



# Government Gazette Staatskoerant

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Pretoria, 18 April 2002

No. 23343



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

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**GOVERNMENT NOTICE**

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**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 15<sup>th</sup> March 2002 to consider the Government Notice No. 192 published in the Government Gazette No. 23125 dated 22<sup>nd</sup> February 2002 and the resolution taken by Council on the 16<sup>th</sup> November 2001 relating to the matter of phenolphthalein.
2. At its Executive Committee meeting held on the 17<sup>th</sup> 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**

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