**Appendix A2 / Module 1.5.2.3**

***Indicate clearly which of the following are relevant and/or not applicable by strikethrough***

**AFFIDAVIT BY THE HCR/APPLICANT** (On company letterhead)

*(In the case of transfer of the certificate of registration, this must be done by the proposed HCR)*

**PRODUCT NAME: REGISTRATION NUMBER:**

I, Accurate Responsible*(insert full name and surname)* Responsible Pharmacist [as defined in Section 22C(1)(b) of Act 101 of 1965] of Example Pharmaceuticals (Pty)Ltd *(insert Company name),* confirm that:

a) I am in possession of the master documentation pertaining to the above-mentioned medicine.

b) This master documentation is the same as that which was in existence when the medicine was initially registered or which has been updated in accordance with amendments of the medicine registration form (MRF1/CTD) in accordance with the provisions of the regulations under the Medicines and Related Substances Control Act, 1965 (Act 101of 1965).

c) The master documentation conforms with the Registration dossier;

d) The master documentation is properly authorised i.e. signed and dated by at least the responsible pharmacist, *and* the quality assurance or production manager as applicable;

1. The master documentation has been supplied to the new manufacturer/packer or laboratory (state company and role) and that applicable control records have been compiled. I confirm further that I have signed these to indicate my approval that they contain all the requirements listed in the relevant master documents; namely

formulation and method of manufacture and packaging

in-process control procedures

specifications for raw materials

specifications for the final product

specifications for the packaging material

specifications for the label

specifications for the package insert

testing procedures for the raw materials

testing procedures for the final product

testing procedures for the packaging materials.

f) I confirm that a technical agreement and/or signed contract(s) exist(s) with all third party manufacturer(s)/packer(s)/laboratory(ies) involved in manufacturing of this product.

g) For an alternative/additional manufacturer:

~~I confirm that the manufacturing procedure (including equipment) is identical to the manufacturing procedure currently used~~ **~~or~~**

~~I confirm that the manufacturing procedure (including equipment) differs, but falls within the Type A and/or Type B amendments~~ **~~or~~**

 ~~I confirm that the manufacturing procedure (or equipment) is different from the manufacturing procedure (or equipment) currently on file outside of the Type A and Type B amendments and that~~

~~comparative data (efficacy),
stability data or protocol (as applicable), and a
validation protocol for the first three production batches,~~

~~are submitted.~~

h) I confirm that the package insert will be updated to reflect the new HCR details and will submit the amended package insert with the first update of the dossier after authorisation of this amendment. *(registration certificate transfer only)*

i) I confirm that the Registration dossier will be fully updated to the current statutory format and current scientific standards within 12 months of transfer of the certificate of registration, or approval of additional, or change of manufacturer. *(Not applicable for Type C changes*)**or**

I confirm that the Registration dossier will be fully updated to the current statutory format and current scientific standards by (stipulate date) in accordance with the programme as approved by the Inspectorate. (*Not applicable for Type C changes)*

A Responsible 23/03/2012

Signature Date