# GOVERNMENT GAZETTE

## OF THE

# REPUBLIC OF NAMIBIA

N$4.00 WINDHOEK - 31 December 2015 No. 5915


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# Government Notice

**MINISTRY OF HEALTH AND SOCIAL SERVICES**

No. 316 2015

AMENDMENT OF SCHEDULES: MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

Under section 44(1) of the Medicines and Related Substances Control Act 2003 (Act No. 13 of 2003), after consultation with the Council and in consultation with the Minister responsible for Finance I -

(a) substituted Annexure XXXVIII of regulation 47 published in Government Notice 1 of 25 July 2008 as set out in the Schedule, and

(b) determined that the fees be effective from 1 April 2016.

**B. HAUFIKU**
**MINISTER OF HEALTH AND SOCIAL SERVICES** Windhoek, 11 December 2015

**SCHEDULE**

**ANNEXURE XXXVIII**

**MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003**

**FEES**
(Regulation 47)

| | | | |
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| 1. | In respect of an application for registration of a Category A medicine - | | |
| | (i) | Screening fee: | N$ 1 000-00; |
| | (ii) | Application fee: | N$ 5 000-00; |
| | (iii) | Expedited registration fee: | N$ 15 000-00; |
| | (iv) | 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: * | |
| | | (a) for a medicine entirely compounded in Namibia: | N$ 500-00; |
| | | (b) for a medicine imported into Namibia: | N$ 1050-00; |
| | (v) | For a line extension of a medicine: | N$ 2 500-00; |
| | (vi) | Any post-registration amendment submission (whether approved or not): | N$ 1 500-00; |
| | (vii) | 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 - | | |
| | (i) | Screening fee: | N$ 1 000-00; |
| | (ii) | Application fee: | N$ 2 500-00; |
| | (iii) | Expedited registration fee: | N$ 7 500-00; |
| | (iv) | 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: * | |
| | | (a) for a medicine entirely compounded in Namibia: | N$ 250-00; |
| | | (b) for a medicine imported into Namibia: | N$ 500-00; |
| | (v) | For a line extension of a medicine: | N$ 1 500-00; |

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|---|---|---|---|
| | (vi) | Any post-registration amendment submission (whether approved or not): | N$ 1 500-00; |
| | (vii) | Transfer of a certificate of registration (whether approved or not): | N$ 125-00; |
| 3. | | In respect of any licence issued in terms of section 31 of the Act: | N$ 1000-00; |
| 4. | | In respect of an authorisation granted for the use or 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 a premises used for the manufacturing of medicines: | N$ 1 000-00; |
| 6. | | For the performance of an inspection to determine whether a premises comply with current good manufacturing practices - | |
| | (a) | in respect of the premises of a manufacturer of medicines in Namibia | N$ 10 000-00 per site; |
| | (b) | in respect of the premises of a manufacturer of medicines outside Namibia | N$ 30 000-00 per site; |
| 7. | | For the performance of an expedited inspection to determine whether a premises comply with current good manufacturing practices - | |
| | (a) | in respect of the premises of a manufacturer of medicines in Namibia | N$ 20 000-00 per site; |
| | (b) | in respect of the premises of a manufacturer of medicines outside Namibia | N$ 100 000-00 per site; |

* Please note:

(a) The fees referred to in paragraph 1(iv) and 2(iv) 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.

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