## Steps before prequalification

# I. BACKGROUND INFORMATION ON THE PROCEDURE

### 1. Submission of the dossier

The company Cipla Ltd submitted in 2008 an application for [HA439 trade name][*] (HA439) to be assessed with the aim of including [HA439 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA439 trade name] was assessed according to the '*Procedure for Assessing the Acceptability, in Principle, of Pharmaceutical Products for Purchase by United Nations Agencies*' by the team of WHO assessors. The assessors are senior experts, mainly from national authorities, invited by WHO to participate in the prequalification assessment process.

### 2. Steps taken in the evaluation of the product

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| July 2008 | During the meeting of the assessment team the safety, efficacy and quality data were reviewed and further information was requested. |
| Feb 2009 | The applicant's response letters were received. |
| March 2009 | During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested. |
| May 2009 | The applicant's response letters were received. |
| May 2009 | During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested. |
| July 2009 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| Sept 2010 | The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP. |
| Oct 2010 | The applicant's response letters were received. |
| Nov 2010 | During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested. |
| Jan 2011 | The applicant's response letters were received |
| Jan 2011 | During the meeting of the assessment team the safety, efficacy and quality data were reviewed and further information was requested. |
| Feb 2011 | The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP. |
| March 2011 | The applicant's response letters were received |
| March 2011 | During the meeting of the assessment team the safety, efficacy and quality data were reviewed and further information was requested. |
| April 2011 | The applicant's response letters were received. |
| May 2011 | During the meeting of the assessment team the additional safety and efficacy were reviewed and found to comply with the relevant WHO requirements. |

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

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| Aug 2011 | The company's response letter was received. |
| Aug 2011 | The additional quality data were reviewed and found to comply with the relevant WHO requirements. |
| Sept 2011 | The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP. |
| 5 Oct 2011 | [HA439 trade name] was included in the list of prequalified medicinal products. |

## II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

### 1. Manufacturer and Inspection status

**Manufacturer of the finished product and responsible for batch release**

Cipla Ltd
Unit VII, III, IV
Plot No: L-139 to L-146 and L-147 to L147-1
Verna Industrial Estate Goa – 403722,
India

**Inspection status**

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

### 2. (Advice on) Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Further information is available at:

https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products