updated with respect to section 4 of the SmPC and PIL	3,4	02 September 2018
Product information updated with respect to section 4 of the SmPC and PIL	3,4	August 2021
Change in the address of the manufacturer of the FPP	3,6,7	August 2021

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.