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Relevant National Measure Ghana, Breastfeeding Promotion Regulations, 2000

Highlights

The Regulations in Ghana were made pursuant to the Ghana Food and Drugs Law, 1992 and came into effect on 9 May 2000.

The scope of the Regulations is defined by the term *designated products*, thus avoiding the ambiguity of the term *breastmilk substitutes*. *Designated product* is defined to include "infant formula, any other product marketed or represented as suitable for feeding infants up to six months of age, follow-up formula, feeding bottles, teats and pacifiers", and gives the Minister of Health the power to designate other products.

The Regulations prohibit the sale of designated products in any health care facility. Prior to the adoption of the Regulations, feeding bottles and infant foods had been common items sold in hospital shops and clinics. Advertising and other types of promotion of designated products are not permitted in any health care facility or in any public place.

Manufacturers and distributors of products within the scope of the Regulations may not produce or distribute educational materials related to the feeding of infants or young children unless the material is first approved by the Food and Drugs Board. Ghana has closed a loophole in the International Code by prohibiting any reference in such materials not only to designated products, but also to the name or logo of a manufacturer or distributor (except in indicating a copyright). Manufacturers and distributors may, however, provide product information for health personnel if the information is "restricted to scientific and factual matters that relate to the technical aspects and method for the use of the product".

No person is permitted to distribute free supplies or samples of any designated product to health personnel or health care facilities. The Regulations also forbid manufacturers and distributors of designated products from providing fellowships or other kinds of financial assistance to health personnel or to sponsor their attendance at a conference or related professional meeting.

The labelling provisions of the Regulations, unlike those of the International Code, apply to all designated products. Moreover, the Regulations prohibit any photograph, drawing or graphic on labels except for illustrating preparation instructions. The Regulations also improve on the International Code by providing detailed requirements for the labels of feeding bottles and teats.

The Ghana National Breastfeeding Promotion Regulation Committee has been set up in Ghana and is charged with coordinating investigations concerning allegations of violations of the Regulations, submitting its findings to the Ministry of Health and following-up on actions taken pursuant to those allegations.

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Breastfeeding Promotion Regulations, 2000

In exercise of the powers conferred on the Minister responsible for Health by section 47 of the Food and Drugs Law, 1992 (P.N.D.C.L.305B), and after consultation with the Food and Drugs Board these regulations are made this 19th day of January, 2000.

Prohibition of sale and promotion of designated products

- 1. (1) No person shall
 - (a) sell, advertise, promote or assist in the sale, advertisement or promotion of a designated product in any health care facility; or
 - (b) undertake or participate in any promotional practice in respect of a designated product in any public place.
 - (2) For the purpose of paragraph (b) of subregulation (1) promotional practice includes
 - (a) sale devices such as rebates, special display to promote sales, tie-in sales, grant of rewards, discount coupons, prizes and gifts;
 - (b) the distribution without charge of one or more samples of a designated product to any person;
 - (c) direct or indirect contact between marketing personnel of a designated product and members of the public in furtherance of or for the purpose of promoting the business of the marketing personnel; and
 - (d) the distribution of any information or educational material on feeding of infants and young children except in accordance with regulations 7 and 8 of these Regulations.
 - (3) The Minister may, by legislative instrument, specify a product as a designated product for purposes of these regulations.

Exhibition of manufacture and expiry dates

- 2. (1) No person shall sell, distribute for sale, exhibit for sale or stock for sale any designated product
 - (a) which does not have the dates of manufacture and expiry on the label; and
 - (b) which is not in its original container
 - (2) No person shall sell, distribute for sale or exhibit for sale any designated product the expiry date for which has expired.

Distribution of free and low cost designated products

- 3. (1) No person shall distribute free or at low cost, supplies or samples of any designated product to
 - (a) a health personnel;
 - (b) a health care facility; or
 - (c) a person known to that other person as an employee of a health care facility on the premises of the facility.
 - (2) No health personnel shall accept or give to any other person a sample of a designated product.
 - (3) No person shall without the prior written approval of the Minister, carry out professional evaluation, research or activities of any other description at a health care facility in respect of a designated product.

Prohibition of display of printed material or designated products in a health care facility

4. No person shall display or permit to be displayed in a health care facility or in any public place printed material that bears the name, logo or trademark of any other description of a designated product.

Prohibition of donation of equipment and material

- (1) No manufacturer of distributor of a designated product shall directly or indirectly donate any equipment or material to a health care facility unless it is with the prior approval in writing of the Minister given after consultation with the Board.
 - (2) No person shall donate or distribute within a health care facility equipment or material that bears the name, logo, graphic, trademark or any other description of a designated product.

Provision of fellowship and sponsorship prohibited

- 6. (1) No manufacturer or distributor of a designated product shall directly or indirectly
 - (a) provide a fellowship, research grant or any other financial assistance to a health personnel; or
 - (b) sponsor the attendance of a health personnel at a conference, seminar or any health related professional meeting
 - without the approval of the Minister given after consultation with the Board.
 - (2) No manufacturer or distributor of a designated product shall for the purpose of promoting his business, directly or indirectly offer a gift in cash or in kind to a health personnel of a health care facility.
 - (3) No health personnel shall accept a gift in cash or in kind from a manufacturer or distributor of a designated product for the purpose of promoting the use of the designated product.

Distribution of information and other material

- 7. (1) Subject to the other provisions of this regulation and regulation 8, no person shall directly or indirectly produce educational material, any other material or distribute information that relates to feeding of infants or young children.
 - (2) Subregulation (1) does not apply where a manufacturer or distributor provides information about a designated product to a health personnel where the information is restricted to scientific and factual matters that relate to the technical aspects and methods for the use of the designated product.
 - (3) Any manufacturer or distributor who produces any educational material or who intends to distribute any information referred to in subregulation 7(1) shall submit copies of the material or information to the Board in such form and at such time as the Board may direct.
 - (4) The Minister may in writing authorise a person specified in the authorisation to produce educational material, any material or information relating to feeding of infants and young persons.

Information and educational material

8. Any information, educational material or other material whether written, audio or visual on infant feeding made available in the country by any person shall

- (a) clearly explain
 - (i) the benefits and superiority of breastfeeding;
 - (ii) how to initiate and maintain breastfeeding including maternal nutrition;
 - (iii) a recommended duration of six months exclusive breastfeeding from birth and sustained breastfeeding after the six month period until the child is two years or more;
 - (iv) how and why the introduction of bottle feeding or early introduction of complementary foods interferes with breastfeeding;
 - (v) why it is difficult to return to breastfeeding after a period of bottle feeding even if limited to a few bottles per day;
- (b) contain correct and current information and shall not use any pictures or texts that encourage bottle feeding or discourage breastfeeding:
- (c) be written in English; and
- (d) not make any reference to any designated product or contain the name or logo of any manufacturer or distributor of a designated product except by way of indicating a copyright.

Explanatory material

- 9. (1) Where material or information referred to in regulation 7(2) and (4) includes the subject of feeding infants with breastmilk substitutes through feeding bottle the material or information shall clearly and conspicuously state
 - (a) the proper preparation and use of the product;
 - (b) the approximate financial cost of feeding an infant with the product for a period of six months;
 - (c) the health hazards of bottle feeding and improper preparation of the product; and
 - (d) how to feed infants with a cup.
 - (2) Where the material referred to in regulation 7(2) and (4) includes the subject of feeding infants with complementary food the material shall explain
 - (a) the health hazards of introducing food complement before the infant is six months old;
 - (b) that food complement can easily be prepared at home using local ingredients; and
 - (c) the benefit and value of sustaining breastfeeding after the child is six months until the child is two years or more.

Labelling of designated products

- 10. (1) A manufacturer or distributor shall not offer for sale or sell a designated product if the container or label affixed to it does not
 - (a) have a clear, conspicuous and easily readable message that breastmilk is the best food for infants and prevents diarrhoea and other illnesses;
 - (b) provide instructions for the proper preparation and use of the designated product;
 - (c) include a warning preceded by the words "Important notice" against the health hazards of improper preparation and use of the designated product; and
 - (d) indicate the health hazards of introducing the product prior to the recommended age.

- (2) A manufacturer or distributor shall not offer for sale or sell a designated product if the container or label affixed to the container includes as a means of expression the terms "maternalised" or similar expression.
- (3) In addition to any other requirement in respect of designated products provided in these Regulations the label of a designated product shall
 - (a) not show any photograph, drawing or other graphic representation other than for illustrating the method for preparation of the designated product;
 - (b) be written in English;
 - (c) contain
 - (i) the name and address of the manufacturer and where applicable the distributor;
 - (ii) the dates of manufacture and expiry;
 - (iii) the composition and contents of the product;
 - (iv) the batch number;
 - (v) the required storage conditions for the product; and
 - (d) indicate the quantity of the food in the containers necessary to feed an infant during the first six months of its life.
- (4) Where a designated product does not satisfy all the nutritional requirements of an infant but can be modified to do so, its label shall include a warning that the unmodified product should not be the sole source of the infant's nourishment and that the designated product should not be used to feed an infant except under the guidance of health personnel.
- (5) Where modification is required under subregulation (4) the manufacturer shall indicate how the modification should be made on the label.

Labels on feeding bottles and teats

- 11. (1) A label on a feeding bottle or package or container of a feeding bottle or teat shall include
 - (a) a statement on the superiority of breastmilk for feeding infants;
 - (b) a statement that feeding with a cup is safer that bottle feeding;
 - (c) instructions for proper cleaning and sterilization of feeding bottles and teats;
 - (d) a warning on the potential health hazards of using a feeding bottle especially if it is not properly sterilized;
 - (e) a warning on the negative impact of bottle feeding and the need to follow preparation instructions carefully to ensure that an infant does not fall ill; and
 - (f) the name and address of the manufacturer or distributor of the product or the local agent.
 - (2) The label on a pacifier shall have a notice that use of a pacifier can interfere with breastfeeding.

Labels on condensed milk

12. A label on a container of condensed milk shall have a clear and conspicuous warning that it shall not be used for infant feeding.

Authorised officer

13. Pursuant to section 36(1) of the Food and Drugs Law, 1992 (P.N.D.C.L.305B), a person appointed and designated as an authorised officer of the Board shall carry out such functions as may be necessary to give full effect to the provisions of these Regulations.

Health personnel to support breastfeeding

14. Health personnel in any health facility shall support, protect and encourage breastfeeding.

Offences and penalties

- 15. Any person who
 - (a) advertises, sells or promotes any designated product contrary to regulation 1;
 - (b) distributes, exhibits or stocks for sale any designated product which does not indicate the manufacture and expiry dates or that the expiry date has passed contrary to regulation 2;
 - (c) distributes free of charge or offers for sale any designated product contrary to regulation 3;
 - (d) displays or permits to be displayed printed material contrary to regulation 4;
 - (e) donates equipment or material contrary to regulation 5;
 - (f) provides a fellowship or sponsorship or gives any gift contrary to regulation 6;
 - (g) distributes information on infant feeding that contravenes regulation 7 or 8;
 - (h) labels a designated product, a container, or a condensed milk product contrary to regulation 10, 11 or 12; or
 - (i) fails to indicate a modification required under regulation 10(5);
 - (j) contravenes any other provision of these Regulations, commits an offence and is liable on summary conviction to a fine not exceeding five million cedis or to imprisonment for a term not exceeding twelve months or to both.

Interpretation

16. In these Regulations unless the context otherwise requires

"advertise" includes to make any representation by any means for promoting directly or indirectly the sale or disposal of a designated product and is not limited to

- (a) a written publication;
- (b) television, radio, film, video or telephone;
- (c) a display of signs, hoarding, notices or goods; or
- (d) an exhibition of pictures or models;

"authorised officer" has the same meaning as provided in the Law;

"Board" means the Food and Drugs Board established under section 27 of the Food and Drugs Law, 1992 (P.N.D.C.L.305B);

"breastmilk substitutes" means any food that is marketed or otherwise represented as a partial or total replacement for breastmilk whether suitable for that purpose or not;

"complementary food" or "food complement" means any food substitute or alternative to breastmilk suitable as a complement to breastmilk or to infant formula, when either becomes insufficient to satisfy the nutritional requirements of the infant;

"container" means any form of packaging products for sale including wrappers;

"designated product" includes infant formula, any other product marketed or otherwise represented as suitable for feeding infants up to six months of age, follow-up formula, feeding bottles, teats and pacifiers and a product so designated by the Minister;

"distributor" includes means a person engaged in the business, whether wholesale or retail of marketing any designated product and includes any person engaged in the

business of providing information or public relations services in relation to any designated product;

"follow-up formula" means an animal or vegetable based product intended for infants older than six months and young children and formulated industrially in accordance with the standards of the Ghana Standards Board or in the absence of such standards in accordance with the International Codex Alimentarius Standards;

"health care facility" includes a public or private health care institution, organisation or practice engaged directly or indirectly in the provision of health care or health care education, and day-care centres, nurseries or other infant-care facilities;

"health personnel" includes a person working in a health care facility whether professional or non professional including a person providing voluntary service;

"infant" means a child from birth up to the age of twelve months;

"infant formula" means an animal or vegetable based product formulated industrially in accordance with the standards of Ghana Standards Board or in the absence of such standards in accordance with the International Codex Alimentarius Standards to satisfy some or all of the nutritional requirements of infants up to the age of six months and adapted to their physiological characteristics for use as food or drink;

"label" includes any tag, brand mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, impressed or attached to a container of a designated product;

"Law" means the Food and Drugs Law, 1992 (P.N.D.C.L305B);

"manufacturer" means a person engaged in the business of manufacturing a designated product whether directly or through an agent;

"marketing personnel" means a person who promotes the sale of a designated product;

"maternalised" means infant formula processed in a manner that makes it similar to breastmilk;

"Minister" means the Minister responsible for Health;

"pacifier" means a rubber teat not attached to a bottle;

"promote" means any direct or indirect method of introducing or encouraging any person to purchase a designated product;

"public place" means a place to which, the public have or are permitted to have access whether on payment or otherwise;

"sample" means a single or small quantity of a designated product provided without cost;

"sell" has the same meaning as provided in the Law;

"tie-in-sales" means the sale of any designated product that is linked to the purchase of any other product including a designated product.

ALHAJI MAHAMA IDDRISU Ag. Minister responsible for Health

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