

Steps taken following prequalification of [HA516 trade name]*:

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

Changes	WHOPAR parts affected	Date
Addition of manufacturing and quality control testing site for the FPP	3	June 2014
Change in the FPP primary packaging pack	3, 4	October 2016
Requalification	1	December 2019
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	2, 3, 4	March 2020
Addition of manufacturing and quality control testing site for the FPP	3	April 2022
Update of the WHOPAR to reflect new safety information, the current WHOPAR structure, WHO guidelines, and state of scientific knowledge	2, 3, 4, 5	July 2023
Change in the FPP shelf-life involving extension	4	August 2023
Change in the FPP shelf-life involving extension	4	March 2024

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