



**The Rule and Executive Decisions
of the Saudi Arabian Code of
Marketing Breastmilk Substitutes**

The Saudi Code of Marketing Breastmilk Substitutes

Kingdom of Saudi Arabia
Ministry of Health

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MINISTERIAL RESOLUTION

As per the jurisdiction of The Minister of Health, the Royal Ordinance No M/49, dated 211425/9/ H issued on the approval of the Code for Marketing Breastmilk Substitutes and according to the Article 26 of Breastmilk Substitutes that gives power to the Minister of Health in coordination with the Minister of Industry and Trade to issue the required rules and regulations for this code within ninety days of its publication in the official gazette.

And after the issuance of the minutes of the committee formed by the Ministry of Health, Ministry of Industry and Trade for preparing this code. And after the issuance of the letter of the Minister of Industry and Trade No 227711/, dated 51428/5/ H regarding the study and approval of the code.

And after the issuance of the letter of the General Manager of Legal Directorate regarding this code and for the requirement for the public utility.

The Minister of Health decides the following:

Article No 1: Issue the executive regulations of the code of marketing breastmilk substitutes as per the attached formulation.

Article No 2: Publish this code in the official gazette to become effective from the date of its publication.

Minister of Health
Dr. Hamad Bin Abdullah Almania

General rules

Article 1:

The following words and phrases shall have the meanings stated against them, wherever they are stated herein unless otherwise required by the context.

Breastmilk Substitute

Any substitute of Breastmilk manufactured according to the standards of International Food Codex (International Codex Alimentarius) and Saudi Arabian Standards Organization in order to meet the normal nutritional requirements up to the age of six months. It is a substitute prepared for the physiological growth of a child. It also includes foods prepared domestically.

Complementary Foods

Any food, whether manufactured or prepared at home, suitable as a complement to Breastmilk or to infant formula when either becomes insufficient to meet the nutritional requirements of the infant. These must be used from sixth months onwards.

Dealing

It is one process or more that include manufacturing, storing, marketing and sale of the products within the scope of this code.

Marketing

It is an activity through which the study of promoting, distributing and selling of the product is carried out. It also

includes market and consumer related research.

Label

Any written, pictured or descriptive statement printed, embossed or impressed on a container of any product within the scope of this code.

Container

Any form of packaging of products for sale as a normal retail unit, including wrappers.

Samples

One container or small quantities of a product provided free of charge.

Manufacturer (Producer)

Any individual, establishment or company which is operating directly or through an agent or an entity under its control or one it has contracted, for manufacturing a product within the scope of this code.

Marketing Personnel

Any individual whose job includes the marketing of a product or products coming within the scope of this code.

Supplier & Distributor

Any individual, establishment or a company, operating directly or indirectly, in the field of marketing, at the wholesale or retail level, of a product within the scope of this code.

Health Care Institutions

Means governmental or private institutions engaged, directly or indirectly, in health care of mothers, infants and pregnant

women and nurseries and child care associations, excluding the pharmacies and stores licensed to sell such products.

Health Care Worker

Any individual working in health care institutions, including employees and workers dealing with the nutrition of mother and child. This also includes those working in the charity and benevolent societies working in the field of health care.

Minister

Is the Minister of Health.

National Coordinator

Is the National Coordinator of the Breastfeeding Promotion Program (Director General, Directorate General of Nutrition.

Ministry

Means the Ministry of Health.

Article 2

This code aims to provide safe and adequate nutrition for infants by the protection and promotion of breastfeeding and by ensuring the proper use of Breastmilk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution.

2.1: Set up a National Committee for the promotion of breastfeeding in the Kingdom in coordination with the concerned authorities for formulating plans that ensure implementation of the code, rule and executive decisions and resolutions necessary to protect and promote breastfeeding.

2.2: Set up local committees to promote breastfeeding at the regional and district levels to implement the code, rule and executive decisions and resolutions necessary to protect and promote breastfeeding.

2.3: Guarantee the proper use of breastmilk substitutes when required for premature babies, children with special needs and unidentified babies. The authorized doctor shall decide the need for breastmilk substitutes that shall be provided through official channels.

Article 3

This code applies to the marketing and practices related thereto, of the following products: Breastmilk substitutes, milk based complementary foods and other foods and drinks which are given by the bottle or through other methods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breastmilk; feeding bottles and teats. It also applies to their quality and availability and to information concerning their use.

3.1: Prohibit dealing or promoting breastmilk substitutes, complementary foods and other products mentioned in the Article 3 for age up to one year, at sale centers except pharmacies and authorized sale centers.

3.2: Local manufacturers, producers and importers of breastmilk substitutes and complementary foods must comply with the Saudi Standards.

3.3: Publicize intensively the code, rule and executive decisions by issuing memos, holding training courses or

workshops, publishing brochures, posters and using all available methods. Include these in training curricula of health workers.

3.4: Translate the code, rule and executive decisions in English language in order to health workers and other non-Arabic health speakers. The Arabic text is the main reference in implementing the code and the Ministry is not responsible for any mistake in translation.

Article 4

All information and education materials, whether written, audio or visual, dealing with the child nutrition, issued by the Ministry of Health or other relevant authorities should include clear information on the following points:

A.the benefits and superiority of breastfeeding over other feeding methods;

B.importance of maternal nutrition and preparing mothers for breastfeeding and maintaining breastfeeding for the longest possible period.

C.the negative effect on breastfeeding of introducing partial bottle feeding.

D.health hazards resulting from improper use of breastmilk substitutes and other complementary foods.

4.1: The information and education materials mentioned in Article 4 shall be prepared by experts.

4.2: Other relevant authorities mean government health institutions other than the Ministry and private health sectors.

Article 5

It is prohibited to advertise and promote in any way breastmilk substitutes and complementary foods. The prohibition

includes the following:

A. Using health care institutions for the promotion, advertisement, offer or distribution of these products;

B. Providing samples, gifts, tools or equipments to the mothers or health care institutes directly or indirectly.

C. Giving financial rewards or samples to health care personnel by manufacturers, producers, importers or distributors in order to promote such products.

5.1: Manufacturers, producers, importers or others should not advertise, promote or distribute breast milk substitutes at public places, health care institutions and others.

5.2: Manufacturers, producers, importers and distributors should not deliver lectures for workers in health care institutions except with the written permission from the Ministry or other government institutes.

Article 6

As exclusion to the provisions of Article 5 of this code, the manufacturers, producers, importers or distributors are permitted to give scientific information on child nutrition with approval of the Ministry of Health. This material is only for the professionals working in the field of maternal and child care. Information is limited to the scientific facts. The superiority of breastfeeding should be shown on it.

6.1: Scientific publications prepared by the manufacturers, producers, importers and distributors must be approved by the National Coordinator, Breastfeeding Promotion Program. It shall include the benefits and superiority of breastfeeding for infants.

Article 7

The audio-visual and print media shall contribute effectively in creating awareness in order to support the targets of this code through programs and publications by professionals in this field.

7.1: Encourage and support audio-visual and print mass media to prepare, advertise, publish and distribute materials to promote breastfeeding.

7.2: Do not advertise breastmilk substitutes in audio-visual or print media. It is also not allowed to show feeding bottles and teats in any advertisement or educational material,

Article 8

The concerned authorities such as Ministry of Health, other Public and Private Health Sectors, Ministry of Education, Ministry of Culture and Information, Ministry of Social Affairs, Ministry of Higher Education, Ministry of Islamic Affairs, Endowments, Da,wah and Guidance shall contribute in publicizing the health information and scope of this code.

8.1: National Committee of the Breastfeeding Promotion Program shall coordinate as per Para 2.1 with other ministries to disseminate correct health information in this code and also to follow up and evaluate the measures taken by these sectors.

Article 9

It is not permitted for Health Care Institutions to employ staff members, the manufacturers, producers, importers or distributors of breastmilk substitutes to work in the field of mother and child care. Further, the personnel of such institutions are not allowed to work with manufacturers, producers, importers and distributors.

9.1: It is not permitted for government or private Health Care Institutions to employ the staff of the manufacturers, importers or distributors of breastmilk substitutes to work with or without money.

9.2: Government or private Health Care personnel should not work with companies that manufacture, produce, import or distribute breastmilk substitutes with or without money.

Article 10

Without prejudice to the Saudi standards pertaining to breastmilk substitutes, a label should be fixed on each packet in a clear way that is easy to read and understand and difficult to remove. It shall include the following particulars:

1. Statement indicating the superiority of breastfeeding, preceded by (Important Notice) to be written in clear and visible way. That statement is to be determined by the competent authority in the Ministry.

2. Instructions about the correct method of preparation and warning on the health risks that may result from inappropriate preparation. The label or package should not bear any picture of children or any other photo or any text which might give impression that it is better than breastfeeding.

3. Statement indicating that the product should only be used when necessary and on the advise of doctors or expert in infant nutrition and must show the proper method to use.

4. statement should show the following:

a. the ingredients used

b. the composition of the product

c. the storage conditions required, and

d. the serial number, production date and expiry date clearly without symbols.

10.1: Without contradicting Saudi Standards of breastmilk

substitutes and the Saudi Standards of packaged foods (SASO 1995 /1), a label should be fixed on each packet in a clear way that is easy to read and understand and difficult to remove and shall contain all the information mentioned in Article 10.

Article 11

Breastmilk substitutes and complementary foods should be in conformity with the Saudi Arabian Standards Organization (SASO) and should feature on the package the appropriate age to use.

11.1: Breastmilk substitutes and complementary foods should be in accordance with SASO.

11.2: Apply Saudi Arabian Standards Organization specifications to the breastmilk substitutes and complementary foods for infants. If they are not available, they should comply with the Gulf Standards and if these are not available, they should comply with the Codex Alimentaris.

Article 12

Health care institutions shall take appropriate action for protecting and encouraging breastfeeding through giving advice, information and training to health personnel working in this regard.

12.1: Health care institutions (government or private) shall regularly send their employees working in maternal and child care for training course or arrange lectures of not less than 18 hours on breastfeeding. The contents of the training course and lectures should be approved by the National Coordinator of the Breastfeeding Promotion Program and Saudi Commission for Health Specialities.

12.2:The Health Care Institutions shall perform the following:

1.Periodically raise awareness among pregnant women and lactating mothers and the rest of the society about the benefits of breastfeeding and hazards of artificial or bottle feeding.

2.Provide consultations, newsletters and other means to help mothers to comeback to breastfeeding.

3.Create awareness about breastfeeding during the International Breastfeeding Week.

4.Do not separate mothers from their infants even if the mother is accompanying another sick child in hospital.

5.Cooperate and coordinate with the International organizations such as World Health Organization and UNICEF in protecting and promoting breastfeeding through consultation and funds for training and education.

Article 13

Health Care Institutions shall not accept any free or discounted samples of breastmilk substitutes or complementary foods to minimize the spread of breastmilk substitutes.

13.1: Health Care Institutions (government or private) are not permitted to receive any discounted samples of the breastmilk substitute products from the manufacturers, importers or distributors.

13.2: Medical suppliers in the Ministry of Health and other related health sectors are allowed to purchase breastmilk substitutes for distributing these products by pediatricians among the inpatient infants such as premature, unidentified and other babies with special needs.

Article 14

Social societies caring for orphans are permitted to accept the free samples of the breastmilk substitutes and foods.

14.1: Article 13 is not applicable to social societies that care for orphans.

14.2: A committee comprising of the Ministry of Social Affairs, Ministry of Health and other related sectors is constituted for setting guidelines to receive free samples and distribute them to the needy people.

Article 15

The health workers in charge of maternal nutrition should encourage and protect breastfeeding and should be well aware of their responsibilities and qualified to provide information, advice and training when necessary.

15.1: Health care institutions should employ health workers – doctors, nurses, midwives, nutrition specialists, social workers, health educators and others in maternal and child nutrition with sufficient skills and experience.

15.2: Encourage health care institutions to use effective means of communications for guidance and education such as hotline for receiving and answering questions and enquiries.

15.3: Use all possible means to communicate with mothers.

Article 16

Health workers and their family members shall not accept any material or non-material rewards or gifts that may be offered to them by the manufacturers, importers and distributors of the breastmilk substitutes and complementary foods.

16.1: Health care employees and their family members are not permitted

to ask for or accept cash, samples or special favors to them by manufacturers, importers or distributors of breastmilk substitutes and complementary foods.

16.2:Manufacturers, importers or distributors of breastmilk substitutes are not permitted to present equipments or educational materials for health care institutions except on request of the specified authorities and on approval from the Ministry or other concerned authorities.

Article 17

No individual from health care institutions shall utilize contributions that may be offered to him/her by the manufacturers covered in this code or their distributor for attending training courses, seminars or scholarships except on approval from the Ministry or other concerned authorities.

17.1: Manufacturers, importers or distributors of breastmilk substitutes are not permitted to finance training courses, conferences or scholarships or research for health workers unless approved by the Ministry or the concerned authorities.

Article 18

No person other than health workers and pharmacists are allowed to explain how to give the breastmilk substitutes prepared or manufactured domestically, provided the same is limited to the mothers and family members in need of them and the provided information shall include clear explanation on the risks of improper use of such products.

Violations and Penalties and their Provisions

Article 19

A committee or more is to be formed through a ministerial resolution and such a committee shall include:

A.A representative from the Ministry of Justice, nominated by the Minister of Justice.

B.A representative from the Ministry of Health, nominated by the Minister of Health.

C.A representative from the Ministry of Commerce and Industry, nominated by the Minister of Commerce and Industry.

At least one or more members should be an official legal advisor. This committee will resolve the disputes arising from the violations of this code and will take necessary decisions and the Minister will be the ultimate authority to approve the decisions of the committee. The executive regulation of this code will specify the duration of membership of this committee and how to implement the same and that the remuneration of the members of the committee will be determined through a resolution passed by the Council of Ministers based on the recommendation of the Minister.

19.1:The Minister will take the decision of forming the committee after consultations with the Minister of Justice, Minister of Commerce and Industry to nominate their candidates in the membership of the committee, upon renewal and replacing the membership, provided that one

of its members shall be a regular consultant.

19.2: The committee will look at the violations committed in applying the Code of Marketing Breastmilk Substitutes and its executive decisions and imposing appropriate punishment within its jurisdiction.

19.3: The duration of the membership of this committee is three years, renewable, from the date of its formation.

19.4: This committee will be based at the Ministry or at Health Affairs Department of the areas where similar committees might be created.

19.5: The committee shall assume its tasks according to the following procedures:

A. The committee holds its sessions with attendance of all its members and takes its resolutions with absolute majority.

B. The committee shall adhere in its tasks to perform the required investigation and inform the related personnel and listen to the violator. It shall take down its tasks in written minutes.

C. The pertinent persons shall be informed in writing to appear before the committee in the time and at the place specified by the committee. Consider adding an appropriate period upon specifying the appointments, if the attendance needs moving from city to other.

D. When the violator or his/her authorized representative do not attend, the session shall be rescheduled for another date within no less than thirty days. In case the violator or his/her authorized representative does not attend the second appointment, the committee shall decide in the violation.

E. The committee submits its decision to the Health Minister

or his/her duly authorized representative for approval. Interested parties shall be informed about the approved decision of the committee within thirty days.

19.6: Except otherwise is not stipulated in the regulation, the procedures stipulated in this executive decisions shall be followed for practicing the position of human medicine and dentistry related to the issues with the Legislative Medicine Committee.

19.7: The remuneration of the committee members shall be decided by the resolution from the Council of Ministers based on the recommendation of the Minister.

Article 20

Without prejudice to any other severe punishment stipulated by any other law, whoever breaches any provision whether manufacturer, importer or distributor of breastmilk substitutes, or individual, establishment or company will be punished by one or more of the following:

A. Admonition.

B. Fine of not less than five thousand Saudi Riyals and not more than one hundred and fifty thousand Saudi Riyals.

C. Closure of the violating firm for a period of not more than 180 days.

Article 21

Without prejudice to any other severe punishment stipulated by any other law, whoever breaches any provision of the code whether private health care institution or their employee will be punished by one or more of the following:

A. Admonition.

B. Fine of not less than five thousand Saudi Riyals and not

more than one hundred thousand Saudi Riyals.

C.Closure of the violating firm for a period of not more than 60days.

Article 22

If the committee finds that the violation requires to apply fine higher than the amount specified under articles 20 & 21 hereof or cancellation of license, then the committee has to raise the subject to the Minister to forward the dispute to the Grievances Board to resolve what is seen necessary.

Article 23

The decision of the committee may be challenged in the Grievances Board within sixty days of informing such a decision to the violating party.

Article 24

The Grievances Board may allow publishing the penalty sentence in one or more local newspapers at the expense of the violator.

Article 25

Any employee who breaches the violations of articles 5, 9, 12, 15, 16, 17 and 18, hereof shall be punished according to the provisions of the Employee Disciplinary Code.

25.1: The committee formed as per Article 19 of this code shall decide in employee violations of provisions Articles 5, 9, 13, 15, 16, 17, 18 of this code and punish them as per employee discipline after performing investigation with them in writing, listen to his say, maintain his defense and prove

that in the attached minutes.

25.2: Consider that the punishment shall be suitable to the violation. Consider also previous convictions, the conditions associated to the violation.

25.3: The committee shall submit to the Minister the appropriate proposed resolution and all violation documents included in the activities of the personnel in order to approve the decision or to select other punishment more suitable to the or transfer to the Observation and Investigation Authority, if the violation requires the punishment of dismissal.

Article 26

The Minister in coordination with the Minister of Commerce and Industry shall issue the Executive Regulations and Decisions of this code within 90 days its publication in the official gazette.

26.1:The Minister reserves the right of issuing the required modification of this rule and executive decisions.

Article 27

This code cancels all other laws conflicting with it.

Article 28

This code shall be published in the official gazette and shall be effective within 90 days after its publication.

28.1:This rule and executive decisions shall be published in the official gazette and will be effective after ninety days of its publication.

