

---

## GOVERNMENT NOTICES GOEWERMENSKENNISGEWINGS

---

### DEPARTMENT OF HEALTH DEPARTEMENT VAN GESONDHEID

No. 779

4 August 2006

#### CANCELLATION OF REGISTERED MEDICINES AND WITHDRAWAL OF APPLICATIONS FOR REGISTRATION OF MEDICINES CONTAINING PHENOLPHTHALEIN AND ITS VARIATIONS

1. The Medicines Control Council, established in terms of section 2 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), considered the safety of medicines containing phenolphthalein and their availability to the public in terms of section 1 (3) read with section 16 (1) (c) of the Act, at its meeting held on 7 July 2006, and resolved that -
  - 1.1 there is sufficient evidence that carcinogenicity could develop from use of medicines containing phenolphthalein;
  - 1.2 Council is concerned about the potential risk of skin toxicity to individuals exposed to medicines containing phenolphthalein; and that
  - 1.3 safer agents are available for the same or similar purposes.
  
2. On the grounds that these medicines present a health risk and are not in the public interest, Council therefore resolved that -
  - 2.1 The registration of all medicines containing phenolphthalein is hereby cancelled in terms of section 16 (1) (c) of the Act, with immediate effect;
  - 2.2 All applications for the registration of medicines containing phenolphthalein are hereby rejected in terms of section 15 (3) (c) of the Act, with immediate effect;
  - 2.3 All applicants and holders of certificates of registration for medicines affected are hereby notified to cease manufacturing, importation and distribution of these medicines and to withdraw such products from the market within a period of six months from the date of this notice; and that
  - 2.4 This notice is applicable to any medicine containing phenolphthalein, whether or not it is registered; whether or not application for registration thereof has been submitted.

**REGISTRAR OF MEDICINES****DATE: 26 JULY 2006**