

Steps taken following Prequalification of [TB159 trade name]*:

This document will only list changes endorsed by WHO Prequalification Team – Medicines that affect the WHOPAR.

Changes	Product information affected	Accepted on
Addition of FPP primary packaging type	3, 4, 5	25 May 2010
Change in the FPP shelf-life involving shelf extension	4	9 February 2011
Change in the FPP shelf-life involving shelf extension	4	30 April 2012
Change in the FPP pack size	3, 4, 5	06 January 2014
Addition of FPP manufacturing site	3	12 June 2015
Addition of FPP manufacturing site and testing site	3	24 August 2015
Addition of FPP manufacturing primary packaging type	3, 4, 5	23 September 2016
Change in the shelf-life of the FPP (as packaged for sale) involving: extension of shelf-life	4	05 October 2022

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