NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES

FEES PAYABLE TO THE REGISTRAR

(Regulation 47)

1. In respect of an application for registration of a Category A medicine -

(a) **in respect of a medicine compounded in its entirety in Namibia -**

(i) for a new chemical entity, including novel dosage forms or delivery systems -

(aa)	per application:	N$ 3,000-00;
(bb)	for registration:	N$ 1,000-00;

(ii) for an interchangeable multi-source medicine -

(aa)	per application:	N$ 1,000-00;
(bb)	for registration:	N$ 500-00;

(iii) for a line extension of a medicine -

(aa)	per application:	N$ 1,000-00;
(bb)	for registration:	N$ 500-00;

(iv) for a medicine not referred to in subparagraphs (i), (ii), or (iii) -

(aa) per application: N$ 1,000-00;
(bb) for registration: N$ 500-00;

(v) annually, in respect of the retention of the registration of a medicine, and this fee will be payable before or on the expiry of 12 months after the date on which the registration of the said medicine has been approved by the Council: * N$ 500-00;

(vi) in respect of an application for -
(aa) the amendment of an entry in the register (whether approved or not): N$ 500-00;
(bb) the transfer of a certificate of registration (whether approved or not): N$ 250-00;

(b) **in respect of a medicine, not compounded in its entirety in Namibia** -

(i) for a new chemical entity, including novel dosage forms or delivery systems -
(aa) per application: N$ 3,500-00;
(bb) for registration: N$ 1,050-00;

(ii) for an interchangeable multi-source medicine -
(aa) per application: N$ 1,750-00;
(bb) for registration: N$ 700-00

(iii) for a line extension of a medicine -
(aa) per application: N$ 1,750-00;
(bb) for registration: N$ 700-00;

(iv) for a medicine not referred to in subparagraphs (i), (ii), or (iii) -
(aa) per application: N$ 1,750-00;

(bb) for registration: N$ 700-00;

(v) annually, in respect of the **retention** of the registration of a medicine, and this fee will be payable before or on the expiry of 12 months after the date on which the registration of the said medicine has been approved by the Council:* N$ 1,050-00;

(vi) in respect of an application for -

(aa) the amendment of an entry in the register (whether approved or not): **N$ 1,050-00;**

(bb) transfer of a certificate of registration (whether approved or not): **N$ 700-00**.

2. In respect of an application for registration of a Category C medicine -

(a) **in respect of a medicine compounded in its entirety in Namibia -**

(i) for a new chemical entity, including novel dosage forms or delivery systems -

(aa) per application: N$ 1500-00;

(bb) for registration: N$ 500-00;

(ii) for an interchangeable multi-source medicine -

(aa) per application: N$ 500-00;

(bb) for registration: N$ 250-00;

(iii) for a line extension of a medicine -

(aa) per application: N$ 500-00;

(bb) for registration: N$ 250-00;

(iv) for a medicine not referred to in subparagraphs (i), (ii), or (iii) -

(aa) per application: N$ 500-00;

(bb) for registration: N$ 250-00;

(v) annually, in respect of the retention of the registration of a medicine, and this fee will be payable before or on the expiry of 12 months after the date on which the registration of the said medicine has been approved by the Council: * N$ 250-00;

(vi) in respect of an application for -

(aa) the amendment of an entry in the register (whether approved or not): N$ 250-00;

(bb) the transfer of a certificate of registration (whether approved or not): N$ 125-00;

(b) **in respect of a medicine, not compounded in its entirety in Namibia –**

(i) for a new chemical entity, including novel dosage forms or delivery systems -

(aa) per application: N$ 2,100-00;

(bb) for registration: N$ 7,100-00;

(ii) for an interchangeable multi-source medicine -

(aa) per application: N$ 875-00;

(bb) for registration: N$ 350-00

(iii) for a line extension of a medicine -

(aa) per application: N$ 875-00;

(bb) for registration: N$ 350-00;

(iv) for a medicine not referred to in subparagraphs (i), (ii), or (iii) -

(aa) per application: N$ 875-00;

(bb) for registration: N$ 350-00;

(v) annually, in respect of the **retention** of the registration of a medicine, and this fee will be payable before or on the expiry of 12 months after the date on which the registration of the said medicine has been approved by the Council:* N$ 525-00;

(vi) in respect of an application for -

(aa) the amendment of an entry in the register (whether approved or not): N$ 525-00;

(bb) transfer of a certificate of registration (whether approved or not): N$ 350-00.

3. In respect of any licence issued in terms of section 31 of the Act: N$ 1,000-00.

4. In respect of an authorisation granted for the sale of an unregistered medicine -

(a) registered outside Namibia but not registered in Namibia N$ 4,000-00;

(b) not registered at all N$ 6,000-00;

(c) not registered at all, but forming part of a clinical trial N$ 6,000-00;

(d) registered in Namibia, but forming part of a clinical trial for purposes of other indications N$ 2,000-00;

(e) prescribed for a specific patient N$ 50-00.

5. In respect of an application for the registration of premises used for the manufacturing of medicines: N$ 1,000-00.

6.	For the performance of an inspection to determine whether a premises referred to in item 5 are suitable to be registered as such –	
(a)	in respect of the premises of a manufacturer of medicines in Namibia	N$ 400-00 per hour.
(b)	in respect of the premises of a manufacturer of medicines outside Namibia	N$ 9,000-00 per site, plus travelling and accommodation costs for two inspectors.

* Please note:

(a) The fees referred to in paragraph 1(a)(v) and (b)(v) payable during a particular calendar year must be paid on or before the last working day of March of that year, failing which the Registrar must cancel the registration of the medicines concerned as contemplated in terms of section 22(4) of the Act.

(b) For the purposes of this Annexure “line extension of a medicine” means any additional strength to the pharmaceutical form, excluding novel dosage forms or delivery systems.