



Government Gazette Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Vol. 442

Pretoria, 18 April 2002

No. 23343



9771682584003



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

CONTENTS • INHOUD

No.

Page
No. Gazette
 No.**GOVERNMENT NOTICE****Health, Department of***Government Notice*

- 489 Medicines and Related Substances Control Act (101/1965): Amendment to the Notice No. 192 published in *Government Gazette* No. 23125 dated 22 February 2002 and provision for phasing out period — Cancellation of registration of medicines containing phenolphthalein

3 23343

GOVERNMENT NOTICE

DEPARTMENT OF HEALTH**No. 489****18 April 2002****AMENDMENT TO THE NOTICE NO. 192 PUBLISHED IN GOVERNMENT GAZETTE NO 23125 DATED 22 FEBRUARY 2002 AND PROVISION FOR PHASING OUT PERIOD – CANCELLATION OF REGISTRATION OF MEDICINES CONTAINING PHENOLPHTHALEIN**

1. The Medicines Control Council, established in terms of Section 2 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), directed the Executive Committee at its meeting of the 15th March 2002 to consider the Government Notice No. 192 published in the Government Gazette No. 23125 dated 22nd February 2002 and the resolution taken by Council on the 16th November 2001 relating to the matter of phenolphthalein.
2. At its Executive Committee meeting held on the 17th April 2002, it was resolved that the Notice No. 192 published in Government Gazette No. 23125 dated 22 February 2002 be amended to read as follows:
 - 2.1. that the registration of medicines containing phenolphthalein be considered for cancellation in terms of Section 16. (1)(c) of the Act on the grounds that
 - (i) there is sufficient evidence that carcinogenicity exists;
 - (ii) skin toxicity is of concern; and that
 - (iii) safer agents are available.
 - 2.2. that all persons affected by such resolution may, within one month from publication hereof, submit to the Registrar of Medicines any comment he or she may wish to put forth in connection with the matter;
 - 2.3. that a six months phase out period, in the event of cancellation, will be allowed.
3. This notice replaces Government Notice No. 192 published in the Government Gazette No. 23125 dated 22 February 2002.

Registrar of Medicines

Printed by and obtainable from the Government Printer, Bosman Street, Private Bag X85, Pretoria, 0001
Publications: Tel: (012) 334-4508, 334-4509, 334-4510
Advertisements: Tel: (012) 334-4673, 334-4674, 334-4504
Subscriptions: Tel: (012) 334-4735, 334-4736, 334-4737
Cape Town Branch: Tel: (021) 465-7531

Gedruk deur en verkrygbaar by die Staatsdrukker, Bosmanstraat, Privaatsak X85, Pretoria, 0001
Publikasies: Tel: (012) 334-4508, 334-4509, 334-4510
Advertensies: Tel: (012) 334-4673, 334-4674, 334-4504
Subskripsies: Tel: (012) 334-4735, 334-4736, 334-4737
Kaapstad-tak: Tel: (021) 465-7531