Steps taken following Prequalification of Duovir N[*]

Changes	Product information affected	Accepted on
Change in the batch size of the FPP		17 July 2009
Change in the shelf life of the FPP	SmPC	17 July 2009
Addition of manufacturer for Nevirapine API		01 September 2009
Minor change in the test procedures for the FPP		10 December 2009
Change in the specifications for Nevirapine API		15 December 2009
Change in the in-process control tests during manufature of the FPP		07 January 2010
Addition of manufacturer for Zidovudine API		07 April 2010
Update of Lamivudine APIMF		18 May 2010
Change in the batch size and addition of manufacturing site for the FPP	PIL	24 May 2010
Addition of manufacturing site for the FPP	PIL	23 June 2010
Addition of manufacturer for Nevirapine API		24 June 2010
Addition of manufacturing site for the FPP	PIL	12 August 2010
Change in the batch size of Nevirapine API		11 October 2010
Addition of manufacturing site for Lamivudine API		07 December 2010
Change in test procedure of Nevirapine API.		08 December 2010
Minor change in the manufacturing process of Nevirapine API		15 December 2010
Change in batch size of Nevirapine API		10 January 2011
Addition of manufacturing block for Lamivudine API		31 March 2011
Change in specification of Lamivudine API		20 April 2011
Minor change in the manufacturing process, change in batch size and change in retest period of Nevirapine API		15 September 2011
Addition of manufacturer for Lamivudine API		11 November 2011
Change in the batch size of Nevirapine API		11 November 2011
Change in the in-process control specifications of the FPP		11 November 2011
Addition of manufacturing site for Zidovudine API		12 January 2012
Addition of manufacturing and quality testing site for the FPP	PIL	30 January 2012
Addition of manufacturing site for the FPP	PIL	03 August 2012
Change to in-process tests or limits applied during the manufacture of the FPP		04 October 2013
Changes to the published information	WHOPAR parts affected	Accepted on
Change in the name of a manufacturer of the FPP	3	29 August 2014
Change in the shelf life of the FPP	4	12 July 2017

[*] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Change in FPP packaging components	3,4,5	05 April 18