

Steps taken following Prequalification of [TB068 trade name]*

Changes	WHOPAR parts affected	Accepted on
Change in the shelf life of the FPP	4	26 January 2007
Addition of FPP manufacturing and quality control site	3	9 December 2011
Change in the address of the supplier	3, 4, 5	11 July 2016
Addition of a primary packing type, additional pack (cold alu/alu blister pack 24x28)	3,4	1 November 2017
Change in the shelf of FPP involving extension from 24 months to 36 months for Alu Alu blister pack	4	24 March 2021
Addition of primary packaging material	3, 4, 5	06 July 2023

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