Report

Consultative meeting on

'Protection of Breastfeeding & Child Nutrition Ordinance 2002'

TheNetwork
for Consumer Protection

Contents

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Preamble:

Breastfeeding forms a focal point of infant health protecting the child from a plethora of diseases including diarrhea and malnutrition. It saves 6 million lives of infants in developing countries annually and can save another 1.5 million infants each year if every infant was exclusively breastfed. Infants who are not breastfed are up to 14 times more likely to die from diarrhea compared to those who are exclusively breastfed.[1]

Having recognized the link between breastmilk substitutes and infant mortality UNICEF and WHO developed 'International Code of Marketing of Breastmilk Substitutes' in 1981 which aims to 'contribute to the provision of safe and adequate nutrition for infants…. through appropriate marketing and distribution (of breastmilk substitutes)' and does not allow any form of

1. Breastfeeding saves lives: NUTURE and Institute of Reproductive Health June 1996.

advertising and promotion to the general public including health care providers. Pakistan was amongst the 118 countries who endorsed the 'Code' in May 1981. 17 countries including India, Iran, Nepal, Sri-Lanka and Bangladesh have also adopted this 'Code' as a national legislation, since then.

Pakistan in October 2002 also translated the 'Code' into legislation by the promulgation of an Ordinance entitled, 'Protection of Breast-feeding and Child Nutrition Ordinance 2002'.

Considering the fact that 51% infants in Pakistan suffer from moderate to severe malnourishment and despite a breast-feeding culture, only 16% of infants are exclusively breast fed till the age of 3 months[2], the implementation of the 'Ordinance' needs to be carefully drafted and monitored in order for it to be effective in addressing the issue.

One of the factors which greatly undermines the ability of mothers to breast feed is the promotion of breast milk substitutes. The expenditures on imported formula grew from US$ 4 million in 1982-83 to almost US$ 44 million by 1995-96[3]. One of the leading manufacturers of breastmilk substitutes poured US$ 1.15 million for its promotional campaigns in Pakistan in year 1997[4].

The Breastfeeding project of TheNetwork for Consumer Protection has been actively engaged in the advocacy of the 'Ordinance' and has followed its various steps of development and promulgation. The 'Ordinance' is now in its implementation phase for which rules and regulations are being developed. Though the 'Ordinance' has different areas which are not consistent with the 'Code'. Carefully worded rules and regulations may be helpful in decreasing the gaps present in the 'Ordinance'.

2. State of the World's Children 2001 UNICEF
3. Breastfeeding, Foundation for a healthy future, UNICEF 1999.
4. Advertising age, Magazine

A consultative meeting of important stake holders was arranged by TheNetwork for Consumer Protection in which representatives of the National Breastfeeding Steering Committee (NBSC), Federal Steering Committee on Breastfeeding (FSCBF) Pakistan Pediatric Association (PPA), WHO Consultant, Ministry of Health and health professionals, who have been associated with the breastfeeding project over the years, were invited. The support of NBSC, and PPA has been critical in the promulgation of the 'Ordinance' as well.

Objectives of the meeting

1. To develop an understanding of the different clauses of the 'Ordinance' with an aim to assess its weaknesses and strengths.
2. To highlight the different sections for which rules and recommendations should be developed in order to improve the effectiveness of the 'Ordinance'.

List of participants

The meeting was held in the office of TheNetwork for Consumer Protection on the 21st of January 2003. The following attended the meeting:
(in alphabetical order)

1. Dr. Asad Hafeez
2. Mr. Aziz ur Rehman
3. Prof. D S Akram
4. Dr. Ehsan Latif
5. Prof. Dr. Iqbal Memon
6. Prof. Dr. Khawaja Abbas
7. Prof. Dr. Mehar Taj Roghani
8. Mr. Nadir Altaf
9. Dr. Rashid Zar
10. Ms. Rukhsana Faiz
11. Ms. Samina Zafar
12. Mr. Abdul Sattar Choudhary
13. Dr. Shabina Raza
14. Dr. Zafar Mirza

Proceedings

1. Dr. Zafar Mirza, Executive Coordinator for TheNetwork for Consumer Protection presented the need for an effective Breastfeeding Protection Ordinance and its implementation and introduction of the various efforts of the breastfeeding project for the promulgation of the 'Ordinance'.

2. A thorough anatomy of the Protection of Breastfeeding and Child Nutrition Ordinance 2002, was presented by Nadir Altaf, an advocate and program coordinator of the Law and Governance Unit of TheNetwork for Consumer Protection followed by a discussion on various aspects of the Ordinance, with identification of areas where the rules and regulations could serve to bridge some gaps in the 'Ordinance'.

3. Recommendations for the future course of action and collaboration in the advocacy efforts for the implementation of the 'Ordinance'.

The presentation of Dr. Zafar Mirza highlighted the various international moves for the protection of breastfeeding and linked the effectiveness of the International Code of Marketing of Breastmilk Substitutes in terms of developing national legislations. He also cited the SAARC Code of August 1996 and the history of the development of the law in Pakistan on the protection of breastfeeding which was shared by the Ministry of Health in 1992.

It was also emphasized that this meeting was not a formal meeting amongst different institutions or organizations rather it was a gathering of participants from various organizations and people who have been associated with the work of TheNetwork for Consumer Protection in one form or another.

Prof. Iqbal Memon wanted a more formal involvement of the PPA as every member of PPA was committed to

the issue and would have contributed positively for the development of regulations.

1. Prof. Memon also restated for the record that he was invited as Gen Sec PPA and has responded as well. He was representing PPA as the code is a major task and commitment of PPA.

2. It was also reiterated that PPA, a body of over one thousands technically sound promoters of Breastfeeding and Nutrition, should have representation [at least one or more] in the Board or Committees formed for such a purpose;

General Recommendations:

The presentation of Mr. Nadir received an input from all the participants and these suggestions/ recommendations were recorded for incorporation into the final text. The detailed section wise comments are given as annexure (I) while some important recommendations are as follows:

1. *Recognizing* the importance of the 'Ordinance' it was suggested that TheNetwork should form a coalition between PPA, NBSC, PBSC and others to bring everyone on an even footing.
2. *Elaborating* the role of the provincial governments, it was emphasized that the provincial governments should be given a more pro-active role in the development of rules and regulations.
3. *Specifying* the role of the lady health visitors and lady health workers, it was recommended that they should be included in the definition of the health worker and/or health professional and be included while enumerating these in the rules and regulations.
4. *Identifying* the scope of the 'Ordinance', it was decided that it deals primarily with the marketing practices of the all kinds of Breastmilk Substitutes and complementary foods but not foods in general and the recommendations should be made in this conjecture.

Chapter II

5. *Agreeing* that there is no role of the commercial sectors in the protection of the breastfeeding which is described in Section 3 sub 2, "at least one member of the board/committees shall be selected from the industry" it was recommended that these should not be any presence of industry people in the committees and board on breastfeeding.
6. *Declaring* the term 'professional qualified' used in section 3 sub 2 as being vague, there is a need to fix the parameters of professional qualification in the rules of the Ordinance.

Chapter III

7. *Recognizing* the role of board and committees like the BFSC, it was suggested that all board and committees under this 'Ordinance' should have a role of regulatory nature instead of merely an advisory one and the rules of the 'Ordinance' should explicitly address the board and committees' constitution, relationship with each other, their working procedures, quorums, time frame for investigation, meetings etc.
8. *Deliberating* on the reporting of violations under the 'Ordinance', the question of the relevance of legal forums to be exhausted was discussed and it was decided that criminal courts should take cognizance under the 'Ordinance'. However, it was decided with consensus that special arrangement for redressal procedure should be clearly defined in the rules and regulations section of the 'Ordinance'. The doctors should be answerable to their registration authority (PMDC) and should be litigated against in a civil court under the violations of this 'Ordinance'.

Chapter IV

9. *Defining* the health professional in section 2 sub O, this right should be restricted only to qualified persons such as physicians and nutritionists. This is more important in the light of the fact that such a material is only made available after approval from the committees suggested under the 'Ordinance'.

10. *Recommending* that bottles and teats should also be subject to warnings due to their non-safe nature, it was suggested that the rules should be extended to include these as well.

Chapter V

11. *Assessing* the nature of the Breastmilk Substitutes, it was recommended that it should be treated like a prescription drug and a statement to that effect should be given on the label as a warning.

12. *Considering* the development of the guidelines for the warnings for the labels of Breastmilk Substitutes it was suggested that guidelines should be established while developing the rules and regulations.

13. *Mentioning* the term "medical literature" in Section 9 sub 3, the need to be more explicit in the definition through the process of rules was agreed upon by the group.

14. *Identifying* the need to remove any disparity in the terms in Section 10 sub 4 the rules should define and explain what constitutes "a gift" or "financial benefit" and what is the time period in which health workers is required to report to the board about any such offer?

15. *Acknowledging* the utility of a proper mechanism for taking cognizance of violations under the 'Ordinance' it was recommended that the procedure of such a mechanism should be clearly outlined in the rules to be developed under the 'Ordinance'. The right to file a case under section 13 is reserved to federal government only, it was recommended to extend this to provincial government as well.

Chapter V

16. *Elaborating* on the role of different tiers in complaint handling for the violations under this 'Ordinance', the group agreed that the board to be setup under this 'Ordinance' should take notice of violations on its own, the role of the 'inspector' should be clearly defined under the rules, person held responsible and who is liable to pay the fines should also be defined in case of a violation by a company or a manufacturer, A maximum time period should also be defined in which the 'board' has to execute some kind of action on the receipt of a complaint.

Recommendations for the future:

The group recommended following actions at the conclusion of the meeting.

1. TheNetwork to enter into a more formal relationship with PPA, Breastfeeding steering committees and other stake holders including representatives of nursing profession, family medicine and gynecologists for developing and arranging a more effective group for the implementation and monitoring of the 'Ordinance'.

2. Guidelines for PMDC to be developed by the input from the group which attended the meeting.

3. TORs for the committees to be developed at the earliest.

4. Dissemination of this report after finalization to all concerned.

Sections on which rules and regulations need to be developed.

Section 3.	National Infant Feeding Board and Provincial Infant Feeding Committees
Section 4.	Powers and functions of the Board and Provincial Committees.-
Section 5.	Meeting of the Board and Provincial Committees
Section 6.	Implementation and monitoring.-
Section 8.	Prohibitions and guidance relating to labels of designated products
Section 9.	Informational and educational materials
Section 11.	Quality assurance
Section 12.	Investigation and inspection
Section 13.	Investigation and filing of a case
Section 15.	Public Enforcement
Section 16.	Revocation or suspension of license, etc.-

ANNEX I

Detailed Comments on Breast-feeding & Child Nutrition Ordinance, 2002

CHAPTER I

- Definition of "designated Product" in Section 2 (f) encompasses all products but as a consequence of Sec 2 (g) and (h) and (l) which define complementary food, infant formula and follow up formula it has become vague and unclear. In absence of clarity the possibility the interpretation of the word becomes vulnerable and subject to expediency and the interest of the person who interprets it.

Sections of the Ordinance:

(f) ("designated product" means-

i. Any milk manufactured, marketed. promoted for the use of a infant or otherwise represented as a partial or total replacement for mother's milk, whether or not it is suitable for such replacement;

ii. Any products manufactured, marketed, promoted or otherwise represented as a complement to mother's milk to meet the growing nutritional needs of

an infant:

iii. Any feeding bottle, teat, valve for feeding bottle, pacifier or nipple shield; and

iv. Such other product as the Federal Government may, by notification in the official Gazette, declare to be a designated product for the purposes of this Ordinance;

(g) "complementary food" means any food suitable as an addition to breast milk or to a breast milk substitute when either becomes insufficient to satisfy the nutritional requirements of an infant, also commonly called "weaning food" or "breast milk and Young child supplement";

(h) "infant-formula" means an animal or vegetable based milk product manufactured in accordance with the standards recommended by the Codex Alimentarius Commission and the Codex Code of Hygienic Practice for Foods for Infants and Children to approximate the normal nutritional requirements of an infant up to the age of six months;)

(l) "follow-up formula" means an animal or vegetable based milk product marketed for infants older than six months or young child and formulated industrially in accordance, with the standards of the Codex Alimentarius Commission and the Codex Code of Hygienic Practice for Foods for Infants and Children;

CHAPTER II

Chapter II generally deals with Administration. It envisages the establishment of National Infant Feeding Boards on Federal level and Provincial Infant Feeding Committees.

- The powers and jurisdiction of the Boards however are very limited and restrictive in scope. The Board is non judicial entity. The Board cannot thus exercise quasi judicial or judicial powers such as granting ad interim injunctions and temporary relief to ensure the adherence to the Ordinance.

  The absence of such powers like injunctions resultantly can frustrate the proceedings before the Board and Committees since the violators will find it encouraging to delay the working of these Boards and Committee as during the period of investigation no action can be taken under the present Ordinance to prevent the continuous violations.

- The working and other modalities of these boards and committees is not exhaustively defined. The investigation carried out by the Board and Committees should be time bound so that its working can become efficient and effective.

- The law places no requirement or obligation upon these Board and Committees on how to accept and reject the complaints and what would be the manner of investigation. The procedure and working of such bodies should be codified and rule based with clear time frame in order to ensure transparency and efficiency. The capacity of how much work a Board should handle and how frequently should it meet is another issue which needs clarity.

- Boards can not take the cognizance of a case on its own. This power is given only to the extent of receiving the reports of violation under Section 4 (a)**. Furthermore Boards can only recommend the investigation of case against manufacturers, distributors and health workers found to be violating the provisions of the 'Ordinance'. What if the Board

does not recommend an investigation and the complaint is genuine? The Ordinance should make it obligatory on the part of the Board to investigate all complaints received.

- Currently Drug Courts are working as specialized courts under Drug Act. Keeping in view the relevant experience of these courts a proposal can be made to designate such type of judicial forum as a court which can take cognizance under this 'Ordinance' since the intricacies and technicalities involved in interpretation of such law may be beyond the capacity of civil courts.

Sections of the Ordinance:

(2) The Board shall consist of a Chairperson and not more than such number of members as the Federal Government may prescribe:

Provided that not less that half of the total number of members of the Board shall comprise of such persons who are professional qualified with respect to infant and young child nutrition and at least one member of the board shall be selected from the industry involved in the manufacturing and marketing of designated products. Secretary of the Provincial Health Department or his nominee shall be ex - officio member of the board.

- The phraseology of the law needs to be reviewed in general. The section 7 sub (2) states that "No person shall in any manner assert…….. " . The term asserts can be misinterpreted. It may be replaced with any other suitable word.

- Section 7 sub (6) states that no distributor or manufacturer shall in furtherance or for the purpose of its business have contact, directly or indirectly, with general public within a health care facility. In order to make this prohibition more effective and practical the geographical limitation of health care facility should be removed. In its present form the provision indirectly entices and encourages the manufacturer and the distributor to contact the general public outside the health care facility.

- There is no prohibition to restrict free sampling explicitly. Although the law restricts in offering or making gifts but free sampling has not been prohibited in clear terms. The experience shows that the "free sampling" is rampant to encourage the sales of the product hence a specific clause should be incorporated to this effect.

- Section 7 sub (7) permits the production and distribution of educational or informational material relating to designated products. Strict rules should be made or formulated in this regard to prevent the promotional use of scientific and educational material. It is suggested that such material should not contain unnecessary graphics and images (such as bottles etc) and strict monitoring should be exercised to check abuse of this provision.

- Section 8 sub (4) lays down guidelines for labeling. These guidelines need to be improved and translated in standard Urdu and also in "respective" regional languages where the product is made available for sale, highlighting that "mother milk is best food for your baby and helps in preventing diarrhoea and other illnesses" may

be made for better understanding. The label should also carry suitable warnings in accordance with the spirit of law.

Sections of the Ordinance:
Section 7 sub (2) No person shall in any manner assert that any designated product is a substitute for mother's milk, or that it is equivalent to or comparable with or superior to mother's milk.
Section 7 sub (6) No distributor or manufacturer shall in furtherance of or for the purposes of its business have contact, directly or indirectly with the general public within a health care facility.
section 7 sub (7) No manufacturer, distributor or any person engaged by them shall produce or distribute any educational or informational material relating to infant and Young child feeding:
section 8 sub (4) Guidelines for developing warnings (details attached as annex II)

CHAPTER IV

- Section 9 sub (1) provides that any informational and educational material shall be submitted to the Board. Mere submission is not enough. The material submitted to the Board should be for the purpose of approval and till the time the approval is not sought the material may not be disseminated.

- Section 10 sub (4) imposes a duty on Health Workers to make a report in writing about any offer of gift or financial benefit from manufacturer or distributor to the relevant Board or Committees. No time frame to launch such report is specified nor does it make clear what constitutes violations. Failing on the part of 'health worker" to report is another issue since whenever law places a duty its violations is supported by a sanction.

Sections of the Ordinance:
Section 9 sub (1) Any person who produces or distributes any informational and educational materials referred in this section shall submit copies thereof to the Board as may be prescribed.
Section 10 sub (4) Health workers falling within the jurisdiction of the Federal Government shall make in writing a report to the Board, and in all other cases to a concerned Provincial Committee any offer of a gift or other financial benefit made by a manufacturer or distributor or any other contravention of the provisions of this Ordinance or the rules, noticed by them.

CHAPTER V

- The procedure of investigation and filing a case in court as proposed under section 13 is ludicrous and needs rethinking and clarity. An inspector shall investigate a matter and will submit its finding report before Board or Committees which shall thereafter be recommended to Federal Government whether or not to institute prosecution. The Board/Committees have no powers to initiate prosecution before a court of law since there powers are of recommendatory nature only. If Board/Committees find that a manufacturer is accused of guilt and recommends prosecution but Federal Government fails to initiate any legal action the law is silent and provides no answer. No time frame is mentioned on the part of board/committees or inspector to conclude investigation and make recommendations accordingly.

- Under the 'Ordinance' the Federal Government reserves all the right to initiate legal action against the violators and even courts cannot take the cognizance directly. This restricts the scope of law and reflects the political expediency to converge all the powers within administrative setup with little faith on judicial forums. The right to initiate complaints and cases before the court should be given to Board/Committees.

- No time frame is allocated as to when the Federal Government would initiate prosecution on the recommendation. Practically it may take several years before the case is brought before the Court.

- Sec 14 gives right of appeal only to sentenced person. It would be appropriate if this right is extended to any party which feels aggrieved with the decision under the principle of law, equity and fairness.

- Section 15 deals with public enforcement and gives right to any person to make an application in writing to the board/committee reporting the violation of the 'Ordinance'. This right is very limited and it restricts the direct access of public to the court. It is

recommended that the Board/Committes should be given more powers to act on behalf of public. The exclusive right to administration to decide whether they act or do not act has in the past failed to deliver positive results. It is suggested that instead of providing administrative mechanisms the law should rely more on judicial forums.

CHAPTER VI

This chapter deals with penalties and procedures. These penalties impose fines as well as imprisonment. However, these penal clauses seem to do very little to ensure the compliance and it make enforcement and implementation of law vague and complex.

- Section 16 sub 1 lays down the penalty of suspension or cancellation of license of any person except medical practitioner who have contravene the provisions of this 'Ordinance'. The sections only focus to suspend and cancel professional license with a presumption that whoever contravene holds a professional license which would then be cancelled. It fails to acknowledge the possibility of violation committed by a person(s) who do not hold any license and examples are available in health sector where people are involved without any license requirement.

- Section 16 sub 2 deals with the case of contravention involving a medical practitioner registered under PMDC Ordinance stating that violation committed by a medical practitioner can only be referred to PMDC for an action. Experience shows that PMDC absolutely failed to tackle the cases involving disciplinary action against a doctor. PMDC should be asked to develop a mechanism so that it could act effectively towards the enforcement of the Ordinance.

- Section 17 deals with the instances of violation committed by manufacturers and distributors. It is absurd to narrow the application of this section only to manufacturers and distributors. The term "manufacturer or distributor" may hence be replaced with "any person" to make this provision more effective. In that case the penalty provided in section 16 would be considered in addition to this section or section 16 can be deleted if so required. Furthermore the law should be very specific to curb and stop the continuous violation of the 'Ordinance' and in that case the possibility the imposing penalties till the contravention is not removed may be incorporated.

- Perusal of Section 17 (2) is vague. Reading this section with Section 10 sub 4, leads to a interpretation that health workers, (defined in Section 2 sub p), failing to comply with the requirement of section 10 sub 4, may be punished with a fine up to the extent of Rs. 500,000/. On the other hand section 16 sub 2 provides a different penalty for medical practitioners, who again are also a "health workers". It reflects ambiguity and makes it uncles that under what instance the different provision of laws would be invoked.

Sections of the Ordinance:
Section 16 sub (1) Where any person, except a medical practitioner, has been found to have contravened ant of the provisions of this Ordinance, or the rules, then the concerned authority upon written recommendation of the Board, or a Provincial Committee, as the case may be, and after giving such person an opportunity of being heard, may recommend a Court to suspend or cancel, his license for the practice of his profession or occupation or for the pursuit of his business.

Section 16 sub (2) In the case of a contravention involving a medical practitioner registered under the Medical and Dental Council Ordinance, 1962 (XXXII of 1962), the matter shall be referred to the Pakistan Medical and Dental Council for further action.

Section 17 sub (2) Any person, who contravenes any other provision of this Ordinance, or the rules, shall be punishable with a fine, which may extend to five hundred thousand rupees.

ANNEX II

ORDINANCE NO. XCIII OF 2002

AN ORDINANCE

To provide for protection of breastfeeding and nutrition for infants and young children

WHEREAS it is expedient to ensure safe and adequate nutrition for infants and young children by promoting and protecting breast-feeding, and by regulating the marketing and promotion of designated products including breast milk substitutes, and of feeding bottles, valves for feeding bottles, nipple shields, teats and pacifier and to provide for matters connected therewith or ancillary thereto;

AND WHEREAS the President is satisfied that circumstances exist which render it necessary to take immediate action;

NOW, THEREFORE, in pursuance of the Proclamation of Emergency of the fourteenth day of October, 1999, and the Provisional Constitution Order No. 1 of 1999, read with the Provisional Constitution (Amendment) Order No. 9 of 1999, and in exercise of all powers enabling him in that behalf, the President of the Islamic Republic of Pakistan is pleased to make and promulgate the following Ordinance:-

CHAPTER I
INTRODUCTORY

1. Short title extent and commencement.- (1) This Ordinance may be called the Protection of Breast-feeding and Child Nutrition Ordinance 2002.

(2) It extends to the whole of Pakistan.

(3) It shall come into face at once.

2. Definitions.- In this Ordinance, unless there is anything repugnant in the subject or context,

(a) "infant" means a child up to the age of twelve months;

(b) "young child" means a child from the age of twelve months up to the age of two years;

(c) "advertise" or "advertising" means to make any representation by any means whatsoever for the purpose of promoting sale or use of a designated product;

(d) "Board" means the National Infant Feeding Board constituted under section 3;

(e) "container" means any form of packaging of a designated product for sale as a retail unit;

(f) "designated product" means-

i. Any milk manufactured, marketed. promoted for the use of a infant or otherwise represented as a partial or total replacement for mother's milk, whether or not it is suitable for such replacement;

ii. Any products manufactured, marketed, promoted or otherwise represented as a complement to mother's milk to meet the growing nutritional needs of an infant:

iii. Any feeding bottle, teat, valve for feeding bottle, pacifier or nipple shield; and

iv. Such other product as the Federal Government

may, by notification in the official Gazette, declare to be a designated product for the purposes of this Ordinance;

(g) "complementary food" means any food suitable as an addition to breast milk or to a breast milk substitute when either becomes insufficient to satisfy the nutritional requirements of an infant, also commonly called "weaning food" or "breast milk and Young child supplement";

(h) "infant-formula" means an animal or vegetable based milk product manufactured in accordance with the standards recommended by the Codex Alimentarius Commission and the Codex Code of Hygienic Practice for Foods for Infants and Children to approximate the normal nutritional requirements of an infant up to the age of six months;

(i) "feeding bottle" means any bottle or receptacle marketed for the purpose of feeding an infant or a young child;

(j) "nipple shield" mealy an appliance with a teat for a baby to suck from the breast;

(k) "pacifier" means an artificial teat for babies to Sucks, also referred to as "dummy

(l) "follow-up formula" means an animal or vegetable based milk product marketed for infants older than six months or young child and formulated industrially in accordance, with the standards of the Codex Alimentarius Commission and the Codex Code of Hygienic Practice for Foods for Infants and Children;

(m) "distributor" means any person engaged in the

business of marketing, whether wholesale or retail, and includes a person providing product public relations an information services;

(n) "health care facility" means a government, non-government, semi-government or private institution or organization or private medical practitioner engaged directly or indirectly in the provision of health care to infants young children, pregnant women or mothers, and includes a day-care center, nursery and other child-care institutions;

(o) "health professional" means a medical practitioner nurse nutritionist or such other persons as the Federal Government may, by notification in the official Gazette, specify

(p) "health worker" means any person providing services to infants, young children, pregnant women or mothers as a medical practitioner, and includes a health professional, homeopath practitioner, hakim, nurse, midwife, traditional birth attendant, pharmacist, dispensing chemist. nutritionist, hospital administrator or employee, whether professional or not, paid or not, and any other person providing such services as the Federal Government may, by notification in the official Gazette, specify

(q) "Inspector" means any person designated as Inspector under section 12;

(r) "label" means any tag, mark, pictorial or other descriptive matter which is written, printed, stenciled, marked, embossed, attached or otherwise appearing on a container;

(s) "manufacturer" means a person, corporation or other entity engaged or involved in the business of producing, processing, compounding, formulating, filling packing, repacking, altering. ornamenting,

finishing and labeling a designated product, whether directly, through an agent, or through a person controlled by or under an agreement;

(t) "market" means any method of introducing or selling a designated product, and includes, but not limited to, promotion, distribution, advertising, distribution of samples, product public relations and product information services;

(u) "person" means any individual, partnership, association, unincorporated Organization, company, co-operative, corporation, trustee, agent or any group of persons;

(v) " prescribed" means prescribed in rules;

(w) "promote" or "promotion" means of introducing a person to, or familiarizing a person with, a designated product or inducing a person to buy or use a designated product, and includes, but not limited to, advertising,, offer of samples or gifts, distribution of literature, public relations and information services related to a designated product, belt does not include any prescription issued by a medical practitioner based on health grounds;

(x) "Provincial Committee" means a Provincial infant Feeding Committee constituted under section 3;

(y) "rule" means rules made under this Ordinance; and

(z) "sample" mean any quantity of a designated product provided free of cost.

CHAPTER II
ADMINISTRATION

3. **National Infant Feeding Board and Provincial Infant Feeding Committees**.-

(1) The Federal Government shall, by notification

in the official Gazette, constitute a National Infant Feeding Board.

(2) The Board shall consist of a Chairperson and not more than such number of members as the Federal Government may prescribe:

Provided that not less that half of the total number of members of the Board shall comprise of such persons who are professional qualified with respect to infant and young child nutrition and at least one member of the board shall be selected from the industry involved in the manufacturing and marketing of designated products. Secretary of the Provincial Health Department or his nominee shall be ex - officio member of the board

(3) A Provincial Government shall, by notification in the official Provincial Gazette, constitute a Provincial Infant Feeding Committee for a Province.

(4) Subject to sub-section (5), a Provincial Infant Feeding Committee shall consist of a Chairperson and not more than such number of members as a the Provincial Government may prescribe:

Provided that not less than half of the total number of members of a Provincial Committee shall comprise of such persons who are professional qualified with respect to infant and young child nutrition, and at least one member shall be selected from industry involved in the manufacturing and marketing of designated products.

(5) The Federal Government shall nominate the members of the Board and a Provincial Government shall nominate the members of a Committee, Who shall hold office for a term as may be prescribed by the respective Governments.

4. Powers and functions of the Board and Provincial Committees.- The following shall be the powers and functions of the Board in the case of the Federal Government and a Provincial Committees in the ease of a Provincial Government, namely:-

(a) To receive reports of violations of provisions of this Ordinance or the rules;

(b) To recommend investigation of cases against manufactures, distributors or health workers found to be violating the provisions of this Ordinance or the rules;

(c) to plan for and co-ordinate the dissemination of informational and educational materials on the topic of infant feeding and recommend continuing education courses for health workers on topics related to this Ordinance;

(d) to advise the Federal Government, and the Provincial Governments on national policies for the promotion and protection of breastfeeding, and matters relating to designated products especially infant and young child nutrition, particularly through national or provincial education campaigns, and to organize health education on the same for health workers and the general public; and

(e) to propose guidelines to the Federal Government or to a Provincial Government, as the case may be, in respect of matters specified in clause (d).

5. Meeting of the Board and Provincial Committees.- The Secretary of the Board or, as the case may be, a provincial committee, shall call meetings of the Board or a Provincial Committee, as the case may be, at the direction of the Chairperson, and maintain minutes of such meetings.

6. Implementation and monitoring.- The Federal Government may give such directions to a Provincial Government as may appear to it to necessary for carrying into effect in a Province any of the provisions of this Ordinance, or of any rules, or any order or direction made thereunder, or for achievement of uniformity in respect of any matter related thereto in different parts of Pakistan.

CHAPTER III
PROHIBITIONS

7. **Prohibited practices**.- (1) No person shall, in any form whatsoever, promote any designated products except as provided for under this Ordinance.

(2) No person shall in any manner assert that any designated product is a substitute for mother's milk, or that it is equivalent to or comparable with or superior to mother's milk.

(3) No manufacture or distributor shall offer, or make gift or contributions of any kind, or pay to any extent for any reason whatsoever, or give any kind of benefit, to a health worker or his family, or any personnel employed directly or indirectly in a health care facility, or any member of the Board or a Provincial Committee, as the case may be, or the employees thereof.

(4) No manufacturer or distributor shall donate any designated product and equipment or services related to a designated product free of charge or at low cost to a health care facility, or offer or give any benefit to a professional association of medical practitioners for this purpose.

(5) No person other than a health worker who is not engaged by a manufacturer or distributor shall instruct any user on the need and proper preparation and use of any designated product:

Provided that a manufacturer or distributor may instruct any user on the need and proper preparation and use of any designated product in accordance with the provisions of section 8.

(6) No distributor or manufacturer shall in furtherance of or for the purposes of its business have contact, directly or indirectly with the general public within a health care facility.

(7) No manufacturer, distributor or any person engaged by them shall produce or distribute any educational or informational material relating to infant and Young child feeding:

Provided that any educational or informational material relating to a designated products may be provided by a manufacturer or distributor to a health professional subject to the prescribed conditions, and that the same shall be restricted to scientific and factual matters, and shall not imply or create a belief that bottle-feeding is equivalent or superior to breast-feeding.

8. Prohibitions and guidance relating to labels of designated products.- (I) No designated product shall be marketed or sold in Pakistan unless its label is in accordance with the provisions of this Ordinance and the rules, and approved in the manner as may be prescribed by the Federal Government:

Provided that for any designated product already being sold in Pakistan, a manufacturer or distributor shall provide for the label of such product within one hundred and eighty days of its approval in the manner as may be prescribed.

(2) Label of a designated product shall be designed so as not to discourage breastfeeding and shall provide the necessary information in Urdu about the appropriate use of such product and the age before which a designated product should not be used.

(3) Every container shall have a clear, conspicuous and easily understood message printed on it, or on a label that cannot become separated from it, which shall be written in Urdu, and if so desired by the manufacturers, in English as well.

(4) The label shall-

(a) not contain anything that may discourage breast-feeding;

(b) contain a conspicuous notice in bold characters in the prescribed height stating the following, namely:-

"MOTHER'S MILK IS BEST FOR YOUR BABY AND HELPS IN PREVENTING DIARRHOEA AND OTHER ILL-NESSES'

(c) instead of or in addition to the notice specified in clause (b), contain any other message as may be prescribed with the respect to any designated product;
(d) neither uses expressions such as "maternalized" or "humanized" or equivalent nor contains any comparison with mother's milk;

(e) not show photographs, drawings or graphics, except that graphics may be used to illustrate the correct method of preparation;

(f) contain the name and address of manufacturer and of wholesale distributors if a designated product is an imported item; and

(g) except for bottles, teats, pacifiers and nipple shields, contain appropriate instructions in Urdu for the correct preparation in words and easily understood graphics, and indicate the ingredients, composition and analysis of a designated product, required storage conditions, batch number and expiry date, and contain any warning as may be prescribed for

the implementation of this Ordinance, in characters of the prescribed height in Urdu or regional languages.

CHAPTER IV
INFORMATIONAL AND EDUCATIONAL MATERIALS

9. Informational and educational materials.- (1) Any person who produces or distributes any informational and educational materials referred in this section shall submit copies thereof to the Board as may be prescribed.

(2) Informational and educational materials, whether written, audio or visual, which refer to infant feeding shall contain only correct information and shall not use any pictures, graphics or text that encourage bottle-feeding or discourage breast-feeding.

(3) The Federal Government shall, in consultation with the Board, arrange for and approve the dissemination of objective and consistent informational and educational materials on infant and young child feeding, excluding medical literature and may, by notification in the official Gazette, publish such instructions, guidelines or policies as it seems necessary or appropriate, for the purposes of producing and distributing informational and educational materials.

10. Health workers and health care facilities._ (1) Health workers shall encourage, support and protect breast-feeding. They shall be expected to know the provisions of this Ordinance, in particular, any instructions, guidelines or policies published under section 9, and to implement the same whenever possible.
(2) Health workers shall not accept or give samples of any designated product to any person, particularly pregnant women, mothers of infants and young children, or members of their families.
(3) Health workers and their Associations shall not promote, in any way whatsoever, any designated product.

(4) Health workers falling within the jurisdiction of the Federal Government shall make in writing a report to the Board, and in all other cases to a concerned Provincial Committee any offer of a gift or other financial benefit made by a manufacturer or distributor or any other contravention of the provisions of this Ordinance or the rules, noticed by them.

(5) There shall be kept posted in every health care facility in Urdu and English, and in such other language as may be deemed appropriate by the health care facility, such abstracts of this Ordinance as may be prescribed by the Federal Government, or a Provincial Government, as the case may be, for this purpose.

CHAPTER V

REGISTRATION OF DESIGNATED PRODUCTS AND QUALITY ASSURANCE

11. Quality assurance.- (1) No designated product shall be manufactured, sold or otherwise distributed in Pakistan unless it is formulated industrially in accordance with the standards recommended by the Codex Alimenttarius Commission and the Codex Code of Hygienic Practice for Foods for Infants and Children, and in addition, shall meet such applicable standards specified in this Ordinance and the rules.

(2) The Board or a Provincial Committee, as the case may be, may require an inspector or any other person invested with powers under this 'Ordinance' to test any designated product sold in Pakistan in order to determine whether it is fit for human consumption.

(3) A designated product that does not meet the standards for use in the country of manufacture shall not be sold in Pakistan.

(4) A designated product that has reached the expiry date shall not be marketed, sold or distributed.

(5) A designated product shall be sold only in the original container in order to prevent quality deterioration, adulteration or contamination thereof.

12. Investigation and inspection.- (1) The Federal Government may designate any number of persons, professionally qualified with respect to infant and young child nutrition as Inspector to conduct inspection and investigation and prosecution for the purposes of this Ordinance, and to monitor compliance with the provisions of this Ordinance.

(2) After an inspection for purpose of this Ordinance, an Inspector shall refer the case, and if so required, provide one portion of the sample of a designated product, or the whole of a designated product if it is such that it cannot be divided, to the Board, or a Provincial Committee, as the case may be.

13. Investigation and filing of a case.- (1)Upon completion of an investigation and receipt of a complete report, and after giving the concerned party an opportunity of being heard, the Board, or a Provincial Committee, as the case may be, shall recommend to the Federal Government whether or not to institute prosecution under this Ordinance.

(2)No court shall take cognizance of any offence punishable under this Ordinance except on a report in writing by an officer authorized by the Federal Government, or any other person as the Federal Government may, by notification in the official Gazette, authorize in this behalf.

(3) An offence punishable under this Ordinance shall be non-cognizable.

14. Appeal.- (1) Any person sentenced by a Court under this Ordinance may prefer an appeal to the High Court within thirty days of the judgement.
(2) The provisions of sections 5 and 12 of the

Limitation Act, 1908 (IX of 1908), shall be applicable to an appeal preferred under sub-section (1).

15. Public enforcement.- (1) Any person whomsoever may make an application in writing to the Board, or a Provincial Committee, concerning contravention of any of the provisions of this Ordinance or the rules.
(2) In the event an investigation reveals an offense, the Board or a Provincial Committee, as the case may be, shall follow the procedure specified in section 13 for recommending prosecution.

CHAPTER VI
PENALTIES AND PROCEDURES

16. Revocation or suspension of license, etc.- (1) Where any person, except a medical practitioner, has been found to have contravened any of the provisions of this Ordinance, or the rules, the concerned authority upon written recommendation of the Board, or a Provincial Committee, as the case may be, and after giving such person an opportunity of being heard, may recommend to the Federal Government to suspend or cancel, his license for the practice of his profession or occupation or for the pursuit of his business.

(2) In the case of a contravention involving a medical practitioner registered under the Medical and Dental Council Ordinance, 1962 (XXXII of 1962), the matter shall be referred to the Pakistan Medical and Dental Council for further action.

17. Penalties.- (1) Any manufacturer or distributor who contravenes the provisions of sub-sections (1) to (7) of section 7, sub-section (1) of section 8, sub-sections (1) (3), (4) or (5) of section 11, shall be punishable with imprisonment for a term which may extend to two years, or with fine which shall not be less than fifty thousand rupees or more than five hundred thousand rupees, or both.

(2) Any person, who contravenes any other provision of this Ordinance, or the rules, shall be punishable with a fine, which may extend to five hundred thousand rupees.

18. Responsibility of an individual for the act of a company, corporation, partnership, or an institution.- where the offence is found to have been committed by a company, corporation, partnership or an institution, as a result of an institutional or operational instructions issued by it or implemented by it, the company, corporation, partnership or the institution may be found guilty in addition to the individuals directly responsible for the commission of such offence.

19. Power to make rules.- (1) The Federal Government may, by notification in the official Gazette, make rules for carrying out the purposes of this Ordinance.

(2) A provincial Government may, by notification in the official Provincial Gazette, make rules for the administration of a Provincial Committee in a province.

20. Power to delegate- the Federal Government may delegate any of the functions and its powers under this 'Ordinance' to a Provincial Government.

21.Overriding effect: the provisions of this Ordinance shall have effect notwithstanding anything to the contrary contained in any other law for the time being in force.

GENERAL
PERVEZ MUSHARRAF.
President

Mr. Justice
(MANSOOR AHMAD)
SECRETARY

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