**EXAMPLE PHARMACEUTICALS (PTY) LTD**

123 ANYWHERE ROAD

PRETORIA

P.O.BOX 456

PRETORIA

0001

 23/03/2012

**PERFECT CURE 500 mg (S0786)**

POST REGISTRATION AMENDMENT

AMENDMENT CODES: VAC, VPC, VLC

VOLUME 1 OF 1

This volume contains:

MODULE 1 – ADMINISTRATIVE INFORMATION

# 1.0 Cover letter

1.1 Comprehensive table of contents

1.2 Application

1.2.1 Application form

1.2.2 Annexes

1.2.2.1 Proof of payment

1.2.2.2 Letter of authorisation for communication on behalf of the applicant/PHCR

1.2.2.5 Curriculum vitae of the person responsible for pharmacovigilance

1.3 South African labelling and packaging

1.3.1 South African Package Insert

1.3.1.1 Package insert

1.3.1.2 Standard References

1.3.2 Patient Information Leaflet

1.3.3 Labels

1.5 Specific requirements for different types of applications

1.5.2 Amendments/Variations [[1]](#footnote-2)

1.5.2.1 Tabulated schedule of amendments

1.5.2.2 Medicines Register Details

1.5.2.3 Affidavit by Responsible Pharmacist

1.7 Good Manufacturing Practice

1.7.1 Date of last inspection of each site

1.7.2 Inspection reports or equivalent document

1.7.3 Latest GMP certificate or a copy of the appropriate licence

1.7.4.3 Finished Product Release Control (FPRC) tests

1.7.4.4 Finished Product Release Responsibility (FPRR) criteria

1.7.7 Proof of current registration of the Responsible Pharmacist by the SAPC

1.7.8 Proof of current registration by the SAPC of the pharmacist signing the dossier

1.7.9 Proof of registration of the Applicant/PHCR as a pharmacy or a pharmacist

1.7.12 Inspection flow diagram

1.7.13 Organogram

1. [↑](#footnote-ref-2)