

Steps taken following prequalification of [HA403 trade name]*:

This document will only list changes endorsed by WHO that affect the WHOPAR.

Changes	WHOPAR parts affected	Date
Change in the shelf life of the FPP	4	25 May 2010
Change in the packaging material of the FPP	3, 4	13 July 2010
Change in the name of the supplier and manufacturer of the FPP	3, 4, 5	18 October 2011
Addition of manufacturing site for the FPP with change in batch size	3	20 September 2013
Change in the pack size of the FPP	3, 4, 5	27 February 2015
Addition of FPP manufacturing site	3	09 December 2016
Change in the name and/or address of the supplier of the FPP	3, 4, 5	01 March 2017
Addition of FPP manufacturing and testing site	3	24 November 2017
Addition of alternate FPP packaging	3, 4, 5	29 June 2020
Requalification	1	19 December 2018
Update of the WHOPAR to reflect new safety information, the current WHOPAR structure, product specifics, WHO guidelines, and state of scientific knowledge	3, 4	July 2023

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.