

Steps taken following Prequalification of [HA561 trade name]:

Changes	WHOPAR parts affected	Accepted on
Addition of a FPP manufacturing site	3	7 January 2016
Change in the colouring or flavouring of the FPP	3, 4	7 January 2016
Change in the dimensions of the FPP packaging	3, 4	18 January 2016
Reduction of the shelf life of the FPP	4	14 December 2017
Addition of a FPP manufacturing and testing site	3	3 April 2019
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	2, 3, 4	April 2020

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