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CERTIFICATE

I, the undersigned, MIGUEL-ÂNGELO ALMEIDA, Sworn Translator dully admitted by the Maputo City Judicial Court, dweller of Maputo city, officially authorized as a translator, hereby CERTIFY and ATTEST, to whom it may concern, that the attached document is to the best of my knowledge and belief a true and correct translation of a document from Portuguese into English, for which I hereby assume full responsibility.

IN WITNESS THEREOF, I sign this Certificate, in Maputo, Mozambique, on 7 July 2015


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Reconheço a assinatura de Miguel Ângelo Almeida, Tradutor Oficial Ajuramentado, com poderes suficientes para o acto de Tradução de 22 de Julho de 2015. Emol. 22.07.15. AJUDANTE DO 3º CARTÓRIO NOTARIAL



OFFICIAL GAZETTE

OFFICIAL NEWSLETTER OF THE REPUBLIC OF MOZAMBIQUE

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NOTICE

The subject-matter to be published on the <<Official Gazette>> must be submitted in a duly certified copy, one for each subject-matter, consisting of, apart from the required indications for that purpose, the following endorsement signed and certified: for publishing in the <<Official Gazette>>.

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SUMMARY

Health and Industry and Trade Ministries

Ministerial Order no. 129/2007

Approves the Code of Breast milk Substitutes.

Ministerial Order no. 130/2007

Approves the Boards of Health Regulation.

Ministerial Code no. 131/2007

Creates the Infrastructures unit, hereinafter designated by the acronym DI, within the Planning and Cooperation Directorate.

Dispatch:

Disaggregates the Tuberculosis and Leprosy Program, to constitute two distinct programs: the Tuberculosis National Program and the Leprosy Control National Program.

Dispatch:

Creates the technical Committee of Medicine Records abbreviated as CTRM, which is directly under the Minister of Health.

Dispatch:

Disintegrates the central expiry sections of the Administration and Finance Directorate, being then an integral part of the Human Resources Directorate.

Dispatch:

Extinguishes GACOPI, created by the ministerial order of October 10, 1988 and amended on March 30, 1989.

Dispatch:

Determines that the National Program Director for HIV/AIDS Control will be directly under the Minister of Health.

Dispatch:

Determines that the National Program Director for Malaria will be directly under the Minister of Health.

Dispatch:

Determines that the National Program Director for Tuberculosis Control will be directly under the Minister of Health.

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MINISTRIES OF HEALTH AND OF INDUSTRY AND TRADE

Ministerial Order no. 129/2007 of October 3rd

The article 89 of the Constitution of the Republic of Mozambique states that all citizens of the Republic of Mozambique have the right to Medical and Health care, under the law, as well as the responsibility of defending public health.

In order to improve breast-feeding protection and promotion in an effective way, ensuring the adequate use of breast-milk substitutes and aiming to regulate the trading, advertising and sale of infant foods, an adequate legal framework must be established.

Accordingly, and under the competencies granted by law, the Ministers of Health and of Industry and Trade resolve:

Article 1. The Code for the Breast-milk Substitutes is approved and attached to this ministerial order as an integral part of the same.

Article 2. All legal provisions that contradict this Code are revoked.

Article 3. This Ministerial Order becomes effective 12 months after its publication in the *Official Gazette*.

Maputo, November 30, 2005. – The Minister of Health, *Paulo Ivo Garrido* – The Minister of Industry and Trade, *António Fernando*.

Breast-milk Substitutes Commercialization Code

CHAPTER I

Objectives, Application Scope and Definitions

ARTICLE I

Objectives

The objectives of this Code are:

1. Contribute to the safe and adequate nourishing of infants, protecting them from the related risks of the lack of breastfeeding or early and inadequate weaning, so as to protect the beneficial African ancestral tradition of breastfeeding and its efficient promotion and protection, ensuring the adequate use of breast-milk substitutes based on scientific information, solely and exclusively when these are strictly necessary.
2. Discipline, monitor and regulate the trading, distribution, advertising and sale of the breast-milk substitutes and add-ons and of other products used as a means for the administration of these substitutes and add-ons.

ARTICLE 2

Application Scope

This Code applies to trading and related practices of the following products manufactured in-country or imported:

1. Infant formulas and other dairy products or not, liquid, powder or in other semi-liquid or pasty form, pasteurised, sterilized, in its natural state or modified, when marketed or otherwise presented as adequate for use as partial or total substitutes of breast-milk.
2. Follow-up formulas and other complementary foods used for weaning: porridge, soups, fruits, other desserts, milk, milk derivatives and milk based drinks, or not.
3. Feeding bottles, as well as closed cups with straws or nipple, marketed or indicated for

use as containers for liquid and semi-liquid as per the above numbers.

4. Teat cups and pacifiers.
5. Products that must not be used to feed infants (condensed, skimmed, semi-skimmed and whole milk), even though modified for this purpose.
6. Other products that, by Ministerial Order, the Minister of Health decides to indicate.

ARTICLE 3

Definitions

For the purposes of this Law and solely for these purposes, the following concepts are defined as per below:

1. *Trading Agent* – any person whose functions involve the participation in any steps of trading of a product or products covered by this Code.
2. *Complementary Food* – any food, whether industrialized for direct use, prepared in an artisanal manner or homemade, appropriate or presented as such, as a complement to breast-milk or to infant formulas or follow-on formulas, when any of these becomes insufficient to meet the infants nutritional needs. These foods are also designated as “weaning foods” or “breast-milk supplements”.
3. *Free Sample* – unit or small quantity of a product which is provided for free.
4. *Feeding Bottle* – container for the administration of water, milk and other liquid and semi-liquid products to infants and other children, used as infant formula, follow-on formula and/or complementary food. A Teat cups is attached to a feeding bottle so that the child can suck.
5. *Teat cup or Pacifier* – malleable object, usually plastic, with a format similar to a nipple so that children can suck in between meals. In general, the Teat cup has a ring that serves as a handle to hold the Teat cup without touching the part where the child will suck.
6. *Trading* – a set of promotion, distribution, sale, propaganda and advertising activities for the products covered by this Code, including public relations and information services.

7. *Distributor* – natural person, company or any other entity of public or private nature direct or indirectly involved in the whole or retail sale of a product or products covered by this Code;
8. *Donation* – free supply of a product in a larger quantity than the one defined as “sample”.
9. *Packaging* – see “Container”.
10. *Manufacturer*: any person, company or other public or private entity involved in the manufacture of a product or products covered by this Code, whether directly, through an agent or a controlled person or under an agreement.
11. *Infant formula* – milk, milk derivative or product or mixture of products of animal or plant origin, formulated in accordance with the Mozambican Standards regarding the subject-matter or, in the lack of these Standards, with the applicable Codex Alimentarius Standards, that aim to meet the nutritional needs of infants since their birth until 6 months old in substitution of breast-milk. The “Infant Formulas” can also be prepared at home and, in this case, these are described as “homemade formulas”.
12. *Follow-on Formulas* – milk, milk derivative or product or mixture of products of animal or plant origin, formulated in accordance with the Mozambican Standards regarding the subject-matter or, in the absence of these Standards, with the applicable Codex Alimentarius Standards, marketed or otherwise presented as appropriate to feed infants or children up to 3 years old (weaning foods). The “Follow-on Formulas” can also be prepared at home and, in this case, these are described as “homemade formulas”.
13. *Infant* – child up to one year old.
14. *Standard* – document, established by consensus and approved by a recognised entity, which provides for the common and repeated utilization, rules, recommendations or characteristics for the activities or its results, ensuring the optimal organization level in a certain context.
15. *Mozambican Standard* – document established by consensus and approved by the National Institute for Standardisation and Quality (INNOQ) of the Republic of Mozambique, which provides for the common and repeated utilization, rules, recommendations or characteristics for the activities or its results, ensuring a optimal organization level in a certain context.
16. *Sales Personnel* – any professional whose functions involve marketing of the referred products in this Code (vendor, sales promoter, demonstrator, agent or representative).
17. *Healthcare Professional* – Health Sector worker, with high, medium or basic level technical training, acknowledged by the Ministry of Health to work in the Health Units of the National Health System (SNS) or in the private sector health units.
18. *Promotion* – use of any method to, directly or indirectly, lead a person to buy or use a product or products covered by this Code.
19. *Advertising* – presentation of the products covered by this Code using any means, with the objective of promoting its sale or distribution, including but not limited, i) written, television, radio, cinema, video, electronic or telephone transmission advertising, ii) exhibit of boards, placards, posters or adverts, iii) exhibit of frames or models, iv) direct or indirect contact with healthcare professionals, mothers, pregnant women and relatives, and with the public in general, or iv) samples, gifts or gratitude, donations or sales at special prices.
20. *Container or packaging* – any way of packaging of a product or products covered by this Code as a normal unit of retail sale of that product, including the casing.
21. *Label* – any tag, brand, image, illustration or other graphic indication, written, printed, mimeographed, embossed or heat affix marked on the container of any product referred in this Code or adhered to it.
22. *Healthcare Service* – set of institutions, entities or services and set of Health professionals from the public or private sector (profitable and non-profitable), directly or indirectly committed to the populations Healthcare.
23. *Breast-milk Substitutes* – any food marketed or otherwise presented as partial or total

substitute for breast-milk, adequate or not for that purpose.

24. *Supply* – quantity of the product supplied for use during a long period, for free or at a low price for social purposes, including the distribution to the families in need, destined to meet the needs that their economic capacity cannot meet.
25. *Teat cup* – artificial nozzle or other gadget, usually on a malleable material, for infants and other children to suck the content inside the feeding bottle.
26. *Healthcare Worker* – any person working on a Healthcare Unit of the National Health System or private sector healthcare unit (profitable and not-profitable), whether professional or not, including the unpaid volunteer workers.
27. *Infant care unit* – nursery, day-care facilities, kindergarten, crèches and other care giver institutions of any kind to children up to 3 years old.

CHAPTER II

Promotion and Advertising

ARTICLE 4

Advertising Promotion

1. The manufacturers and distributors acting on their own or through a third party are prohibited from promoting and advertising any product covered by this Code in sales points, Health Units or another location. The forbidden promotional practices include, but are not limited to:
 - a) Publicity, of any kind;
 - b) Sales techniques such as special exhibits, discount vouchers, prizes, discounts, special sales, teasers, interlinked sales, gifts or gratitude;
 - c) Delivery or distribution of one or more samples of the products covered by this Code to any person;
 - d) Delivery or distribution of information or educational material related to infant and other children feeding practices or to the performance of education roles related to infant and other children feeding practices.
2. The provisions on sub-heading b) above must not prejudice the establishment of lowering

policies and practices, in a stable manner, of the prices of the products covered by this Code.

3. Any type of direct or indirect contact, professionally, with pregnant women, infant mothers and/or children in pre-schooling age is also forbidden for the marketing personnel of the products covered by this Code, and particularly, it is forbidden to provide them with any information, education or another type of elements.
4. It is nonetheless authorized to manufacturers and distributors to provide information about the products covered by this Code to higher level Healthcare professionals if this information is limited to specific scientific matters related to technical aspects and methods of utilization of products covered by this Code, and if it is in accordance with the provisions of Chapter VII of this Code.
5. Breaches of the provided in numbers 1 and 3 of this Article are punishable with a fine equivalent to 15 monthly minimum wages for the first breach, a fine equivalent to 40 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 3 months, or even cancellation of the registration in cases of more than one reoccurrence.

ARTICLE 5

Promotional Donations

1. Without prejudice of the provisions in the following article, the manufacturers and distributors acting on their own or third person oriented are prohibited from:
 - a) Donating or providing any quantity of the products covered by this Code to healthcare workers or Healthcare Units, at a price below the retail sale price if it is stipulated, or if not, below 80% of the whole sale price.
 - b) Donating or distributing to the Health care units any equipment or utilities, as well as other material (including but not limited to pens, calendars, posters, note books, growth charts, key holders, caps, t-shirts, badges, stickers and toys) that refer to the use of the products covered

by this Code or that can promote its utilization;

- c) Offer or give any present, contribution or benefit to Healthcare workers or association of Healthcare workers, including but not limited to scholarships, budget for researches or financing of meetings, seminars, further education courses or conferences.
 - d) Sponsor events, tenders, telephone lines for counselling or campaigns destined to mothers breastfeeding, parents of children younger than or with 3 years old or their families that, in a direct or indirect manner, refer to fertility, pregnancy, childbirth, infant feeding or other children younger than 3 years old, or correlated matters;
 - e) Include the sales turnover of the products covered by this Code on the estimate of the main or accessory remuneration (bonus, subsidies, and commissions) of its workers, nor establish sales quotas of the products covered by this Code.
2. Breaches to the provided above are punishable with a fine equivalent to 15 monthly minimum wages for the first breach, a fine equivalent to 40 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 3 months, or even cancellation of the registration in cases of more than one reoccurrence.
 3. The provided for in number 1 of this article does not prevent the Minister of Health to, exceptionally, take donations from the manufacturers or distributors of the products covered by this Code, which will be compulsory and exclusively distributed to the Health Units of the National Health System.
 4. Likewise, manufacturers and distributors of the products covered by this Code, acting on their own or third person oriented, can make donations or sales of their products at a low price to social institutions or organizations such as nurseries, kindergartens or orphanages for their exclusive use or for the distribution controlled by them, infants families, which have reasonable justification to be fed with breast-milk substitutes, as per

prescribed by Healthcare professionals. These donations or sales at a low price require previous authorization from the Minister of Health.

5. Breaches to the provided above are punishable with a fine equivalent to 5 monthly minimum wages for the first breach, a fine equivalent to 20 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 4 months, or even cancellation of the registration in cases of more than one reoccurrence.
6. The donated or sold material at a low price under paragraphs 3 and 4 of this Article can bear the name or brand of the donating company, yet, without any record that may contradict the provisions in this Code.

ARTICLE 6

Donations for research

1. With the sole aim of scientific research, at the level of a Health institution, manufacturers or distributors of the products covered by this Code can donate adequate quantities of a product or products for this purpose, if the beneficiary institution has requested so and after having the previous authorization of the Minister of Health.
2. The Ministerial authorization request process must contain the detailed explanation of the research objectives and of the reasons of the request, and must also contain the research protocol attached to it.

CHAPTER III

Labelling of the Products covered by this Code

ARTICLE 7

General Requirements Related to the Packaging and Labels of all products covered by this Code

1. The messages in the packages and/or labels on the products covered by this Code must be written in Portuguese and explicit, easily readable and understandable so as to avoid any doubt.
2. Breaches to the provided above are punishable with a fine equivalent to 5 monthly minimum wages for the first breach, a fine equivalent to 20 monthly minimum wages for cases of reoccurrence and suspension of

activity for 1 to 4 months, or even cancellation of the registration in cases of more than one reoccurrence.

3. The packages and labels of the products covered by this Code must only contain written or graphic information strictly necessary for the preparation and adequate use of the product, being absolutely forbidden to include photographs, drawings or other form of graphic representation of infants and/or children or any reference or suggestion prone to, directly or indirectly, discourage breastfeeding.
4. Breaches to the provided above are punishable with a fine equivalent to 10 monthly minimum wages for the first breach, a fine equivalent to 30 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 3 months, or even cancellation of the registration in cases of more than one reoccurrence.
5. The messages on the packages must be printed or engraved on the package or on the labels that cannot be easily peeled off.
6. Breaches to the provided above are punishable with a fine equivalent to 5 monthly minimum wages for the first breach, a fine equivalent to 20 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 4 months, or even cancellation of the in cases of more than one reoccurrence.

ARTICLE 8

Compulsory Contents for Packages and Labels

1. The messages on the packages and/or labels of the products covered by this Code, except for feeding bottles, Teat cup and pacifiers, must compulsorily mention the following elements:
 - a) Instructions for the preparation and adequate use of the products, in words and images easy to understand;
 - b) Age, in numbers, as of which the use of the product is recommended;
 - c) Warning regarding the health risks of inadequate preparation and introduction of the product before the recommended age;

- d) Indication of the used ingredients and its implication on the product, in descending order, weight or volume and the origin of the used dairy products;
- e) Chemical composition and nutritional information of the product;
- f) Identification of the net weight in the package;
- g) Storage conditions required before and after opening the package, considering the climate conditions;
- h) Batch number, date of production and expiry date, considering the climate conditions and storage conditions;
- i) Other elements derived from the applicable Standards and Regulations.

2. Breaches to the provided above are punishable with a fine equivalent to 10 monthly minimum wages for the first breach, a fine equivalent to 30 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 3 months, or even cancellation of the registration in cases of more than one reoccurrence.

ARTICLE 9

Labelling of Infant Formulas

1. Apart from the elements referred on point 1 of the previous Article, the packages and/or labels of the infant formulas must compulsorily contain, in a well-placed location, readable and easy to see, the following elements:
 - (a) The expression "IMPORTANT NOTICE" in uppercase, followed by: "Breastfeeding is the best practice. Breast-milk is the ideal food for the healthy growth and development of infants and other children. It protects them from diarrhoea and from other illnesses" in cases of at least a third of the size of the product name characters, never smaller than 2mm in height;
 - (b) Have the word "WARNING" followed by: "Before deciding to supplement or substitute breastfeeding with this product, please consult a Healthcare professional. If you use a feeding bottle, it is likely that your baby will no longer want

breastfeeding. It is more hygienic to use a cup". In cases of at least a third of the size of the product name characters, never smaller than 1,5mm in height;

- (c) Include a feeding plan on the preparation instructions and inform that: "in case there are any leftovers of the infant formula, these must be disposed of".
- 2. It is forbidden to use terms such as "maternalized", "humanized" or similar terms on the packages and/or labels, and to make comparisons with breast-milk.
- 3. Breaches to the provided in paragraphs 1 and 2 of this Article are punishable with a fine equivalent to 15 monthly minimum wages for the first breach, a fine equivalent to 40 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 3 months, or even cancellation of the registration in cases of more than one reoccurrence.

ARTICLE 10

Labelling of Follow-on Formulas

- 1. Apart from the elements referred on point 1 of Article 8, the packages and/or labels of the follow-on formulas and of the complementary foods must compulsorily contain, in a well-placed location, readable and easy to see, the following elements:
 - a) An "IMPORTANT NOTICE" exactly the same as on sub-heading a) of paragraph 1 of the previous Article, with the same wording, distinction and same size cases;
 - b) A "WARNING" with the same distinction and size cases as in paragraph 1 of the previous Article with the following wording: "Before deciding to supplement or substitute breastfeeding with this product, please consult a Healthcare professional. It is very important for the health of your baby to follow carefully all preparation instructions. It is more hygienic to use a cup than a feeding bottle";
 - c) A distinct and clear statement saying that: "the product must not be used for children under six months of age";

d) Include a feeding plan on the preparation instructions and inform that: "in case there are any leftovers of the infant formula, these must be disposed of".

- 2. It is forbidden to use terms such as "maternalized", "humanized" or similar terms on the packages and/or labels, and to make comparisons with breast-milk.
- 3. Breaches to the provided on paragraphs 1 and 2 of this Article are punishable with a fine equivalent to 15 monthly minimum wages for the first breach, a fine equivalent to 40 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 3 months, or even cancellation of the registration in cases of more than one reoccurrence.

ARTICLE 11

Labelling of Condensed, Skimmed, Semi-skimmed and Integral Milk

- 1. The packages and/or labels of condensed or skimmed milk must compulsorily contain, on a well-placed location and easy to see, in cases of at least a third of the size of the product's name characters, never smaller than 2 mm in height, a NOTICE saying that: "This product is not for baby feeding".
- 2. It is expressly forbidden to include on condensed and sweetened milk labels indications that it is modified for infant feeding.
- 3. The packages and/or labels of semi-skimmed and integral milks must compulsorily contain, on a well-placed location and easy to see, in cases of at least a third of the size of the product's name characters, never smaller than 2 mm in height, a NOTICE saying that: "This product must not be used as a single source for feeding children under 3 years old".
- 4. As long as the provided on paragraphs 1 to 3 of this article is complied with, condensed, skimmed, semi-skimmed or integral milks are no longer covered by other provisions of this Code.
- 5. Breaches to the provided on paragraphs 1, 2 and 3 of this Article are punishable with a fine equivalent to 15 monthly minimum wages for the first breach, a fine equivalent to 40

monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 3 months, or even cancellation of the registration in cases of more than one reoccurrence.

ARTICLE 12

Labelling of Modified Products for Feeding Children Under 3 Years Old

1. Products that do not meet all requirements for infant feeding but that can be modified for this purpose must contain, on the package or label, a NOTICE saying: "this product is not adequate for baby feeding".
2. Breaches to the provided above are punishable with a fine equivalent to 10 monthly minimum wages for the first breach, a fine equivalent to 30 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 3 months, or even cancellation of the registration in cases of more than one reoccurrence.

ARTICLE 13

Labelling of Feeding Bottles and Teat cups

1. Apart from complying with all provisions of article 7, the packages and/or labels of the feeding bottles and Teat cups must compulsorily contain, in a well-placed location, readable and easy to see, the following elements:
 - a) An "IMPORTANT NOTICE" exactly the same as in sub-heading a) of paragraph 1 of article 9, with the same wording and distinction and same size cases;
 - b) A "WARNING" with the same distinction and same size cases as in sub-heading b) of paragraph 1 on article 9 with the following wording: "It is very important for the health of your baby to follow carefully all cleaning and sterilization instructions. It is more hygienic to use a cup to serve the foods";
 - c) A "WARNING" with the same distinction and same size cases as in sub-heading b) of paragraph 1 on article 9 with the following wording: "Children must not feed themselves alone with the feeding bottle for long periods";

- d) Instructions for cleaning and sterilizing the feeding bottle and Teat cups, using words and images or another form of graphic representation;
- e) Identification and address of the manufacturer or distributor, and production site.

2. Breaches to the provided above are punishable with a fine equivalent to 10 monthly minimum wages for the first breach, a fine equivalent to 30 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 3 months, or even cancellation of the registration in cases of more than one reoccurrence.

ARTICLE 14

Labelling of Teat cups and Pacifiers

1. Apart from complying with all provisions of article 7, the packages and/or labels of Teat cups and pacifiers must compulsorily contain, in a well-placed location, readable and easy to see, the following elements:
 - a) A "WARNING" with the same distinction and same size cases as in sub-heading a) of point 1 on article 9 with the following wording: "The use of Teat cups or pacifiers can interfere with breastfeeding";
 - b) Instructions for cleaning and sterilizing Teat cups and pacifiers, using words and images or another form of graphic representation;
 - c) Identification and the address of the manufacturer or distributor, and production site.
2. Breaches to the provided above are punishable with a fine equivalent to 5 monthly minimum wages for the first breach, a fine equivalent to 20 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 4 months, or even cancellation of the registration in cases of more than one reoccurrence.

CHAPTER IV

Storage and Sale of the Products covered by this Code

ARTICLE 15

Storage Conditions

1. Storage of the products covered by this Code must comply with the terms and conditions already established or to be established, for any of these types of products.
2. Breaches to the provided above are punishable with a fine equivalent to 10 monthly minimum wages for the first breach, a fine equivalent to 30 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 3 months, or even cancellation of the registration in cases of more than one reoccurrence.

ARTICLE 16

Sales Conditions

1. The sale, exhibit for sale, storage and any other form of marketing of the products covered by this Code is only permitted to manufacturers and/or distributors registered under the provisions of Chapter VIII in this Code.
2. Breaches to the provided above are punishable with a fine equivalent to 10 monthly minimum wages for the first breach, a fine equivalent to 30 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 3 months, or even cancellation of the registration in cases of more than one reoccurrence.

ARTICLE 17

Sale of expired products

1. The products covered by this Code, except for feeding bottles, Teat cups and pacifiers, exposed for marketing, must compulsorily contain the explicit indication of the expiry date.
2. Breaches to the provided above are punishable with a fine equivalent to 10 monthly minimum wages for the first breach, a fine equivalent to 30 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 3 months, or even cancellation of the registration in cases of more than one reoccurrence.
3. The sale and exhibit for sale of the products covered by this Code which have already reached the expiry date is expressly forbidden.

4. Breaches to the provided above are punishable with a fine equivalent to 15 monthly minimum wages for the first breach, a fine equivalent to 40 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 3 months, or even cancellation of the registration in cases of more than one reoccurrence.

CHAPTER V

Technical Standards of the Products covered by this Code

ARTICLE 18

Compliance with National and International Standards

1. The quality of food products is essential for the Health of infants and other children, wherefore the products covered by this Code must comply with the respective Mozambican Standards, or in the lack of these standards, with the CODEX and other relevant International Organization standards.
2. Breaches to the provided above are punishable with a fine equivalent to 15 monthly minimum wages for the first breach, a fine equivalent to 40 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 3 months, or even cancellation of the registration in cases of more than one reoccurrence.
3. The National Institute of Standardization and Quality (INNOQ) must identify the International Standards applicable to the subject-matter products of this Code as well as the sampling methods appropriate for the compliance verification, on a period of up to 12 months after its publication on the *Official Gazette*.
4. INNOQ must prepare and seek approval of the national standards for the products covered by this Code, up to 24 months after its publication on the *Official Gazette*.
5. INNOQ must develop a compliance assessment scheme for the products covered by the code.

ARTICLE 19

Exclusive Sale of intact Packages to Avoid Deterioration of Products

1. In order to prevent damage to the quality, tampering or contamination, the sale of dosages different from the original package and that imply opening and fragmentation of the packages and distribution into cups, mugs, boxes or other containers other than the original package of the products covered by this Code is expressly forbidden.
2. Breaches to the provided above are punishable with a fine equivalent to 10 monthly minimum wages for the first breach, a fine equivalent to 30 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 3 months, or even cancellation of the registration in cases of more than one reoccurrence.

CHAPTER VI

Responsibilities of the Healthcare Workers

ARTICLE 20

Specific Responsibilities of the Officers

1. The Healthcare officers, whether at the Central, Provincial and District level, must by all means promote the implementation of this Code and take all actions to stimulate, encourage, support, promote, value and protect breastfeeding and inform and give counselling to the remaining Healthcare workers regarding their duties and responsibilities and, particularly, ensure that they are familiarized with this Code with special focus on Chapters VI and VII.
2. Healthcare officers must also ensure that healthcare workers, their subordinates, assume their responsibilities and comply with their duties.
3. The non-fulfilment of the provided above will incur disciplinary sanctions.

ARTICLE 21

Promotion of Breastfeeding

1. All Healthcare workers must stimulate, encourage, support, promote, value and protect breastfeeding and disseminate its benefits compared to artificial feeding. They must also know this Code, particularly the provided for in Chapters VI and VII.
2. In particular, Healthcare workers must act in order to eliminate practices that directly or

indirectly interfere with the beginning and continuance of breastfeeding.

3. The non-fulfilment of the provided above will incur disciplinary sanctions.

ARTICLE 22

Forbidden practices

1. To any Healthcare worker and workers trade unions or associations, is expressly forbidden to:
 - a) Accept any sample, gift, contribution or benefit, financial or otherwise, of any value, from manufacturers or distributors of products covered by this Code or any other person acting on their behalf;
 - b) Accept or offer samples of products covered by this Code, to pregnant women, breastfeeding women, infant's or of children in schooling age mothers, family members or any other person;
 - c) Demonstrate the use of infant or follow-on formulas, except for mothers and other children's relatives, with very special needs, to which these products were prescribed by qualified Healthcare workers. In these cases, Healthcare workers must also clearly explain the risks of using infant or follow-on formula, as well as other required information in this Code.
2. Breaches to the provided above will incur disciplinary sanction (which may be from a simple registered punishment to expulsion) to the Healthcare worker or workers and to workers trade unions or associations responsible for these breaches. However, these breaches also apply to manufacturers, distributors or other people acting on their behalf who have induced Healthcare workers to commit the breach. For these, a fine equivalent to 15 monthly minimum wages for the first breach, a fine equivalent to 40 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 3 months, or even cancellation of the registration in cases of more than one reoccurrence, shall be applied.

ARTICLE 23

Communication Requirement

1. Healthcare workers and workers trade unions or associations that are exposed to attempts from manufacturers or distributors of products covered by this Code, or from any other person acting on their behalf to, as a breach to the provided above, receive samples, donations, gifts, contributions or benefits, financial or otherwise, to make demonstrations of the use of products covered by this Code, or even perpetrate any other breach to the provided in this Code, are obliged to report the occurred in writing to their immediate superior, who must pass this information onto the National Counselling Board as per provided on Chapter IX of this Code.
2. The lack of communication regarding the breach attempt as per above will incur disciplinary sanctions (which may be from a simple registered punishment to expulsion) to the Healthcare worker or workers and to workers trade unions or associations responsible for that concealment.
3. Manufacturers, distributors or other people acting on their behalf, responsible for the reported breaches are subjected to a fine equivalent to 15 monthly minimum wages for the first breach, a fine equivalent to 40 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 3 months, or even cancellation of the registration in cases of more than one reoccurrence.

ARTICLE 24

Previous Approval Requirement for Donations and Benefits to Healthcare Professionals or their Trade Unions or Associations

1. Any contribution from manufacturers or distributors of products covered by this Code or any other person acting on their behalf in favour of Healthcare professionals or trade unions or associations of healthcare workers, scholarships holder, subsidy for scientific research or for participation in technical and scientific and/or professional conferences, must be channelled through the Ministry of Health and requires previous approval from the Minister of Health.

2. Breaches to the provided above are motive for disciplinary sanctions (which may be from a simple registered punishment to expulsion) to the Healthcare worker or workers and to workers trade unions or associations responsible for these breaches. However, these breaches also apply to manufacturers, distributors or other people acting on their behalf who have conducted these illicit donations. For these, it shall be applied a fine equivalent to 15 monthly minimum wages for the first breach, a fine equivalent to 40 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 3 months, or even cancellation of the registration in cases of more than one reoccurrence.

CHAPTER VII

Information and Education

ARTICLE 25

Information and education of the Mothers and Public in general

1. The Ministry of Health has the obligation and responsibility of promoting breastfeeding and of formulating policies and strategies about infant feeding that are consistent and cohesive with the objectives of this Code, as well as ensuring to the families and the community in general the provision of objective and consistent information regarding the appropriate feeding methods of infants and children under 3 years old. Apart from the dissemination that this information may have on the side of the Central Organs of the Ministry of Health, they must be disseminated to the Provincial and District Health Directorates to whom generalized dissemination concerns, on an eventual collaboration with NGOs and other acknowledged institutions.
2. Written or audio-visual information and educational materials about infant feeding and destined to the general community, particularly to pregnant women and infant and children under 3 years old mothers, must be written in Portuguese or in Mozambican local languages and must be clear, easy to

read and understandable, so as not to cause any room for doubt.

3. The information and educational materials referred to above must carry correct and updated information and must not have photographs, drawings or other form of graphic representation of infants and/or children or any reference or suggestion likely to, directly or indirectly, discourage breastfeeding. These materials must never give the impression or lead to the belief that none of the products covered by this Code are equivalent or comparable to breast-milk and, far less that it may be better.
4. These information and educational materials cannot carry the name or logo of any other product covered by this Code, neither of the manufacturer or distributor of a product or products covered by this Code.
5. These information and educational materials must contain explicit information regarding the following aspects:
 - a) Huge benefits, advantages and superiority of breastfeeding;
 - b) Value of exclusive breastfeeding on the first six months of age and value of the continuity during two years or more;
 - c) How to initiate breastfeeding and keep it exclusive and how to maintain it;
 - d) Difficulty in breastfeeding again after a period of use of feeding bottles or mere breastfeeding interruption, even though it lasted for a short period;
 - e) Importance of the introduction of complementary foods from approximately six months;
 - f) How and why the introduction of foods through a feeding bottle or early introduction of complementary foods affects breastfeeding;
 - g) Complementary foods can be easily prepared at home using local ingredients.
6. Healthcare professionals responsible for the default of the provisions above will incur disciplinary sanctions.

ARTICLE 26


Information and Education about Infant and Follow-on Formulas

1. When the materials referred to in the previous article carry information regarding the use of infant, follow-on formulas or any other food or liquid that can be served on a feeding bottle, it must also include the following elements:
 - a) Instructions for adequate preparation and use of the product, including cleaning and sterilization of the used tools;
 - b) Instructions on how to feed infants with a cup;
 - c) Approximate financial cost of feeding an infant with such product, in the recommended amounts.
2. Healthcare professionals responsible for the default of the provisions above will incur disciplinary sanctions.

ARTICLE 27

Information and Education of Healthcare Professionals

1. The Ministry of Health has the duty of providing training, information and adequate technical and scientific orientations to Healthcare professionals regarding the products covered by this Code and of disseminating specific orientations so as to ensure the compliance with the provisions hereof by all Healthcare workers.
2. The manufacturers and distributors of the products covered by this Code can provide technical and scientific information about their products to Healthcare officers at the Central level and to Healthcare professionals of a higher level and solely to them, but this information must be limited only to specific technical and scientific aspects and to utilization methods of the product, they are also forbidden to make any reference to the equivalence or superiority of artificial feeding and the use of feeding bottle compared to breastfeeding.
3. The information referred to above cannot be accompanied by the provision of samples or other materials (including, but not limited to pens, calendars, posters, note books, growth charts, caps, t-shirts, badges, stickers and toys).

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4. That information cannot be accompanied by any kind of financial or material incentive, of any kind.
 5. Breaches to the provided on paragraphs 2, 3 and 4 of this Article are punishable with a fine equivalent to 15 monthly minimum wages for the first breach, a fine equivalent to 40 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 3 months, or even cancellation of the registration in cases of more than one reoccurrence.

ARTICLE 28

Approval of Information and Educational Materials by the Counselling Board

1. All information and educational materials referred to on the two previous articles must be submitted for assessment to the National Counselling Board for the Promotion and Protection of Breastfeeding before being disseminated, as per Chapter IX.
2. Healthcare professionals responsible for the default of the provided above will incur disciplinary sanctions.

CHAPTER VIII

Use of the National Health System Facilities

ARTICLE 29

Interdiction from Using the National Health System for purposes contrary to the ones in this Code

1. It is forbidden to use the National Health System and institution systems for the exhibit of products covered by this Code, as well as the setting or fixing of posters or advertising material related to such products or even for the distribution of materials provided by the manufacturers.
2. Breaches to the provided above will incur disciplinary sanctions (which may be from a simple registered punishment to expulsion) to the Healthcare worker and to workers trade unions or associations responsible for these breaches. However, these breaches also apply to manufacturers, distributors or other people acting on their behalf that have induced Healthcare workers to commit

the breach. For these, a fine equivalent to 15 monthly minimum wages for the first breach, a fine equivalent to 40 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 3 months, or even cancellation of the registration in cases of more than one reoccurrence.

ARTICLE 30

Responsibilities taken for making Demonstrations on the National Health System Facilities

1. In cases where there is technical reason for the use of breast-milk substitutes, the demonstrations of preparation and use of these products before the mothers or other family members of the child that need to use these products, will be from exclusive competence of Healthcare professionals, not allowed to be performed by persons directly or indirectly linked to the manufacturers or distributors of these products.
2. Breaches to the provided above are subject to punishment for the trading agents and the manufacturers and/or distributors, in command of who may have committed it. For them, a fine equivalent to 15 monthly minimum wages for the first breach, a fine equivalent to 40 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 3 months, or even cancellation of the registration in cases of more than one reoccurrence.
3. However, these breaches also give room for disciplinary sanctions (that may be from a simple registered punishment to expulsion) for the Healthcare worker or workers and for the Health Unit chiefs that have allowed the breach to happen.

CHAPTER IX

Implementation and Management

ARTICLE 31

Responsibilities of the Implementation and Compliance with this Code

1. The Ministry of Health is primarily responsible for the implementation of and ensuring compliance to this Code, but will benefit from the collaboration of the Ministry of Industry

and Trade on all things related to marketing matters. Whenever necessary, the Ministry of Health will require the collaboration of other structures of the State Apparatus to ensure the implementation of and compliance to this Code.

2. It is up to the Minister of Health, if required in collaboration with the Minister of Industry and Trade, to regulate the implementation of this Code by Ministerial Order.

ARTICLE 32

National Counselling Board for Promotion and Protection of Breastfeeding

1. The National Counselling Board for Promotion and Protection of Breastfeeding is created.
2. The National Counselling Board for Promotion and Protection of Breastfeeding is chaired by the Minister of Health and vice-chaired by the Vice-Minister of Health. On the absence or impairment of the President, the Council will be chaired by the Vice-President.
3. Apart from the President and Vice-President, the National Counselling Board for Promotion and Protection of Breastfeeding is composed by, inherently:
 - 3.1. Vice-Minister of Industry and Trade;
 - 3.2. National Health Director;
 - 3.3. National Trade Director;
 - 3.4. Director of INNOQ;
 - 3.5. National Health Deputy Director, responsible for the Community Health Area, who will be the Secretary;
 - 3.6. National Director for Women;
 - 3.7. National Director for Social Action;
 - 3.8. Director of the National Institute of Education Development;
 - 3.9. President of the National Board of Social Communication;
 - 3.10. Director of the Information Office next to the Prime Minister Office;
 - 3.11. Head of the Nutrition Unit of the Ministry of Health, that will assist the Secretary;
 - 3.12. Head of the Infant Health Section in the Ministry of Health;
 - 3.13. Head of the Public Health Education Unit in the Ministry of Health.

4. Apart from the members per inherence of roles, the Minister of Health will appoint 10 other members, namely, paediatricians, nutritionists, NGO officers and/or technicians and of cooperation Agencies with great interest on breastfeeding, officers of professional Healthcare workers associations, journalists or other specialists in Communications Science, that will serve in their individual capacity.
5. The appointments provided above are made for 3 years, eventually renewable. These appointments are made by Ministerial Dispatch published on the *Official Gazette* within 90 days of the date of publication of this Code on the *Official Gazette*.
6. The Minister of Health as well as the Vice-Minister of Industry and Trade can invite national or foreign experts to participate as observers on the National Counselling Board for Promotion and Protection of Breastfeeding.

ARTICLE 33

Conflict of Interests

1. The belonging of the National Counselling Board for Promotion and Protection of Breastfeeding is incompatible with the financial interests or of any other kind, on the manufacture or distribution of any product covered by this Code.
2. In these circumstances, any member of the National Counselling Board for Promotion and Protection of Breastfeeding, serving as inherence of roles or in their individual capacity, that has financial interests or of any other kind, direct or indirect, on the manufacture or distribution of any product covered by this Code, must declare it immediately so it can be replaced in those roles.
3. Breaches to the provided above are punishable as corruption, under the prevailing Legislation applicable Law.

ARTICLE 34

Allocation of the National Counselling Board for Promotion and Protection of Breastfeeding

It is the responsibility of the National Counselling Board for Promotion and Protection of Breastfeeding to:

- a) Give counselling to the Government in general and the Ministers of Health and of Industry and Trade, particularly regarding the national policy for promotion and protection of breastfeeding;
- b) Give counselling to the Ministers of Health and of Industry and Trade regarding the implementation of this Code, in relation to the:
 - Definition of the national strategy to develop communication and public education programs aiming the promotion of breastfeeding,
 - Preparation of information and educational manuals and of guidelines about infant feeding and feeding of children under 3 years old,
 - Formulation of further training programs for Healthcare professionals,
 - Approval of training curricula on Healthcare professions, on subject areas covered by this Code,
 - Disseminate this Code and its promotion, in vast ways;
 - All matters related to this Code.
- c) Examine the information materials submitted in accordance with Article 27 and recommend adequate actions, including disciplinary actions, when reasonable;
- d) Raise information regarding eventual breaches to this Code and examine all such information and reports taking the necessary steps including recommend adequate sanctions if the case may be;
- e) Issue instructions for inspectors regarding the actions to be taken, or initiate those actions, depending on the case, against any person that breaches or attempts to breach the provisions of this Code or the promulgated rules hereunder;

- f) Create provincial committees, experts committees to better perform the roles of this Board and designate experts to conduct studies related to the matters arising from the implementation of this Code;
- g) Give opinion on all submitted subjects of the set of objectives of this Code, by the Ministers of Health and of Industry and Trade.

ARTICLE 35

Beginning of roles of the National Counselling Board for Promotion and Protection of Breastfeeding

The National Counselling Board for Promotion and Protection of Breastfeeding will start their functions as soon as their members assigned on their individual capacity have been empowered, and this must occur no later than 150 days after the publication of this Code on the *Official Gazette*. This beginning of functions of the National Counselling Board for Promotion and Protection of Breastfeeding, even before the enforcement of the Code provisions is very important, so that it can assist the Ministers of Health and of Industry and Trade on the steps to take regarding the preparation for the enforcement of the set of provisions of the Code.

ARTICLE 36

Record of the Products Covered by this Code

1. All manufacturers and/or distributors or other agents that aim to be involved on the sale, exhibit for sale, storage and any other marketing form of the products covered by this Code must first register on the Ministry of Health, which will create a mechanism for the registration of manufacturers and/or distributors, issuing Registration Certificates of the approved manufacturers and/or distributors.
2. The mentioned agents above must also first register in the Ministry of Health each of the products they aim to market, presenting a complete documentation of the respective product, its manufacturing process, packaging, labelling, and eventually samples of the product for the purposes of laboratory

analysis so as to prove that the product is in compliance with the provisions herein and the prevailing standards. The Ministry of Health will also create a unique mechanism for the registration of products covered by this Code and will issue a Registration Certificate whenever the product meets the requirements of this Code.

3. Before the complete entry in force of this Code, the import or manufacture of products covered by this Code that have not been registered as per above is not allowed in national territory.
4. Breaches to the provided above are punishable with a fine equivalent to 10 monthly minimum wages for the first breach, a fine equivalent to 30 monthly minimum wages for cases of reoccurrence and suspension of activity for 1 to 3 months, or even cancellation of the registration in cases of more than one reoccurrence.
5. It is responsibility of the Ministry of Industry and Trade and of the National Customs Directorate to promote and monitor the implementation of the provided on point 3 of this Article.

ARTICLE 37

Inspection and Inspectors

1. The Ministries of Health and of Industry and Trade will resolve by Ministerial Dispatch who will bear competences for conducting Inspection actions, who may apply fines and who may determine activity suspension or cancellation of registration.
2. Conflict of interests referred on Article 32 herein is also applicable to workers designated to or that wish to perform inspector roles, whereof, if any of these workers have financial interests or of any other kind, direct or indirect, on the manufacture or distribution of any product covered by this Code, must proceed with the indication on paragraph 2 of the referred Article.
3. The Ministries of Health and of Industry and Trade will resolve by Ministerial Order the procedures for conducting inspection actions (to assess the compliance with the rules) and for the application of sanctions.

ARTICLE 38

Organization of Penalties Record

It is the responsibility of the Ministry of Health to organize a record system of the applied penalties, where the names or designations of the defaulters (natural or legal persons), nature of the breach, indication of the mitigating or aggravating circumstances of the breach, particularly if it is a first breach or reoccurrence, applied penalties and other elements deem fit will be registered.

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MINISTRY OF HEALTH

Ministerial Order no. 130/2007 of October 3rd

Being required to regulate the composition of Health Boards and using the conferred competencies as per paragraph 4 of article 19 of the Ministerial Order no. 94/97 of October 24, I resolve:

Sole. The Health Board Regulation attached hereto is approved, which is an integral part of this Ministerial Order.

Maputo, April 27, 2007. – Minister of Health, *Paulo Ivo Garrido*.
