



**REPUBLIC OF ALBANIA
MINISTRY OF HEALTH**

Protocol No. 2024/1

Tirana 13.04.2017

ORDER

No. 179, Dated 13.04.2017

**ON DEFINING THE MAIN CONTENT ELEMENTS OF THE
INFORMATIONAL AND EDUCATIONAL MATERIALS ON INFANT AND
YOUNG CHILD FEEDING**

Pursuant to Article 100 of the Constitution of the Republic of Albania and Article 11 of Law No. 8528, dated 23.09.1999 “On protecting and promoting breastfeeding” amended, Article 48, paragraph 6 of Law No. 10433, dated 16.06.2011 “On inspection in the Republic of Albania” and Law No. 10109, dated 30.03.2009 “On health care in the Republic of Albania”, amended

I ORDER:

1. Approval of the main content elements of the informational and educational materials on infant and young child feeding, according to the text attached to this order.
2. Every informational and educational material on infant and young child feeding, prepared from manufacturers and distributors of specified products, is reviewed and approved in advance by the Public Health Institute.
3. The respective structure of the Ministry of Health, responsible for reviewing and approving the content of informational and educational materials, is the Public Health Institute, which reviews the submitted documentation from the manufacturers or distributors of specified products and approves them.
4. PHI requires a more specialised expertise, if deemed necessary, on reviewing and approving the content of the informational and educational materials on infant and young child feeding.
5. The Public Health Institute checks the informational and educational materials of the specified products to be launched onto the market. In case these materials are not approved by PHI, the manufacturer or distributor is obliged to remove them from the market, within specified deadlines set by SHI.



In case of failure of complying with this paragraph, the subject shall be submitted to administrative measures according to Law No. 10433, dated 16.06.2011 “On inspection in the Republic of Albania”, Article 48, paragraph 6.

6. The State Health Inspectorate is responsible for the execution of this Order.

This Order shall enter into force immediately.

OGERTA MANSTIRLIU
MINISTER



THE MAIN CONTENT ELEMENTS OF THE INFORMATIONAL AND EDUCATIONAL MATERIALS ON INFANT AND YOUNG CHILD FEEDING

1. PHI, through the Department of Health Promotion, reviews the content of the educational and informational materials on infant and young child feeding and recommends the PHI Director on the approval of the distribution of this material.
2. This is accomplished by:
 - a. Reviewing the main content elements of the educational and informational materials on infant and young child feeding, including information addressed to the public at large.
 - b. Reviewing the main content elements of the informational materials on specific products addressed to the health professionals.
3. In order to be approved by the PHI Director, these materials must contain information in compliance with:
 - a. The stipulations of Law No. 8528, dated 23.09.1999 “On protecting and promoting breastfeeding”, as amended;
 - b. The policies of the Ministry of Health on breastfeeding and healthy nutrition of the infant and young child, and
 - c. The Protocols of the Primary Health Care approved by the Ministry of Health.
4. Every material approved by the PHI must contain the following phrase or sentence:

“Approved by the PHI”

I. The main content elements of the informational and educational materials on infant and young child feeding, addressed to the public at large.

1. No manufacturer or distributor of infant formula should produce or distribute informational or educational, written or audiovisual material on infant feeding for pregnant mothers, mothers of infants and young children, and the public at large, if (unless) the material does not contain clear information on the following:
 - a. The benefits and superiority of breastfeeding;
 - b. The benefits of ~~only-exclusive~~ breastfeeding for 6 months, ~~continuing later and sustained~~ breastfeeding combined with ~~supplementary (Complementary)~~ food ~~(Complementary)~~ up to 2 years ~~or more and beyond~~;
 - c. The importance of introducing ~~supplementary complementary~~ food, after 6 months of life;
 - d. Maternal nutrition;
 - e. ~~The preparation for~~ ~~and maintenance of~~ breastfeeding ~~and continuing breastfeeding~~;
 - f. ~~The negative effect on breastfeeding of introducing~~ ~~partial bottle feeding by using a bottle or spout-cup~~, and early introduction of ~~additional complementary complementary~~ foods, ~~supplementation~~, before 6 months, ~~during breastfeeding~~;
 - g. The difficulty of reversing the decision not to breastfeed, and where necessary, ~~proper use fair use of infant formula for infants~~;
 - h. Complementary feeding that can be easily prepared at home by using locally available foods.

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i. If the informational material contains information regarding bottle-feeding, the following details should be included:

- a. Instruction on proper use and preparation of the product, including cleaning and sterilising food utensils;
- b. Beaker and cup-feeding;
- c. Health risks of bottle feeding and improper preparation of the product/formula;
- d. Explanation regarding the fact that the infant formula powder is not sterile, so in order to minimise serious health ~~risk~~ hazard, one feed at a time ~~it~~ should be prepared, using water of a temperature $\geq 70^{\circ}\text{C}$, and each unused milk portion should be thrown away;
- e. Approximate financial cost of feeding infants with a specific product and the recommended quantities according to age.

2. In case the material made reference to in paragraph 1 contains information related to the use of infant formula, it must necessarily have the following details:

- a. ~~the F~~ financial and social implications of its use;
- b. ~~the h~~ Health ~~hazards~~ risks of inappropriate foods or improper feeding methods ~~or improper food~~, and
- c. ~~the h~~ Health ~~hazards~~ risks of ~~the~~ improper use of infant formula.

3. When the material made reference to in paragraph 1 contains information related to the use of infant formula, it must not contain any image or picture that might idealise the use of infant formula.

4. ~~No manufacturer or distributor of infant formula cannot ?? (dy mohime, nje pohim?)~~ give or distribute within the health system any material, or any informational or educational instrument (tool) for the public at large.

II. The main elements of the informational material on specific products for health care providers.

Scientific publications and informational material for the health care providers.

Informational material for specific products for the health care providers should be mandatory of fact or scientific nature, related to the technical aspects and forms of use of a certain product. Informational material and ~~equipments~~ equipment for the health care providers should not contain any products' logo, any display of the company line of products or ~~publicity~~ any advertisement advertisement that encourages products of a certain company.

Scientific publication

Scientific publications are published periodically (in regular or irregular intervals) and ~~oriented~~

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~~toward~~ ~~are aimed at~~ professionals and/or academics of a scientific field, such as: general practitioners, paediatricians, neonatologists, nurses and midwives. They ~~are a unification~~ ~~consist on an aggregation~~ of the original articles ~~from by~~ different authors published under ~~one single~~ ~~an umbrella title~~. The articles include ~~those that what is reported from the~~ new scientific research or review the existing scientific research. They may ~~contain~~ also ~~include~~ editorials, opinions, books and/or other reviews ~~related to~~ ~~dealing with~~ a ~~specific~~ scientific ~~subject~~ ~~theme~~.

Content of the informational material on infant formula

Informational material on infant formula may contain only facts and scientific nature information. ~~Where that information constitutes a nutrition or health claim~~ ~~When the information is a statement on health or feeding~~, it must be approved according to the EU standards. ~~All other statements on feeding and health are prohibited.~~ ~~All other nutrition and health claims are prohibited.~~

~~For each statement suggesting a connection between a certain product or ingredient and health, child growth and development, references of published scientific studies must be submitted.~~ ~~of any article from a peer-reviewed scientific journal.~~ ~~upon being reviewed by colleagues.~~

To the effect of this regulation, the following list includes some examples of the means by which a representation can be made within the context of advertising. The list is not definitive due to the fact that the nature of advertising is always changing: ~~publicity must contain the following elements, though not restricted only to those, due to the fact that the nature of the publicity is always changing:~~

- a. newspapers, magazines, brochures, leaflets, circulars, direct mail, email, text messages, faxes, catalogues, other electronic or printed materials (including publicity content printing);
- b. publications for health care professionals, ~~that which~~ are not scientific publications;
- c. other promotional media and posters in public locations, including moving images;
- d. cinema and video ~~commercial~~ ~~advertising~~;
- e. ~~electronic unaired non-~~ broadcast media (refer to appendix II for further instruction related to internet);
- f. broadcasted advertisements on TV and radio;
- g. correspondence, written and verbal (including phone calls and customer care lines (electronic or other forms), through a business, trader, company and their clients;
- h. press release and other material or activity in public relations, accessible by the customers;
- i. tickets, time schedules and price ~~listing~~;
- j. ~~support from~~ celebrity ~~endorsement~~ ~~ies in connection of with~~ a business, trade or company;
- k. ~~displaying the~~ product ~~placement~~ ~~in~~ website.

Guideline on the content of web information related to infant formula, follow-on formula and children feeding.

The content of the editorial website must not advertise the infant formula, except for the cases when it is on a scientific publication protected via a password, or for commercial

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purposes pursuant to the requirements of Article 11.

Display for sales

If the infant formula will be displayed on websites, only the information on the label shall be displayed, by not emphasising any part of that information. The information must be given in compliance with the labelling controls (see Articles 7, 8 and 9 of Law No. 8528, dated 16.06.2011, as amended).