



Government Gazette Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Regulation Gazette

No. 7282

Regulasiekoerant

Vol. 440

Pretoria, 22 February 2002
Februarie

No. 23128



AIDS HELPLINE: 0800-0123-22 Prevention is the cure

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GOVERNMENT NOTICE GOEWERMENTSKENNISGEWING

DEPARTMENT OF HEALTH DEPARTEMENT VAN GESONDHEID

No. R. 204

22 February 2002

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965 (ACT 101 OF 1965)

CALL UP NOTICE FOR MEDICINES FREQUENTLY REFERRED TO AS COMPLEMENTARY MEDICINES IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965 (ACT 101 OF 1965)

(a) Preamble

The Medicines Control Council (MCC) has noted that there are increasing numbers of medicines frequently called complementary medicines being sold in South Africa for which claims of safety, quality and efficacy are being made without the approval of the MCC. The Complementary Medicines Working Group of the MCC, after consultation with stakeholders, recommended to Council that a call up of the following categories of medicinal products be undertaken, for purposes of which certain specified exemptions in the application for registration of a medicine (MBR1) form will be allowed.

The categories of the medicines frequently referred to as complementary medicines should include:

1. Anthroposophical medicines
2. Aromatherapeutic medicines
3. Ayurvedic medicines
4. Chinese traditional medicines
5. Energy substances
6. Homeopathic medicines
7. Nutritional substances that purport to have therapeutic or medicinal effects
8. Western herbal medicines
9. Unani-Tibb medicines
10. Combination Homoeopathic / Flower Essence
11. Combination Complementary Medicines

The submission of an application in response to this call up would not constitute product registration but should be considered a primary step in the registration process.

The data compiled from this call up will enable Council to compile an audit of all products currently available in the market place. Council will review the claims of safety, quality and efficacy for all identified products and will determine whether any such claims constitute a public health hazard and act accordingly.

For all products, Council will at a later stage determine which additional Annexures of the MBR1 form will be required for registration purposes.

Any person who contravenes this call up notice shall be subjected to the provisions of Section 14 read with Section 29 (b) and (h) and Section 30 of Act 101, 1965.

Council also noted that similar unsubstantiated claims of safety, quality and efficacy are being made with respect to African traditional medicines that are widely available in the market place. The MCC's African Traditional Medicines Working Group will be asked to consider whether a similar approach to a call up for the purposes of preparing an audit of these products could be gainfully undertaken at this time.

(b) The Medicines Control Council established in terms of Section 2 of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965) by virtue of the powers vested in it by section 14 (2) of the Act has by resolution approved by the Minister of Health, determined that, with effect from the date of publication of this notice –

all preparations or mixtures of substances that fall under the definition of a medicine, including all dilutions, mixtures or derivations of any substances that are *anthroposophical medicines, aromatherapeutic medicines, ayurvedic medicines, Chinese traditional medicines, energy substances, homeopathic medicines, nutritional substances that purport to have therapeutic or medicinal effects, western herbal medicines, Unani -Tibb medicines, combination homoeopathic / flower essences, and combination complementary medicines,*

shall be subject to a call-up process instituted as a primary step towards registration of such as medicines and shall be submitted to the MCC within six (6) months of the date of publication this notice.

It is further notified that, under section 14 (2)(b) of Act 101 of 1965, the above-mentioned resolution shall relate to medicines available for sale or distribution in the Republic on the date on which it comes into operation and shall relate also to medicines that become available after the said date.

Council resolved that -

the medicines called up for registration in terms of the call-up notice number dated issued in terms of Section 14 (2) of the Medicines and Related Substance Control Act, 1965 (Act 101 of 1965) shall by unanimous decision of Council and approved by the Minister of Health be exempted from complying with the provisions of application as contained in the application for registration of a medicine (MBR1) form

Annexures of the MBR1 form that are required;

Front page (cover sheet),

Annexure 1, (all information except 1, 5 and 12),

Annexure 2 (except the chemical name *if not available*)

Annexure 12

This call up shall not be applicable to medicines for which registration application has already been made under the listed call up notices and for which a reference number has already been issued to the applicant by the MCC.

<u>General Notice</u>	<u>Gazette</u>	<u>Date</u>	<u>Subject</u>
424	3815	23/03/1973	Old – Herbal drugs 34
2186	4512	22/11/1974	Old and New – 25special foods for which medicinal claims are made
1029	6029	26/05/1978	Old and New – any medicine which purports to be a medicine by using the terms ...medicated, medicinal, for medical use or similar connotation
559	9620	15/03/1985	Old and New – oral preparations containing vitamins, alone or in combination with other pharmacologically active ingredients, including minerals, whether medicinal claims are made or not...

It is hereby further notified that this call up notice supersedes all previous call up notices for preparations of this nature.

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Printed by and obtainable from the Government Printer, Bosman Street, Private Bag X85, Pretoria, 0001

Publications: Tel: (012) 334-4508, 334-4509, 334-4510

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Cape Town Branch: Tel: (021) 465-7531

Gedruk deur en verkrygbaar by die Staatsdrukker, Bosmanstraat, Privaatsak X85, Pretoria, 0001

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