

A draft to update the

**Executives Regulations (rules and decision) of the code**

**for marketing breast milk substitutes**

Under article M 1/26L of the Executives Regulations of the code for marketing breast milk substitutes which stated that: The Minister reserves the right of issuing the required modification of the executive regulations.

A committee was formed to review and update the executives regulations of the code for marketing breast milk substitutes. Resolution No. 3749 dated 25-3-1435h

**M 1/2 L**

The Minister constitutes a national committee for the promotion and protection of breastfeeding in the Kingdom of the following Ministries and agencies (Ministry of Health, Ministry of Education, Ministry of Social Affairs, Ministry of Islamic Affairs and Endowments, Ministry of Culture and Media, and the Saudi Food and Drug Authority) to develop plans that ensure the application of the executive regulations and other procedures necessary to protect and promote breastfeeding. The Minister can add who is deemed necessary.

**M 2/2 L**

The Directors of Health Affairs Directorates - or similar agencies (in other than MOH health institutes) constitutes a local committee for the promotion and protection of breastfeeding in the lines of the National Committee for the application of the code and the executive regulations and decisions beside applying the instructions of the national coordinator of the breastfeeding promotion program to all health sectors.

**M 2/3 L**

Ensure the proper use of breast milk substitutes when required for premature baby, infants and young children requested by a specialist doctor and are provided in the facilities and health institutes that deal with motherhood and childhood, through official channels according to the Article 14.

**M 3/1 L:**

Prohibit advertising of breast milk substitutes and supplementary food assigned to premature infants, babies and young children feeding from birth until the age of 3 years and other related products include the followings:

(A) Infant formula from birth to 12 months.

(B) Growth milk, follow-up milk or any other named products for age group 12

months to 36 months that marketed, as suitable for feeding infants and young children.

(C) Pacifiers and feeding bottles made of glass or other.

(D) Other related tools and deices (milk suction devices, the nipples cover, etc).

(E) Supplementary food items.

(F) Water used to prepare baby formula.

(G) Any other liquids such as herbal tea, juice or any product(s) marketed or labeled as suitable for children under the age of 36 months.

**M 3/2 L**

Local manufacturers, producers and importers of breast milk substitutes and complementary foods must comply with the Saudi Standards approved by the Saudi Food and Drug Authority (SFDA).

**M 3/3 L**

local committees and similar bodies publicize intensively the code and executive regulations for all employees of the program by issuing memos, holding training courses and prepare educational materials concerning the code and executive regulations.

**M 3/4I**

The National Coordinator should translate the code and executive regulations in English language. The Arabic text is the main reference .

**M 4/1 L**

The National Coordinator constitute a consultative committee of specialists in the field of breast-feeding and infants and young children feeding to review and adopt the information and educational materials that mentioned in Article 4.

**M 4/2 L**

Information and educational materials that (required revision) of health institutions and the Ministry of Health and other sectors to be raised (referred) through local committees or similar agencies in directorate or the provinces and regions to the National Coordinator for approval.

**M 4/3 L :**

Educational and informational(media) materials include the following:

1. The benefit of breastfeeding in general and exclusive breastfeeding until the age of 6 months, introduction of complementary feeding starts after this time with continued breastfeeding until the end of the two years of the age.
2. Maternal nutrition and how to prepare to and continue breastfeeding .
3. The importance to start teaching mothers to begin breastfeeding immediately after birth (within the first hour).
4. To clarify reasons for preventing the use of pacifiers and industrial nipples and

their damage.

5. The difficulty of the decision not to breastfeed.

6. proper use of industrial milk, if necessary, whether it is a homemade or industrial.

7.Explain the importance to start complementary foods after six months of age and how to start it.

8. How to feed an infant using a cup, a spoon or other.

9. Explain the negative impact of the introduction of artificial feeding or any supplementary food before the end of the sixth month of life on breastfeeding and their impact on reduce the milk yield.

10. Statement of preference for complementary food preparation at home using materials that are available to the family in a safe manner.

When these materials contain information about the use of infant formula should include:

1. Social, health, economic, psychological and environmental impacts of use it .

2. the health hazards of foods or feeding inappropriate methods.

3. health risks resulting from the unnecessary or improper use of industrial milk and other breast milk substitutes

These materials should not contain any pictures or texts inspire idealism of using breast milk substitutes.

M 5/1 L

Its prohibited directly or indirectly Advertising and promoting or the distribution of free samples, gifts or tools encouraged the use of products contained in the m 3/1 by producers and suppliers and marketers of infant formula and baby food and other - in health care institutions , pharmacies, public places, educational institutions and other various ways for individual or groups interviews or distribution of the means of communication or provide brochures and other methods.

M 5/2 L:

Prohibits for the produced and supplied or the marketer companies for breast milk substitutes to support the establishment of any educational Or entertaining activities.

M 5/3 L:

Its prevented, direct or indirect contact between parents and workers of producing companies or supplied or marketed products which covered by the scope of this system.

M 6/1 L:

Required for the distribution of scientific literature prepared by the producers, suppliers and marketers of the products contained in the m 3/1 pre-approved by the National Coordinator of the program to encourage breastfeeding and limited to the built-up scientific truth on the evidence and the published scientific evidence from organizations and health authorities International with confirming the breastfeeding advantage and the Benefits For infant.

M 7/1 L

The publication and broadcasting of programs for promotion of breastfeeding through audio, visual and print, which in line to the Code and its Executive Regulations

M 7/2 L:

Panning of advertising or publicity for the products mentioned in the article M3/1 either through audio, print and visual materials or in any advertising or educational material, or by means of modern technology or smart devices.

M 7/3 L :

The adoption of educational materials will be through the Advisory Committee of the breastfeeding promotion program mentioned in article M4/1

M8/ 1L The National Committee coordinate with the government sectors mentioned in article M2/1 L to disseminate the information related to this code according to their specialties and follow-up and evaluate of the actions taken by these sectors.

M 8/2 L

The health scientific information related to the code will be adopted by the National Coordinator of the breastfeeding promotion program .

M 9/1 L:

The governmental and private health institutions are prohibited from employing (paid or unpaid) workers of any companies whether manufacturing or importing or distributing the breast milk substitutes mentioned in article M 3/1 L.

M 9/2 L:

The health care workers of( government or private health institutions) are prohibited to work at any companies whether manufacturing or importing or distributing the breast milk substitutes, whatever paid or unpaid job.

M 10/1 L:

Without prejudice to the provisions of technical regulations and standards approved, and according to the article ten the products label mentioned in article M/11L the following data in a clear and non-removable and easy to read in

Arabic and English as follows:

1. Statement Important Note or it is equivalent.
2. Clear Statement illustrated the singularity and benefit of breastfeeding .
3. A statement illustrated that the product only used by the advice of a doctor or specialists in the field of infant nutrition, when needed and the statement should illustrated how to use the product.
4. Notes how to prepare and warning about health risks that result from incorrect preparation.
5. Warning that the product is unsterile and susceptible to contamination during manufacturing, processing, and preparation.
6. Product name (should explain the nature of the specific food and not generalized
7. Statement or notice by the following:
  - A. The list of ingredients
  - B. Food Composition
  - C. Nutritional value
  - D. The required storage conditions
  - E. Batch Number and date of production and expiry date, in direct manner and clear .

M 11/1 L:

Products mentioned in article M3/1 L must be agreed or congruous to the approved Saudi or Gulf technical regulations and standards

M 12/1 L:

The health institutions (government / private) are committed to train their health workers in the field of maternal and child care. Training course curriculum approved by the National Coordinator of the breast feeding promotion program

M 12/2 L

The Saudi Commission for Health Specialties should bind health practitioners In the field of maternal and child care to a Accredited training curriculum (CME/PD) as a continuous education for maternal and child care medical staff.

M 12/3 L:

Health-care institutions must do follows:

1. Health awareness specially pregnant and lactating women. The education program include awareness of the benefits of breastfeeding, the risks of artificial feeding , the importance of skin to skin contact between mother and newborn immediately after birth, importance and necessity of practice rooming in (allow mother and the infants to remain together throughout the day), the right positions for breastfeeding, benefits of early start breastfeeding immediately

after birth, how to squeeze milk from the breast(suction) and the storage of milk.

2. Development a job under the name of (breastfeeding consultant or adviser) through coordination with the concern authorities . The appropriate qualification approved by the National Coordinator of the breast feeding promotion program . The breastfeeding consultant should help mothers to overcome the difficulties facing the lactating women.

Foster the establishment of breast feeding support group in and out health institution.

3. Take appropriate and safe measures to ensure the continuity of the breast feed for sick mothers or those accompanying another sick child.

M 13/1 L

Prohibit the governmental and private health institutions receive free samples or buy reduced samples less than the wholesale price identifier or less than 80% of the retail price of the products mentioned in article M3\1L.

M 13/2 L

The purchasing of products mentioned in article M3\1L only through Medical Supply Directorate at the ministry or other concerned department. To be prescribe by concern doctor prescription, through official channels approved by the Medical Supply for hospitals when need.

M 14/1 L

Medical Supply at ministry of health and other sectors concerned must be committed to establish a mechanism to accept the free samples and controls of the products mentioned in article M3\1L. It should not be inconsistent with the code and the regulations, for patients mentioned in appendix(1) and presented to the national committee for approval.

M 15 /1L

The health care institutions must be committed that all the health workers in the field of maternity and childhood such as doctors, nurses, midwives, dieticians, social workers or specialists and health educators and others to have the appropriate qualification for taking the measures mentioned in article M12 \ 2's to provide appropriate advice.

M 16/1 L

The health workers and members of their families were prohibited to request or accept any cash or any gift from producers or suppliers or distributors of the products mentioned in article M3\1L

#### M 17/1L

The health care institutions staff were prohibited to accept benefit or contributions may be given to him or her by marketing or supplier companies of products mentioned in article M3\1L such as attending conferences or courses or scholarships, except upon the written approval from his work and the local committee or similar bodies (committee, department...) of other health sectors.

#### M 18/1 L

It is prohibited for non-health workers to explain how to prepare breast milk substitutes. The explanation should be limited the mothers and members of families who need the product(s). The information provided should be individually and not with group as mentioned in appendix (1) e. The information should be clear and include explanation the dangers of improper use of these products.

#### M 19/1 L

The Minister of Health issue a decision to form a committee to resolve the dispute arising from violation of the code after coordination with both the Minister of Justice and Minister of Trade and Industry to nominate their candidates in the Committee and upon renewal and replacement of membership. One of its members should be legal official adviser and the membership duration committee is five years.

#### M 19/5L

Committee should work according to the following procedures:

- A). The Committee hold its meeting or session in the related directorate and the meeting considered as legal if either the chief of the committee or the vice-president and the legal adviser were attending the meeting. The meeting considered legal only if their members not be less than three and shall issue its decisions by an 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 and achieve defenses. 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 another city
- D). When the date decided and 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 and adjudicated.

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.

F). Directors of the Health Affairs Directorates and equivalent personnel (in other health sectors such as military, national guard hospitals and medical cities..ect), formulate committees to inspect the violation in health care institutions and pharmacies and record the violations to be lifted to the director of health affair in the region and to referred to the Committee in a period not exceeding two weeks from the date of the violation.

G). Committee staff jointly or individually, should do the following:

1 . Received and investigate the violations, collection of the evidences and evaluate them. Follow all legal procedures to establish the violation, and where the violation happened.

2 . Receive reports of violation and complaints, record it and prepare minutes includes the place and time of the violation, and full details of the person who reported the violation (name, address and telephone number). Also the names of the persons who violate and where the violation happened. Describe the violation in details with the evidence submitted with the complaint.

3. Go to the violation site or place and check the violations and keep materials as evidence if found.

4. Inspect all establishments and shops where violation may occur an example: Entry to facilities and shops sites, and identify the violators names and addresses etc. Adjust the testimony of witnesses, and hear the statements of the violators, without the need to take permission from any other authority to adjust the violation.

H). The committee shall submit to the Minister or his authorized representative for approval of the decisions (proposed resolution) and returned to the committee. Appeal allowed within sixty days from the date of notification by the Board of Grievances.

I). The committee should give the violators (members / agent / representative of health and private institutions) the committee's decision after the accreditation In case the violator (person/ agent or legal representative) not attended to receive the decision. Committee inform the employer company or his legal representative in less than thirty days of the adoption of the decision (resolution) and in the case of non-receipt the decision will be effective.

J) The Committee should follow the implementation of decisions(resolution).

K). The financial penalties should be deposit in the Ministry of Health Account for



the benefit of breastfeeding promoting program.

Give the person who reported the violation (Complainant) after verification 5% of the value of the violations.

**M 25/1L**

The committee mentioned in article M19 of the code should investigate the Ministry's employees violators of the fifth, ninth, thirteenth, fifteenth, sixteenth, seventeenth and eighteenth articles of the code, shall be punished according to the provisions of Employee Disciplinary Code or system

**M 25/3L**

The committee shall submit to the Minister the appropriate proposed decision (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, or transfer to the Observation and Investigation Authority, if the violation requires the punishment of dismissal.

## **References:**

1. International Code for the trading of breast milk substitutes 1981.
2. Subsequent resolutions or decisions of International Code for the trading of breast milk substitutes.
3. The international strategy of the infants and young children nutrition 2006.