DR. STEPHEN K. OPUNI

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Dear Healthcare Professional,

## OVER-THE-COUNTER COLD AND COUGH PREPARATIONS IN CHILDREN: FOLLOW-UP TO AN EARLIER COMMUNICATION

The Food and Drugs Board (FDB) would like to notify you about the outcome of the review of the use of over-the-counter (OTC) cold and cough preparations in children. Based on consultations with Ghana Paediatric Society and other key stakeholders on the benefit/ risk assessment of the use of these products in children and upon recommendation of the Technical Advisory Committee on Safety Monitoring, the FDB has recommended the following regarding the use of cold and cough preparations in children;

- 1. Over-the-Counter cold and cough preparations should <u>not</u> be used in children less than five (5) years. However, simple cough mixtures containing a demulcent, for example glycerin can be used.
- 2. For children older than five years, care should be taken not to give more than one cold/cough preparation at the same time since most of these preparations contain similar active ingredients.
- 3. When cold and cough preparations are given to children more than 5 years, the <u>direction and duration for use</u> should be clearly stated.
- 4. If cold and cough symptoms in children persists or worsen, a physician should be consulted.

OTC cold and cough preparations containing the following active ingredients are affected by this directive:

Antitusives: Dextromethorphan, Codeine and Pholcodine

**Expectorants:** Guaifenesin, Ipecacuanha and Bromhexine

Nasal decongestants: Ephedrine, Pseudoephedrine and Phenylephrine

**Antihistamines:** Chlorphenamine, Diphenhydramine, Promethazine, Triprolidine, Pheniramine, Phenylpropanolamine and Phenyltoloxamine

The FDB is working with manufacturers and importers of OTC cold and cough preparations to ensure that the above recommendations are implemented and the label and package inserts of products containing the affected list of ingredients stated above are amended to reflect the new recommendations.

Further enquiries, complaints and reports of adverse reactions to OTC cold and cough preparations or any other medicinal product, should be forwarded to the Food and Drugs Board through the following contacts.

Postal address:	The Chief Executive
	Food and Drugs Board
	P. O. Box CT2783
	Cantonments
	Accra

Telephone:	021 235100 / 021 233200 / 0244 310297
Fax:	021 229794
E-mail:	drugsafety@fdbghana.gov.gh

Yours faithfully,

DR. STEPHEN K. OPUNI CHIEF EXECUTIVE