

Steps taken following Prequalification of [RH013 trade name]*:

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

Changes	WHOPAR parts affected	Accepted on
Change in the FPP shelf-life	4	December 2011
Change in the name and/or address of the FPP manufacturer	3	September 2015
Change in the name of the FPP supplier	3, 4, 5	November 2015
Change in the name and address of the FPP supplier	3, 4, 5	February 2017
Change in the name and address of the FPP manufacturer	3	February 2017
Requalification 31 October 2019	1	October 2019
Addition of FPP manufacturing and testing site	3	April 2021
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	2,3,4,5	November 2021
Change in the name of the FPP supplier	3, 4, 5	June 2024
Change in the name of the FPP manufacturer	3	June 2024
Change in the corporate address of the FPP supplier	3, 4, 5	August 2024

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

¹Formerly known as Mylan Laboratories Limited.

² Mylan Laboratories Limited formerly known as Famy Care Ltd