Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

July 1, 2000

ADMINISTRATIVE ORDER
No. 3-B s. 2000

SUBJECT: Guidelines for assistance/sponsorship by manufacturers of products covered by Executive Order 51 (Milk Code).

The following guidelines are issued for the guidance of all concerned in the implementation of the Milk Code (E.O. 51), particularly the provisions pertaining to the assistance and/or sponsorship of research, scholarship, continuing education and donations by manufacturers of products covered by the Milk Code.

Section I — Legal Mandates

For approval of donations from manufacturers/distributors of products within the scope of the Code.

This is embodied in the following:

Section 6 (b)

“Manufacturers and Distributors shall not be permitted to give directly or indirectly, samples and supplies of products within the scope of the Code or gifts of any sort to any member of the general public, including their families, to hospitals and other health institutions as well as to personnel within the health care system, save as otherwise provided in the Code".

Section 6 (f)

“Nothing herein contained shall prevent donations from manufacturers and distributors of products within the scope of this Code upon requests by or with the approval of the Department of health".

Section 8 (e) -
“Manufacturers and distributors of products within the scope of this Code, may assist in research, scholarship and continuing education, of health professionals, in accordance with the rules and regulations promulgated by the Department of Health".

Despite the issuance of this circular and other previous related guidelines, an increasing concern over the availment of assistance or sponsorship by milk manufacturers for certain health activities has been noted. Through the thirteen years of the implementation of the Code, it has been noted that there has been growing dependence by professional organisations/ other parties on the assistance given by these manufacturers.

It is therefore imperative that guidelines on sponsorship be revised and updated to include requirements as well as monitoring mechanisms.

II — Definition of Terms

1. Continuing education shall refer to training courses, workshops, seminars, scientific conferences and conventions for purposes of scientific updates and professional advancement.

2. Training shall refer to residency or post- residency training for purposes of acquiring specialization on a chosen field.

3. Research/Clinical Trials shall refer to investigative or experimental studies in the field of Maternal and Child Health and Nutrition.

4. Donation shall refer to (a) products within the scope of Code, like milk formula, feeding bottles and teats; and (b) equipment, like weighing scale, stethoscope, sterilizer, and autoclave) materials and other related items given for free.

5. Convention kit shall refer to an envelope container of whatever material that serves as holder of important convention journals, publications and handouts.

III — Scope

These guidelines pertain to the following activities sponsored by manufacturers/distributors of breastmilk substitutes, breastmilk supplements and other related products, i.e. feeding bottles, artificial nipples/teats and pacifiers.

1. Continuing education activities, e.g. scientific meetings, conferences and conventions.

2. Training
2.1 Residency training
2.2 Post- residency training

3. Researches/Clinical Trials/Experimental studies

4. Donations
4.1 Milk and related products
4.2 Materials and equipment

IV - Assistance/ Sponsorship from Milk Manufacturers and Distributors

A. Continuing Education

1. General Policies

1.1 It is the responsibility of health facilities and professional organizations to provide continuing education to their staff and members. They may seek assistance from manufacturers of covered products after exhausting all resources.

1.2 Continuing education which have long term benefit to the most number of persons in the health facility or professional organizations shall be encouraged, while those that have short-term individual benefits such as business meetings, fellowship nights may be allowed provided they are contributory to the attainment of the continuing education activity.

1.3 Any allowed assistance to health facilities by the different manufacturers shall be pooled and coursed through the training committees of these institutions and not to a particular individual.

1.4 Any assistance for attendance to local/foreign post-graduate courses, conventions or seminars, to local chapter of professional national organization who shall decide and determine the participant entitled to any privilege. Such organization shall be responsible in monitoring their attendance.

The following items maybe allowed for sponsorship:

a) Food and venue in accordance with the prevailing rate, provided there is no registration fee collected.
b) Transportation and accommodation of main international/local speakers.
c) Streamers, flyers and posters
d) Convention kits

Note: Streamers, logo, posters and convention kits shall not bear the logo and brand name of the product covered by the Milk Code.

1.6 Researcher/Medical Officer employed by milk companies may participate during continuing education activities as lecturers provided topics are related to the program and do not undermine the benefits of breastfeeding.

2.4 Justification for the need to undergo postgraduate specialty training from the requesting institution.

2.5 Report of training, using prescribed report format shall be submitted yearly and within 30 days alter the completion of the residency.

C. Research and Clinical Trial

1. General Policies

1.1 The International Ethics Policies on Researches in Children shall be adopted as follows:
1.1.a Researches using well-infants/ children as subjects shall be limited to physiologic studies, which should not be harmful to infants.
1.1.b Researches using ill-infants/ children as subjects shall be limited to therapeutic studies with potential benefits for the particular subject.
1.2 If there is really a need for local study, this will be subject for renewal based on prevailing international studies/standards.

1.3 Clinical trials/evaluation shall be conducted in accordance with the approved protocol.

1.4 Recipients (individual/organization/group) shall not allow themselves to be used directly or indirectly for any promotional activity related to products within the scope of the Code such as display of posters and streamers patronizing the company and their products or be used as lecturers in the promotion of the products to idealize bottlefeeding.

1.5 Assistance/sponsorship for research projects, clinical trials and fellowships shall be reviewed and approved by the Office for Public Health Services.
1.5.1 Criteria for approval

1.5.1.1 Researches or studies whose outcome shall have valuable contribution to the field of Maternal and Child Health.
1.5.1.2 Researches involving infants as subjects:
1.5.1.2.a Well infants as subject- the research study is limited to physiological studies which should not be harmful to infants.
1.5.1.2.b Ill infants as subject- the research study shall be limited to therapeutic studies with potential benefits for the particular subject.

1.6 The regional, provincial or city Milk Code Monitoring Task Force may check on the progress or may assess and evaluate the approved research anytime during its actual conduct.

1.7 For transparency purposes, disclosure of sponsoring company maybe done through verbal declaration during the public presentation of the research or through acknowledgment upon publication of the research results.

2. Approval of Assistance for Health and Health—Related Researches

2.1 Eligible recipients for research assistance/ sponsorship include health workers in the government/ private sector who are required during their residency training/ fellowship to come up with research studies and or who are in the field of research.

2.2 Requirements
2.2.1 Duly accomplished application form for concerned official at different appropriate level for approval.
2.2.2 Research protocol
2.2.3 Budget
2.2.4 Screening of research protocol
2.2.5 A report of the outcome of the research shall be submitted to the Office for Public Health Services two (2) months afier the completion of the study and before disclosure to the public copy furnished Essential National Health Research (ENHR).

B. Milk Donation

1. General Policies

1.1 Donations are allowed only on the following:

1.1.1 Non-profit institutions, duly accredited by DSWD orphanages who care for abandoned orphaned infants and children.

1.1.2 In times of calamities, disaster or emergencies, provided the guidelines for their distribution and utilization are observed.
1.1.3 Donations should only be the last report when other means such as human milk banking and wet nursing have failed after reasonable effort.
1.1.4 Babies with inborn errors of metabolism

1.2 Criteria for Approval
1.2.1 Requesting institution shall be duly licensed by Security and Exchange Commission (SEC).
1.2.2 Donated products shall meet Bureau of Food and Drug (BFAD) standards.
1.2.3 Ocular inspection shall be done by DOH representative from concerned level to validate donations, organization and target beneficiaries.

1.3 Allowable Quantity
1.3.1 Total supply requirements for 6 months to 1 year based on the number of actual beneficiaries.

1.3.2 In institution where breastfeeding is not possible, donation is allowed depending on the amount or quantity the donor can provide.

1.4 The Milk Code Monitoring Task Force at different levels shall conduct monitoring activity on the utilization/ consumption of the donated products.

2. Requirements

2.1 Duly accomplished DOH request form addressed to any of the following for approval:

a.) Assistant Secretary for Public Health Services- National Level
b.) Regional Health Director- Regional Level inc. Metro Manila
c.) Provincial Health Officer- Provincial/ Municipal Level
d.) City Health Officer- City Level

2.2 In case of request for special milk formula, attach the latest laboratory result of the prospective beneficiary/ies.

C. Materials and Other Related Items

1. General Policies

1.1 Duly accomplished request form for concerned officials at different level for approval.

1.1.1 Criteria for approval
1.1.1.1 Submission of all requirements
1.1.1.2 The institution should have passed DOH criteria for good rooming-in and breastfeeding practices;
1.1.1.3 No name/ no logo of the donating company nor brand names of covered product within the scope of the Code on the donated items;

V- The Role of Infant Milk Producing Companies in Support to Breastfeeding Promotion

1. Creation of a National Committee for the Promotion of Breastfeeding.

2. Milk Formula companies are encouraged to participate in the development, production and distribution of Information, Education and Communication (IEC) material on Breastfeeding with consultation of the Inter-agency Committee (LAC) on Milk Code and support tri-media campaign on Breastfeeding of the Department of Health.

3. Milk formula companies are encouraged to sponsor trainings, workshop, seminars to promote breastfeeding among all pre-service training of health workers.

VI- Implementing Mechanism

A. Structure

1. National Level:

At the National Level, a Milk Code Monitoring Task Force shall be created, chaired by the Assistant Secretary of Office for Standards and Regulations and membership drawn from various offices of DOH. It has the following functions:

1.1 Monitor compliance as well as problems encountered in the implementation of the Milk Code.

1.2 Reviews/ verifies/ acts on reports of violations of the provisions of the code from the national and field levels.

1.3 For violations committed at the national level, an investigation shall be conducted by the Legal Office of the Department of Health and findings submitted to the Undersecretary for Standards and Regulation for appropriate action.

2. Regional/ Provincial/ City Levels:

1. In the field, the task of monitoring shall be the primary responsibility of the Regional Health Director and Provincial/ City Health Officers in collaboration with the Regional/ Provincial/ City Council for Health concerns.

2. A Task Force shall be created at the regional/ provincial/ city level composed of representatives of DOH, other GOs, and NGOs. A regional/ provincial/ city Food and Drug Regulation Officer (FDRO) shall be designated to head the Task Force and shall serve as the focal group in charge of coordinating and monitoring activities relevant to the field implementation of the Milk Code.

3. The Task Force shall verify reports of violation of Milk Code.

4. Monitors labels of products within the scope of the Code and marketing practices in various distribution centers.

5. Problems/ violations arising at the field levels shall be investigated and resolved at these levels whenever appropriate to institute prompt and timely actions. Only cases that require prosecution shall be elevated to the National Level.

6. Provincial/ City Task Force shall submit reports to the Regional Health Director and consolidated quarterly report to be submitted to the National Task Force, Office of Standards and Regulations.

B. Sanctions

1. Reports of finding, decisions and actions taken shall be sent and forwarded to the Office of Undersecretary for Standards and Regulations through the Milk Code Monitoring Task Force.

2. In cases of repeated violations which require the application of sanctions, the Regional Health Director shall conduct an investigation of the violations and submit a report of the findings and

recommendation to the Undersecretary for Standards and Regulations through the Milk Code Monitoring Task Force for appropriate action.

3. For any violation of this Department Circular, sanctions will be imposed based on the provisions of Department Circular 24 s. 1987 which cover the implementing guidelines of the Milk Code.

VI— Repealing Clause

This Order repeals Department Circular No. 58- A s. 1994 and other related orders inconsistent herewith.

VII- Effectivity Clause

This Order takes effect immediately.

ALBERTO G. ROMUALDEZ, JR., MD.
Secretary of Health