



Biro Pengawalan Farmaseutikal Kebangsaan  
National Pharmaceutical Control Bureau  
KEMENTERIAN KESIHATAN MALAYSIA  
MINISTRY OF HEALTH MALAYSIA

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Y. Bhg Dato'/Datin/Tuan/Puan,

**AMARAN DARI U.S. FOOD & DRUG ADMINISTRATION (USFDA) BERKAITAN  
PENGUNAAN UBAT UNTUK RAWATAN 'COUGH AND COLD' PADA KANAK-  
KANAK.**

Adalah saya merujuk kepada perkara di atas.

2. Maklumat yang diterima dari USFDA dan Health Canada baru-baru ini telah mengesyorkan penggunaan produk 'cough and cold' yang boleh didispens tanpa preskripsi adalah tidak boleh digunakan untuk merawat kanak-kanak yang berusia dibawah dua (2) tahun (products should not be used in children under 2 years of age). Ini adalah disebabkan kemungkinan berlakunya kesan adwers yang serius dan berpotensi untuk

menyebabkan kematian. Ubat yang dimaksudkan ini merangkumi 'anti-histamines, anti-tussives and decongestants' yang digunakan untuk rawatan tersebut.

3. Menurut agensi-agensi ini penggunaan produk 'cough and cold' juga didapati tidak berkesan untuk rawatan kanak-kanak yang berusia dibawah enam (6) tahun. Walau bagaimanapun, mereka masih lagi mengkaji penggunaan produk ini bagi kanak-kanak yang berusia dari 2-11 tahun yang mana mungkin boleh memberi risiko yang sama.
4. Di negara kita, produk tersebut dikategorikan sebagai Racun C dimana ianya hanya boleh didispens oleh pengamal perubatan profesional dan juga ahli farmasi. Ubat-ubat ini tidak boleh dijual dipasaran terbuka. Setakat ini hanya produk yang mengandungi promethazine sahaja yang mempunyai amaran berkaitan dengan tidak membenarkan penggunaannya pada kanak-kanak yang berusia di bawah dua (2) tahun.
5. Berikutan dari amaran tersebut, Pihak Berkuasa Kawalan Dadah (PBKD) ingin memaklumkan kepada semua pengamal perubatan mengenai risiko ini dan mengesyorkan agar pendispensan produk 'cough and cold' dipertimbangkan dari segi risiko dan faedahnya terutama sekali kepada kanak-kanak berusia dibawah dua (2) tahun. Sebaik sahaja penilaian terhadap penggunaan produk ini selesai, PBKD akan memutuskan amaran serta pindaan yang perlu dinyatakan pada label dan sisip bungkusan produk yang berkaitan bagi memastikan penggunaannya adalah selamat.
6. Bersama ini dikemukakan beberapa perkara penting yang perlu diberi perhatian oleh semua pengamal perubatan dan ahli farmasi sebelum mendispens produk untuk rawatan 'cough and cold'. Adalah diharapkan maklumat ini dapat dipanjangkan kepada mereka yang berkenaan.

Sekian, terima kasih.

**"BERKHIDMAT UNTUK NEGARA"**

Saya yang menurut perintah,



**(SELVARAJA SEERANGAM)**  
Pengarah Regulatori Farmasi  
Biro Pengawalan Farmaseutikal Kebangsaan  
Kementerian Kesihatan Malaysia

## Appropriate Use of Cough and Cold Products

Health Canada and the U.S. Food and Drug Administration (USFDA) have raised concerns over the safety of cough and cold medicines (which are sold over-the-counter in these countries), especially in children below 2 years of age, and whether the benefits justify any potential risks from the use of such products.

In August 2007, US federal health advisors also recommended to the USFDA that such medicines do not work and should not be used by children aged below 6. Such cough and cold products typically contain one or more of the following ingredients: decongestants, antihistamines and anti-tussives. Although cough and cold medicines may also contain expectorants, current concerns do not apply to this ingredient.

Recently, the USFDA issued a Public Health Advisory for parents and caregivers, recommending that Over-the-Counter (OTC) cough and cold products should not be used to treat infant and children less than 2 years of age because serious and potentially life threatening side effects can occur from such use. The adverse events reported with these products include death, convulsions, rapid heart rates and decreased levels of consciousness. However, USFDA are still evaluating the safety of these products in older children.

Both regulatory authorities are in the midst of determining if the labeling of these cough and cold products is sufficient to ensure that parents, caregivers and prescribers have enough information to make an informed decision regarding the safe use of these products.

In Malaysia, cough and cold products such as decongestants, antihistamines, and anti-tussives are classified as Group C Poison.

In May 2006, the Drug Control Authority (DCA) instructed that all products containing *promethazine* should not be used in children less than 2 years old due to reports of serious adverse events in this group of children and a warning statement to that effect was included for all such products. The DCA is currently undertaking a review of scientific data and evidence on the use of cough and cold products in children and is also monitoring the regulatory moves of other agencies on this matter.

The DCA recommends all healthcare professionals to use cough and cold products containing decongestants, antihistamines and anti-tussives as a single ingredient or in combination when benefits have been assessed to outweigh the risks. The following recommendations need to be considered when prescribing or dispensing these products to patients:

### Children under 2 years of age:

- Not recommended in children less than 2 years of age because of serious and potentially life threatening side effects.

### Children of all ages:

- If it is necessary to give a cough and cold product to a child, make sure all labels and instructions are read before doing so. If the product does not contain dosing information for children then it should not be used in children.
- Do not give a child a larger dose or more frequently than it is recommended in the labeling and instructions.
- Take note of the medicinal ingredients in the product especially if more than one product may be given to a child. Be aware that many products contain the same medicinal ingredient(s) and combined use could lead to overdose. Some herbs used in cough and cold products and some over-the-counter products used to control fever may also have medicinal ingredients similar to those in other cough and cold products.
- It is advised not to give more than one cough and cold product to a child as cough and cold products often contain multiple ingredients.
- There is no cure for the common cold. Children will usually recover from coughs and colds in time on their own. The common cold is a mild, viral infection that can be managed by rest, sufficient fluid intake and comfort measures.
- In young children and babies, it is sometimes important to rule out serious illnesses (for e.g. pneumonia or other infections) which may present with cold-like symptoms; this is especially important if symptoms persist or if the child's condition deteriorates.

### References:

1. Health Canada website, "Recommendations for the Appropriate Use of Cough and Cold Products in Children", [http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2007/2007\\_147\\_e.html](http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2007/2007_147_e.html), 11 October 2007.
2. FDA website, "Public Health Advisory: Nonprescription Cough and Cold Medicine Use in Children", [http://www.fda.gov/cder/drug/advisory/cough\\_cold.htm](http://www.fda.gov/cder/drug/advisory/cough_cold.htm), 15 August 2007.
3. FDA Public Health Advisory (January 17, 2008) [www.fda.gov/cder/drug/advisory/cough\\_cold\\_2008.htm](http://www.fda.gov/cder/drug/advisory/cough_cold_2008.htm)