"Infant Milk" should read as "Mother's Milk"

The Mother's Milk Substitutes (Control of Sale and Distribution) Regulation, 1994 (2051)

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In exercise of the powers conferred by Section 17 of the Mother's Milk Substitutes (Control of Sale and Distribution) Act, 1994 (2051), His Majesty's Government has framed the following Rules.

1. Short title and commencement:

(1) These rules may be cited as the "Mother's Milk Substitutes (Control of Sale and Distribution) Regulation, 1994 (2051)".

(2) This Regulation shall come into force at once.

2. Definitions:

Unless the subject or the context otherwise requires, in this Regulation:

(a) "Act" means the Mother's Milk Substitutes (Control of Sale and Distribution) Act, 1994 (2051).

(b) "inspector" means the person appointed or designated pursuant to sub-section (1) of section 13 of the Act.

3. Supervision:

For the protection and promotion of breastfeeding, the committee may itself or through subcommittees or inspectors supervise or

cause to be supervised as to whether the health care system, health worker and the manufacturer or distributor have observed the provisions required to be observed under the Act and this Regulation.

4. Application for approval:

(1) If a health care system or another institution or organization intends to obtain any product from a manufacturer or distributor for a value less than its retail price or as a grant pursuant to sub-section (7) of section 9 of the Act, the system or institution or organization shall make an application, setting out the reasons for and objectives thereof, to the committee in the format as referred to in schedule-1 for the approval of the committee.

(2) If a manufacturer or distributor intends to donate any equipment or goods to the health care system pursuant to sub-section (9) of section 9 of the Act, an application shall be made to the committee in the format as referred to in schedule-2 for the approval of the committee.

(3) If the health worker intends to obtain from a manufacturer or distributor a scholarship or research grant or such amount as required to organize a professional symposium or conference or to participate in the symposium or conference the worker pursuant to sub-section (11) of section 9 of the Act, the worker shall make an application to the committee in the format as referred to in schedule-3 for the approval of the committee.

5. Approval:

(1) If an application is made under sub-rule (1) of rule 4 and the committee, after making necessary inquiry into the matters, considers it reasonable to give approval, it shall give approval, also specifying the terms and conditions to be observed by the health care system or institution or organization obtaining the product as mentioned in the application.

(2) If an application is made under sub-rule (2) of rule 4 and the committee, after making necessary inquiry into the matters, considers it reasonable to give approval, it shall give approval, also specifying the terms and conditions to be observed by the manufacturer or distributor providing any equipment or goods as mentioned in the application.

(3) If an application is made under sub-rule (3) of rule 4 and the committee, after making necessary inquiry into the matters, considers it reasonable to give approval, it shall give approval, also specifying the terms and conditions to be observed by the health worker to obtain any scholarship or research grant or amount.

(4) The committee shall give the approval as referred to in sub-rule (1) or (2) or (3) no later than thirty days after the date on which an application has been made for such approval.

6. Certification of product:

(1) Prior to the marketing of any product, other than a feeding bottle and nipple, its manufacturer or distributor shall, for the certification of such product, make an application, accompanied

by a sample of that product and the fees prescribed by the committee, to the central food laboratory, in the format as referred to in schedule-4.

(2) If an application is made under sub-rule (1) and the central food laboratory, after making necessary inquiry into the matters, considers that the concerned product conforms to the standard specified or recommended by the Bureau of Nepal Standards and is fit for consumption by the human being, it shall certify such product no later than three months after the date on which such application has been made.

7. Approval of label:

(1) Prior to the marketing of any product, its manufacturer or distributor shall make an application in the format as referred to in schedule-5, accompanied by its label, to the committee for the approval of the label.

(2) If an application is made under sub-rule (1) and the committee considers that all the matters required to be specified under sub-section (6) of section 11 of the Act are specified on it, the committee shall give approval for such label no later than thirty days after the date on which such application has been made.

8. To maintain records:

The committee shall maintain records of all matters approved by it pursuant to rule 5 or 7.

9. Delegation of powers:

The committee may delegate any powers conferred to it under the Act and this regulation to a sub-committee formed pursuant to clause (h) of section 6, member secretary of the committee or any other employee.

10. Identity card:

(1) Every inspector shall be provided with an identity card as referred to in schedule-6.

(2) The inspector shall always keep his identity card with him and show it immediately when any person intends to see it when he performs any act or exercises the powers conferred to him under this Regulation.

11. Inspection:

(1) The inspector shall, at least twice a year, inspect the maternity homes, maternity and infant theatres of hospitals, health service centers, offices and clinics of medical practitioners, other health care systems and offices of health workers and manufacturing sites, warehouses or offices of manufacturers and distributors under his jurisdiction and inquire into whether the matters required to be observed under the Act and this Regulation have been observed.

(2) If, for purposes of carrying out inspection and inquiry pursuant to sub-rule (1), the inspector is to enter the house and compound of any person, he may enter such house and compound by giving a notice to the concerned person by giving a notice to the concerned person in accordance with the prevailing law.

(3) If the inspector request any local body, administration, police or other person for assistance for purposes of carrying out inspection and inquiry or entering the house and compound of any person pursuant to sub-rules (1) and (2), all the concerned shall render assistance to him.

12. Powers to give direction:

(1) If, upon inspection and inquiry carried out pursuant to rule 11, it appears that any irregularity has been committed in any maternity home, maternity and infant theatre of a hospital, health service center, office and clinic of medical practitioner or any other health care system, the inspector may give necessary direction to remove such irregularity or improve the services provided therein.

(2) The chief of the concerned maternity home, hospital, health service center and health care system and the medical practitioner shall observe the direction given by the inspector pursuant to sub-rule (1).

13. Submission of report:

Following inspection and inquiry carried out pursuant to rule 11, the inspector shall prepare an inspection report setting out the direction given by him pursuant to rule 12 and his suggestions, as well as other matters considered by him, and submit the report to the committee.

14. Alteration in schedules:

His Majesty's Government may, as per necessity, make alteration in the schedules, by a notification published in the Nepal Gazette.

Schedule-1

(Relating to sub-rule (1) of rule 4)

Date:

The breastfeeding protection and promotion committee,

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Dear sirs,

I/we have made this application for approval to obtain the following product for a value less than its retail price or as a grant form the following manufacturer or distributor.

(a) Name of manufacturer or distributor:

(b) Address:

(c) Name of product:

(d) Quantity:

(e) Value:

Applicant's:

Signature:

Name:

Designation:

Schedule-2

(Relating to sub-rule (2) of rule 4)

Date:

The breastfeeding protection and promotion committee,

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Dear sirs,

I/we have made this application for the approval of that committee to provide a grant of the following equipment or goods to the following health care system.

(a) Name of health care system:

(b) Address:

(c) Description of equipment or goods:

(d) Quantity:

(e) Value:

(f) Name of manufacturer or distributor:

(g) Address:

(h) Main objectives and reasons for providing grant:

Applicant's:

Signature:

Name:

Designation:

Schedule-3

(Relating to sub-rule (3) of rule 4)

Date:

The breastfeeding protection and promotion committee,

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Dear sirs,

I/we have made this application for approval of that committee to obtain from the following manufacturer or distributor a scholarship or research grant or such amount as required to organize a professional symposium or conference or to participate in the symposium or conference.

(a) Name of manufacturer or distributor:

(b) Address:

(c) Description relating to scholarship or research:

(d) Amount required for scholarship or research:

(e) Description relating to professional symposium or conference:

(f) Venue where symposium or conference is held or organized:

(g) Date when symposium or conference is held or organized and duration:

(h) Amount required to organize or participate in symposium or conference:

(i) Description relating to qualifications of applicant:

(j) Address:

Applicant's:

Signature:

Name:

Schedule-4

(Relating to sub-rule (1) of rule 6)

Date:

The breastfeeding protection and promotion committee,

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Dear sirs,

As I/we need certification of the following product, I/we have made this application, accompanied by a sample of product and necessary fees, for certification of that product.

(a) Name of manufacturer or distributor:

(b) Address:

(c) Name of product:

(d) Means of product:

(e) Analysis and composition of product:

(f) Whether the product's label has been approved or not:

(g) If so approved, date thereof:

Applicant's:

Signature:

Name:

Designation:

Schedule-5

(Relating to sub-rule (1) of rule 7)

Date:

The breastfeeding protection and promotion committee,

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Dear sirs,

I/we have made this application to obtain approval of that committee on the label of the following product.

(a) Name of manufacturer or distributor:

(b) Address:

(c) Name of product:

(d) Whether the certification of product label has been obtained or not:

(e) If certification has been so obtained, date thereof:

Applicant's:

Signature:

Name:

Designation:

Schedule-5

(Relating to sub-rule (1) of rule 10)

His Majesty's Government

Ministry of Health

The inspector's:

Name: Identity card No.:

Signature: Date:

Jurisdiction: -------Districts

Identity card issuing authority's:

Name:

Signature:

Designation:

Inspector's photograph

Office seal: (also over the photograph)