



GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

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Government Notice

OFFICE OF THE PRIME MINISTER

No. 246 2000

PROMULGATION OF ACT OF PARLIAMENT

The following Act which has been passed by the Parliament and signed by the President in terms of the Namibian Constitution is hereby published in terms of Article 56 of that Constitution.

No. 19 of 2000: Medicines and Related Substances Control Amendment Act, 2000.

EXPLANATORY NOTE:

_____	Words underlined with a solid line indicate insertions in existing provisions.
[]	Words in bold type in square brackets indicate omissions from existing provisions.

ACT

To amend the Medicines and Related Substances Control Act, 1965 so as to make provision for the continued retention of the registration of medicines which were registered before the date of Namibia's independence and of which the holders of the certificates of registration thereof elect that the registration thereof in Namibia must be retained; and to provide for matters incidental thereto.

(Signed by the President on 21 September 2000)

BE IT ENACTED by the Parliament of the Republic of Namibia, as follows:-

Substitution of section 13 of Act 101 of 1965, as amended by section 11 of Act No. 65 of 1974

1. The following section is substituted for section 13 of the Medicines and Related Substances Control Act, 1965 (hereafter referred to as the principal Act):

“Medicines register

13.(1) The registrar shall keep in the prescribed form a register to be known as the medicines register, in which he or she shall -

- (a) register all medicines the registration of which has been approved by the council; and
- (b) enter all such particulars in regard to such medicines as are required by this Act to be entered therein.

(2) The council may enter into an agreement with the competent authority of the Republic of South Africa responsible for the registration of medicines and exercising control over the medicines register of that country, for the procurement of the particulars in regard to medicines and the holders of certificates of registration of such medicines that were entered into the medicines register which the Registrar of Medicines of the Republic of South Africa kept in terms of subsection (1) before and until 20 March 1990 in respect of both the Republic of South Africa and Namibia before Namibia attained its independence.

(3) Subject to the succeeding subsections of this section, the particulars procured in accordance with subsection (2) form part of the medicines register of Namibia kept by the Registrar of Medicines of Namibia in terms of subsection (1) with effect from 21 March 1990 and shall, for the purposes of this Act, be deemed to have been contained in that register as on 21 March 1990.

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(4) Within 60 days after the commencement of the Medicines and Related Substances Control Amendment Act, 2000, the council must cause a notice to be published in the Gazette and at least two newspapers, and a public notification to be given in such other manner as the council may determine, which must -

- (a) inform the public of the fact that all medicines the registration of which was approved of by the Medicines Control Council of the Republic of South Africa before 21 March 1990 and the particulars of which were contained in the medicines register kept by the Registrar of Medicines of that Republic as on 20 March 1990, are medicines registered in Namibia in terms of the laws of Namibia;
- (b) invite the holders of certificates of registration of such medicines issued by the Registrar of Medicines of the Republic of South Africa before 21 March 1990 each to inform the registrar of Namibia, in the prescribed form and manner and within the period stipulated in the notice, which may not be less than 90 days after the publication of the notice, whether such holder elects that the registration of the medicine to which any certificate of registration held by such holder relates -
 - (i) be retained on the register; or
 - (ii) be removed from the register; and
- (c) draw attention to the provisions of subsections (6), (8) and (10).

(5) The council may by subsequent notice in the *Gazette* extend the period stipulated in terms of paragraph (b) of subsection (4) in the notice referred to in that subsection by such further period as the council thinks fit.

(6) The registration of any medicine referred to in subsection (4)(a) shall be cancelled -

- (a) in the case of medicine of which the holder of the certificate of registration thereof informs the registrar of such holder's election that the registration of the medicine concerned be removed from the register, with effect from the date on which the registrar is so informed; or
- (b) in the case of medicine of which the holder of the certificate of registration thereof has failed to inform the registrar of such holder's election as contemplated in subsection (4)(b), with effect from the day immediately following the date on which the period referred to in that subsection and, if applicable, as extended under subsection (5), expires.

(7) The registrar shall give notice in the *Gazette* of the cancellation of the registration of every medicine in terms of subsection (6) and shall in such notice specify -

- (a) the name under which such medicine was registered, the name of the person who applied for the registration of such medicine and the registration number which was allocated to the medicine; and

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(b) the date with effect from which such cancellation is of force in terms of that subsection.

(8) Notwithstanding anything to the contrary in this Act contained, no person may, after the expiry of a period of one month after the date of publication of a notice in terms of subsection (7), sell any medicine specified in such notice: Provided that the council may upon application by the holder of a certificate of registration of any such medicine, and if there is good cause for doing so, grant an extension of that period for such further period, not exceeding three months, as the council may determine.

(9) Upon receipt of a notification from the holder of a certificate of registration of any medicine in accordance with subsection (4)(b) informing the registrar of the holder's election that the registration of the medicine concerned be retained, the registrar shall issue to such holder a written confirmation that the registration of that medicine is retained with effect from the date on which the notification is received by the registrar, which date must be stipulated in such written confirmation.

(10) The liability under this Act for the payment of the prescribed annual fee in respect of the retention of the registration of any medicine contemplated in subsection (4)(a) shall be deemed to have been suspended during the period from 21 March 1990 until the date on which the period notified in the notice contemplated in subsection (4)(b) and, if applicable, as extended under subsection (5), expires: Provided that with regard to any medicine of which the holder of the certificate of registration, in accordance with subsection (4)(b), elects that the registration thereof must be retained, such liability revives with effect from the date on which the notification of that election is received by the registrar as if a certificate of registration in respect of the medicine had been issued on that date."

Amendment of section 16 of Act No. 101 of 1965, as amended by section 3 of Act No. 29 of 1968 and section 14 of Act No 65 of 1974

2. Section 16 of the principal Act is amended by the substitution for subsection (4) of the following subsection:

"(4) Subject to section 13(10), if the person by whom or on whose behalf application for the registration of a medicine was made fails to pay the prescribed annual fee in respect of the retention of the registration of that medicine before or on the prescribed date or such later date as the registrar may with the approval of the council determine on application by that person, the registrar shall cancel the registration of that medicine."

Amendment of section 29 of Act 101 of 1965, as amended by section 27 of Act No. 65 of 1974

3. Section 29 of the principal Act is amended by the substitution for paragraph (b) of the following paragraph:

"(b) contravenes or fails to comply with the provisions of subsection (8) of section 13, subsection (1) of section 19 or section 18; or"

Short title and commencement

4. This Act shall be called the Medicines and Related Substances Control Amendment Act, 2000 and shall come into operation on a date determined by the Minister of Health and Social Services by notice in the *Gazette*.