0123959316 Amendment Section (T)

0123958505 N/2/6/2 (S0786)

08 February 2012

The Responsible Pharmacist

EXAMPLE PHARMACEUTICALS(Pty) Ltd

P.O.BOX 1234

Perfect Place

9876

Fax Number: (012 123 4567)

Dear Sir/Madam,

**Re: AMENDMENT FOR PERFECT CURE 500mg, S0786**

Your letter dated 13 October 2011 and received at Post Registration Unit on 01 December 2011,

your ref no: ABC2011-001. The requests as per details in your covering letter regarding the partial

update (conversion / update from MBR1 / MRF1 to ZA CTD format) has been evaluated as follows:

**Module 1 (Administrative and labeling)**

Sections 1.2 to 1.3.3: are noted.

Sections 1.5.2.1 to 1.5.2.3: are noted.

Sections 1.7.1: Noted.

Section 1.7.3 to 1.7.4.4: Noted.

Sections 1.7.7.1 to 1.7.7.3: are noted.

Sections 1.7.8 to 1.7.12: are noted.

**Module 1.7**

Please note that only P&A aspects are addressed in this letter, administration & inspectorate issues will be addressed in a separate response.

**Module 3 (Final Product)**

3.2.P.3.1: Noted.

Yours faithfully

REGISTRAR OF MEDICINES