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## GOVERNMENT NOTICES GOEWERMENTSKENNISGEWINGS

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### DEPARTMENT OF HEALTH DEPARTEMENT VAN GESONDHEID

No. 192

22 February 2002

#### BAN ON PHENOLPHTHALEIN AND PRODUCTS 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), has considered the matter of **Phenolphthalein** and concluded that—
  - 1.1 there is sufficient evidence that carcinogenicity exists;
  - 1.2 skin toxicity is of concern; and that
  - 1.3 safer agents are available.
2. Council therefore resolved that **Phenolphthalein** and all products containing Phenolphthalein be banned on grounds that they present a health risk.
3. All applicants having products affected by the above are advised to cease manufacturing or distribution of these products and withdraw such products from the market with immediate effect.
4. All medicines containing **Phenolphthalein** are hereby deregistered and all applications for registration of such medicines are effectively withdrawn, including those of medicines referred to in section 14 (3) of the Medicines and Related Substances Control Act of 1965 (Act 101 of 1965).
5. Applicants involved must submit a written report to Council detailing all steps taken to effect the terms of this resolution. Such report must reach the Registrar's office together with the original registration certificates, where applicable, not later than thirty (30) days after the date of publication of this notice.

**Registrar of Medicines**Date: 21/01/2002

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