# A Health Workers' Guide to the 12<sup>th</sup> edition

A Health Workers' Guide to the International Code of Marketing of Breastmilk Substitutes

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International Code of Marketing of Breast-milk Substitutes

World Health Organizal

## **Protecting Infant Health**

A Health Workers' Guide to the International Code of Marketing of Breastmilk Substitutes

12<sup>th</sup> edition



#### **PROTECTING INFANT HEALTH**

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- Jean-Pierre Allain for his help in editing.



Mum gets a helping hand to breastfeed in hospital. (Zambia)

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#### Preface

One of the main principles of the International Code of Marketing of Breastmilk Substitutes is to prevent health workers from being used as the prime channel for the promotion of bottle feeding. The bulk of corporate marketing budgets goes into the health care system. Yet, few health workers know anything about marketing and its subtle ways, how they are manipulated by marketing. The people who wrote the Code and subsequent World Health Assembly resolutions studied the impact of company sponsorship, gifts, meals and entertainment on health workers' attitudes to breastfeeding. Those attitudes have a direct influence on mothers.

New mothers often lack confidence for successful breastfeeding. Will they have enough milk? Health workers often do not know how to explain the miracle of supply and demand. Many have not been given practical training about 'attaching' the infant to the breast. This makes the maternity a fertile ground for marketing. This booklet tries to make it easier for doctors, nurses and midwives to understand how they can use the Code to protect breastfeeding, to protect themselves as well as support the mothers and infants under their care.

This 12th edition has been completely revised thanks to my colleagues, Yeong Joo Kean and Constance Ching, who not only rewrote the content but insisted on new illustrations and up-to-date quotes. My turn came with editing down phrases that were too long, text that was too legal and keeping some of the historic illustrations.

We hope that the result achieves the booklet's intention: make the Code, its resolutions and related issues easier to understand for those who are in daily contact with mothers and babies. This is part of IBFAN's effort to mainstream breastfeeding protection, promotion and support.

annelies allain

Director, IBFAN-ICDC March 2019

#### The Miracle of Breastfeeding



Mum breastfeeding premature triplets with neither formula nor fortifier added to her breastmilk. (Canada)

If breastfeeding did not already exist, someone who invented it today would deserve a dual Nobel Prize in medicine and economics. For while "breast is best" for lifelong health, it is also excellent economics. Breastfeeding is a child's first inoculation against death, disease, and poverty, but also their most enduring investment in physical, cognitive, and social capacity.

Hansen, K. (2016). Breastfeeding: a smart investment in people and in economies. The Lancet 387, no. 10017 (2016): 416.

## Introduction and Background

Breastfeeding is the natural way to feed babies and it is important for their healthy growth and development. In fact, there is no substitute for breastmilk.

#### Feeding a baby formula or any other replacement milk increases the chances that the baby will get sick.

In addition to its nutritional value, breastmilk contains antibodies which help protect the baby against many common childhood illnesses. It is safe and clean, always at the right temperature and nearly every mother has more than enough of this high quality food for her baby.

Over the last 80 years, however, more and more babies are being bottle-fed with a variety of industrial formulated milks which try, unsuccessfully, to imitate the goodness of breastmilk.

#### Why breastfeeding is important

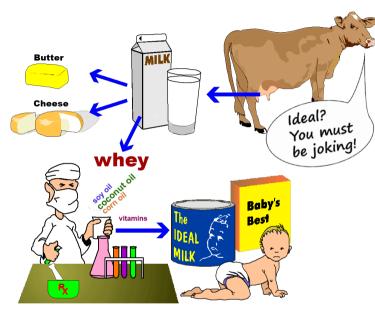
**B** est for baby

- R educes allergies such as asthma & eczema
- *E* conomical no waste
- A ntibodies greater immunity to infections
- *S* tool inoffensive hardly ever constipated
- *T* emperature always ideal
- *F* resh milk never goes off
- *E* motionally bonding
- *E* cologically sound
- **D** igested easily within two, three hours
- *I* mmediately available no mixing required
- N utritionally optimal
- G astroenteritis greatly reduced



Finding mummy's breast within an hour of birth. (Mongolia)

#### Formula demystified



After removing the fat from cow's milk to make butter and cheese, a watery substance remains: whey. It used to be thrown away. Then someone discovered that recombining whey with vegetable oils could make a digestible drink for babies. It is the base for most formulas today.

It is common for different ingredients and formulations to be added to formula. Despite all the complicated mixing, no formula product on the market is able to match the uniqueness of breastmilk.

#### Breastmilk vs formula: no contest!

G Human milk composition can provide guidance on the composition of formula, but compositional similarity to human milk is not the only determinant or indicator of safety and nutritional suitability of formula.

The mere presence of a substance in human milk does not necessarily indicate a specific benefit of this substance for the infant, nor do the concentrations of nutrients in human milk necessarily reflect infants' dietary requirements because they may mirror maternal intakes rather than infants' needs, or because absorption efficiency of certain nutrients differ between breastmilk and formula.

Infant formula cannot imitate breastmilk with respect to its energy and protein content.

EFSA (2014). Scientific opinion on the essential composition of infant and follow-on formulae. Parma, Italy: European Food Safety Authority. Available at http://www.efsa.europa.eu/en/ efsajournal/pub/3760

#### **Recommendation from WHO**

Generative Breastfeeding gives babies the best possible start in life. Breastmilk works like a baby's first vaccine, protecting infants from potentially deadly diseases and giving them all the nourishment they need to survive and thrive.

> Dr Tedros Adhanom Ghebreyesus, Director General, WHO 2017 Press Statement.

As a global public health recommendation, babies should be exclusively breastfed for the first six months of life to achieve optimal growth, development and health. Thereafter, to meet their evolving nutritional requirements, babies should receive nutritionally adequate and safe complementary foods while breastfeeding continues for up to two years of age or beyond.<sup>1</sup> Where mothers cannot, or choose not to, breastfeed, breastmilk substitutes are available. All breastmilk substitutes are an imperfect approximation of breastmilk and there are inherent differences between breastmilk and breastmilk substitutes specifically formula products.<sup>2</sup>

- Breastmilk
- changes in response to the feeding habits of her baby and over time, thus adjusting to the baby's individual growth and development needs. The exact chemical properties of breastmilk are still unknown and cannot be reproduced.
- includes a mother's antibodies and many other defensive factors that help the baby avoid or fight off infections, and gives the baby the benefit of the mother's mature immune system.
- Formula products
- do not promote neurological development as breastmilk does.
- have no positive impact on maternal health.
- require manufacturing, storage and delivery systems with inherent quality control problems.

<sup>1.</sup> World Health Organization (2003). Global Strategy for Infant and Child Feeding. Geneva: WHO.

<sup>2.</sup> In this publication the term 'formula products' is used for all milk products marketed for children from birth to three years. The term 'breastmilk substitute' is much wider in meaning.

## When formula products are necessary

In principle, formula products should be used only when medically indicated.<sup>3</sup>

Some mothers, either through necessity or by choice, do not breastfeed. Formula products must, hence, be available and be well regulated as food products.

Article 6.5 requires health workers to demonstrate the use of infant formula to individual mothers who need to use the product. Companies deliberately misinterpret Article 6.5 implying that it allows them to provide information and educational materials or instructions so as to assist health workers in guiding mothers.

There is no requirement or necessity for companies to do so.

Health workers who give advice to parents and carers about infant feeding can access clear and objective information about the different types of formula products that are currently available. They can obtain preparation instructions from product labels without referring to additional company materials which are inherently promotional.

There are also WHO/FAO guidelines on how to prepare formula safely in care settings and at home. Therefore, any argument that company materials are required, is obsolete.



For information on composition of formula, the claims made and safety of ingredients, go to https://www.firststepsnutrition.org/ composition-claims-and-costs.

3. WHO/UNICEF (2009) Acceptable Medical Reasons for Use of Breastmilk Substitutes", World Health Organization, Geneva, Switzerland. Retrieved from http://www.who. int/nutrition/publications/infantfeeding/WHO\_NMH\_NHD\_09.01/en/

#### Breastfeeding is declining. Why?

#### Despite its advantages, breastfeeding rates continue to decline in many countries. There are many reasons.

#### Social and cultural factors:

- portrayal in the media that the primary function of the breast is sexual.
- mothers are discouraged to breastfeed in public.
- the feeding bottle has become a status symbol even in poor rural societies.

#### **Economic factors:**

- more women working outside the home and in settings that are not conducive to breastfeeding.
- inadequate maternity protection and few child care facilities at work.

## Practices in health facilities which discourage breastfeeding:

• delay in introducing the baby to the breast, separating mother and baby and routine formula feeding.



Exclusively breastfed.



Not breastfed

Sleeping babies. Same place, same time, different health outcomes. (Papua New Guinea)

## Commercial promotion that undermine breastfeeding.

Tactics include:

- scientific arguments equating the use of such products to quality parenting.
- portrayal of bottle feeding as the modern and convenient method of feeding babies.
- describing breastfeeding as ideal but difficult and unsuitable for contemporary lifestyles.
- entrenching the mistaken belief of "insufficient" breastmilk.

These are all reasons which explain the switch from breastfeeding to formula feeding. And they illustrate real problems – problems where the solution is not the feeding bottle.

Wouldn't it be better to tackle the causes of the problems?

- Provide more support for women to breastfeed?
- Lobby for more maternity benefits?
- For improved health care practices?
- And restrict promotion of formula products?



Alternating breastfeeding with formula feeding. The bottle will win. (Botswana)

...breastfeeding contributes to a world that is healthier, better educated, more equitable, and more environmentally sustainable. But the relevance of breastfeeding is questioned across society. Women are drawn to substitutes for breastmilk and doubt their own ability to breastfeed. They, their families, and health professionals are not fully convinced by the benefits of breastfeeding: breastfeeding in public can generate embarrassment and has even been prohibited whereas bottle-feeding causes little reaction.

Rollins, N. C. et al. (2016). Why invest, and what it will take to improve breastfeeding practices? The Lancet, 387(10017), 491-504.

#### Why a marketing code?

While not all the problems associated with poor infant feeding practices can be solved by a code of marketing, it is a first step towards improving the situation.

By removing the pressure of advertising and promotion, by ending the giving of samples of breastmilk substitutes to mothers and by focusing attention on the risks of not breastfeeding, it is more likely that an environment will be created where breastfeeding is once again the norm.

Breastmilk substitutes will then only be used as they were originally intended – as a last resort, a lifesaving tool where all else fails – not as a routine. Then only will health workers be able to concentrate on other aspects of infant health. Less of their time will be taken up with having to deal with the consequences of inappropriate infant feeding.

The International Code of Marketing of Breastmilk Substitutes (hereafter referred to as "the International Code" or "the Code") was adopted as a recommendation for governments in all countries to implement. The Code is a "**minimum requirement**" and all of it should be adopted.



WHO growth charts in health care institutions carry the *Similac* brand mascots alongside the names and logos of the national health and social services. There is value in projecting Abbott as a health partner of the government and WHO. (Colombia)

Manufacturers market their product by making claims about scientific innovation and superiority of ingredients. Company representatives, mailings, websites and conference exhibitors can provide confusing information for health professionals, and the evidence the manufacturers present may appear convincing, although this may sometimes contradict public health guidance.

Crawley, H. & Westland S. (2018) Infant formula – An overview. London: First Steps Nutrition Trust.

## How was the International Code developed?

As public and professional concern over infant mortality grew during the mid 1970s, WHO and UNICEF responded by organising an international meeting on infant and young child feeding in October 1979. This meeting brought together government officials, scientific experts, health workers, representatives from the baby food industry and people's organisations like Consumers International and the International Baby Food Action Network (IBFAN).

An important outcome of the meeting was recognition of the need for a code to control inappropriate marketing practices.

During the next 15 months, WHO and UNICEF held several consultations with all interested parties to produce a final draft of the International Code. In May 1981 the World Health Assembly overwhelmingly approved it, by 118 votes to 1. The opposing vote came from the USA which was concerned that the Code might be detrimental to US business.



Promoting formula instead of breastmilk. Doctor, sponsored by *Wyeth*, insinuates on TV that there is not much difference between the two. (Hong Kong)

#myTV #東張西望 2017.03.08 - 母乳 VS 奶粉

"Breastmilk substitutes are a multi-billiondollar industry, the marketing of which undermines breastfeeding as the best feeding practice in early life. No new interventions are needed—the Code is an effective mechanism for action. However, much greater political commitment is needed to enact and enforce the relevant, comprehensive legislation and national investment to ensure implementation and accountability. Without these commitments, agreed principles of responsible marketing will continue to be violated."

Rollins, N. et al. (2016). "Why invest, and what it will take to improve breastfeeding practices?" The Lancet, 387: 491–504 at p.501

## **The International Code: Overview**

The Code seeks to protect and encourage breastfeeding by restricting marketing practices used to promote breastmilk substitutes. In particular, it bans the use of the health care system and of health workers to increase sales of breastmilk substitutes.

The Code also protects babies who are not breastfed by requiring that product labels carry the necessary warnings and instructions for safe preparation and use. The Code ensures that the choice of products is made on the basis of independent medical advice and not through commercial influence.

Every other year, the World Health Assembly (WHA) adopts recommendations in the form of resolutions to clarify the Code and keep it up-to-date with marketing trends and scientific knowledge.

The Code and these subsequent resolutions are one package and must be read together. A thematic summary is reproduced in Annex A.

## The International Code is universal

Nearly all major companies persist in saying that the Code is only applicable in developing countries and not in the industrialised nations of Europe, North America, Oceania and parts of Asia.

The Code makes no such distinction. The preamble to the Code clearly states that "inappropriate infant feeding practices lead to infant malnutrition, morbidity and mortality in <u>all</u> countries".

Further, WHA resolution 34.22 [1981] which adopted the Code also states that **"breastfeeding must be actively protected and promoted in all countries."** 

Independently of national measures taken to implement the Code and resolutions, health workers can effectively prevent companies from competing with breastfeeding by giving mothers correct and up-to-date information and support.

Most importantly, health workers should know their responsibilities under the Code and apply them in their work so that commercial influence in health facilities is stopped.

#### State of the Code by Country

#### STATE OF THE CODE BY COUNTRY

A survey of measures taken by governments

to implement the provisions of the International Code of Marketing of Breastmilk Substitutes &

By 2018, many countries have taken some kind of action to adopt the Code at the national level: Law (36 countries), many provisions law (31),

few provisions law (61), voluntary measures (12), some provisions in other laws or guidelines (13), some provisions voluntary (17).<sup>4</sup>

While these numbers sound impressive, implementation and enforcement are unsatisfactory particularly in countries where both national measures and legal systems are weak.

#### Scope of the International Code

The scope<sup>5</sup> of the Code can be summarised to cover the following food products, and health workers should be on the alert for their promotion:

- Infant formula.
- Follow-up formula.
- Growing-up milk (also referred to as young child formula, growing-up formula, toddler milk).
- Any other milk for children 0 to < 36 months.
- Any other food or liquid targeted for infants under 6 months of age.



Examples of food products under the scope of the Code. Feeding bottles and teats are also covered.

- 4. See also WHO. UNICEF. IBFAN Marketing of breastmilk substitutes: national implementation of the International Code Status Report 2018. Geneva: WHO; 2018.
- 5. Code Article 2 read together with recommendation 2 of the Guidance on ending the inappropriate promotion of foods for infants and young children (A69/7 Add. 1).

## **Bottles and teats... also under the Code**

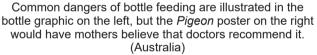
Feeding bottles and teats discourage breastfeeding and their promotion normalises the practice of bottle feeding. They are covered by the Code but are still often advertised to the public. Companies often give free samples and other promotional gimmicks to entice sales although this is strictly forbidden by Article 5.1. Their labelling also discourages breastfeeding.

There are many dangers inherent in the use of feeding bottles and teats. Many cannot be properly sterilised.

Bisphenol-A (BPA), a chemical added to plastic feeding bottles to render them shatter proof, can leach into the formula inside, especially when boiling water is used. This may have a negative effect on the child's reproductive system in later life.

Health workers can play a major part by ensuring that health facilities are not used as promotional channels for feeding bottles, teats or dummies. Posters, booklets, or free samples of these products should also not be permitted.





More and more paediatricians now recommend, even for young infants – that feeding with a cup is a healthier practice. It does away with a host of problems directly caused by feeding bottles.

The use of BPA in plastic feeding bottles has been prohibited in many countries.

#### Relevant terms are defined under Article 3:

*Breastmilk substitute* means any food being marketed or otherwise represented as a partial or total replacement for breastmilk, whether or not suitable for that purpose.

*Health care system* means governmental, non-governmental or private institutions or organisations engaged, directly or indirectly, in health care for mothers, infants and pregnant women; and nurseries or child care institutions. It also includes health workers in private practice. For the purposes of this Code, the health care system does not include pharmacies or other established sales outlets.

*Health worker* means a person working in a component of such a health care system, whether professional or non-professional, including voluntary, unpaid workers.

Two articles of the Code – *Articles 6 and 7* – deal specifically with the use of health care systems and the role of health workers.

## What can health workers do to make the International Code work?

The Code is a set of minimum requirements for governments to translate into national legislation and other measures. Even if no such measure is adopted, companies are required at all levels to abide by the Code.

Experience over the past decades has shown that in reality, it is health workers who ultimately can determine the success or failure of the Code. They are frequently the target for promotion and health facilities are seen by companies as the perfect channel for encouraging the use of their products. Unlike advertising aimed at the general public, focusing on health workers provides manufacturers and distributors with immediate access to a specialised target group which has a direct and authoritative influence over mothers.

Health workers can block all forms of commercial promotion from infiltrating the health care system by ensuring compliance with the requirements of Articles 4, 6 and 7. By doing so, they can ensure that the patients under their care are able to make infant feeding decisions free of commercial influence. They can make the Code work. Protecting Infant Health-14

## International Code Article 4 Information & Education

**4.1** Governments should have the responsibility to ensure that objective and consistent information is provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition. This responsibility should cover either the planning, provision, design and dissemination of information, or their control.

A randomised controlled trial of 547 women demonstrated that educational materials on breastfeeding produced by manufacturers of infant formula and distributed to pregnant women intending to breastfeed had a substantially negative effect on the exclusivity and duration of breastfeeding. This impact was much greater on women with uncertain or short breastfeeding goals.

Howard, C., et al (2000). Office prenatal formula advertising and its effect on breastfeeding patterns1. Obstetrics & Gynecology, 95(2), 296-303.

#### **Interpreting the International Code**

The difference between "information" and "promotion" is sometimes so subtle that it is difficult to distinguish between the two. The International Code therefore lays the responsibility for controlling information with governments.

Any information provided by companies must conform to government controls and to the requirements of Articles 4.2 and 4.3 of this Code.

It is not up to the companies to decide what should be said about infant and young child feeding. People should not be given conflicting messages such as: "breastfeeding is best, but formula feeding is okay too." **4**.2 Informational and educational materials, whether written, audio or visual, dealing with the feeding of

infants and intended to reach pregnant women and mothers of infants and young children, should include clear information on all the following points:

- a. the benefits and superiority of breastfeeding;
- b. maternal nutrition, and the preparation for and maintenance of breastfeeding;
- c. the negative effect on breastfeeding of introducing partial bottle feeding;
- d. the difficulty of reversing the decision not to breastfeed; and,
- e. where needed, the proper use of infant formula, whether manufactured industrially or home-prepared.

When such materials contain information about the use of infant formula, they should include the social and financial implications of its use; the health hazards of inappropriate foods or feeding methods; and, in particular, the health hazards of unnecessary or improper use of infant formula and other breastmilk substitutes. Such materials should not use any pictures or text which may idealise the use of breastmilk substitutes.

#### Time to change the paradigm!

#### Not breastfeeding is risky.

Messages which idealise breastfeeding may actually undermine it. Telling mothers that "breastfeeding is best" makes formula feeding an acceptable standard for comparison and implies that breastmilk substitutes provide satisfactory nutrition.

Companies are clever in using this idea in their marketing and position their products as "inspired by breastmilk" and "closest to breastmilk".

Emphasising the virtues of breastfeeding conceals the health risks associated with not breastfeeding and the hazards of using breastmilk substitutes.

In order to meet the intent of Article 4.2, materials on infant and young child feeding should emphasise the **importance of breastfeeding** for the **normal** healthy growth and development of babies.

Anything else is "less good". Babies who are **not** breastfed miss out on immunisation and protection. Formula feeding undermines babies' health, making it a risky option.

**4.3** Donations of informational or educational equipment or materials by manufacturers or distributors should be made only at the request and with the written approval of the appropriate government authority or within guidelines given by governments for this purpose. Such equipment or materials may bear the donating company's name or logo, but should not refer to a proprietary product that is within the scope of this Code, and should be distributed only through the health care system.

#### WATCH OUT !

All "educational" materials prepared by companies should be examined carefully for factual over promotional value. Companies resist to comply with Article 4 of the Code. They often use different wording, which is much less specific, and therefore, much less effective at protecting and promoting breastfeeding.

Source: BTR 2017/ IBFAN-ICDC

#### No product promotion to parents

Companies may only supply materials at **the request** of and with the written approval of the appropriate government health authority. None of that material should refer to brand names of products covered by the Code. None of that material should be given directly to mothers by the companies.

When searching for education materials on infant and young child feeding, it will be better for health workers to obtain such materials from their own health authorities or from international agencies like WHO and UNICEF.<sup>6</sup> Many of these materials are now available online.



In Niger, Nestlé educational brochures promotes its entire range of formula products. This is not the kind of IYCF materials mothers need.

6. An excellent source is the UNICEF UK Baby-Friendly Initiative at https://www.unicef.org.uk/babyfriendly/baby-friendly-resources/ which offers many ready-to-print booklets and leaflets on different topics and in a number of languages.

## **Enterobacter Sakazakii**

Article 4.2 must be read together with WHA resolution 58.32 [2005] which addresses concerns about 'intrinsic contamination' of powdered infant formula (PIF). This resolution requires that health workers be provided with information and training on the preparation, use and handling of PIF to minimise health hazards.

Health workers should be aware that PIF is not a sterile product; that during production, PIF can become contaminated with harmful bacteria, such as *Enterobacter Sakazakii* and *Salmonella enterica* which can cause serious illness.

Companies admit that the manufacturing process is imperfect and can cause such 'intrinsic' contamination. Surveys have identified *Enterobacter Sakazakii* in 3-14% of PIF samples\*. Few people know about this, resulting in much of the blame going to the victims, the mothers!

Inappropriate handling practices during preparation can make the problem worse.



Following up on WHA resolution 58.32 [2005], WHO's Food Safety Department issued guidelines on safe preparation of powdered infant formula. They recommend that PIF be prepared with boiled water cooled to at least 70°C to reduce the risk of infection. Minimising the time from preparation to consumption also reduces the risk, as does storage of prepared formula at temperatures no higher than  $5^{\circ}$ C.

\*FAO/WHO. 2006. Enterobacter Sakazakii and Salmonella in powdered infant formula. Meeting Report. Joint FAO/WHO Technical Meeting on Enterobacter sakazakii and Salmonella Powdered Infant Formula, Rome, Italy, 16-20 January 2006. [FAO/WHO] Microbiological Risk Assessment Series, No. 10.

## International Code Article 6 Health Care System

**6.1** The health authorities in Member States should take appropriate measures to encourage and protect breastfeeding and promote the principles of this Code, and should give appropriate information and advice to health workers in regard to their responsibilities, including the information specified in Article 4.2.

## Health authorities should promote breastfeeding, not formula feeding

Health authorities should make sure health workers know about the Code, know what it means and help put it into practice. Measures considered appropriate to encourage and protect breastfeeding may include breastfeeding and lactation management courses in the curricula of health workers.



VIOLATION

Amidst wallpaper decoration promoting products of rival company Abbott (circled), Danone-*Dumex* shows a 2-minute video on infant feeding (blue arrows) in a busy private clinic in Singapore. The *Dumex* product logo is clearly visible in the video.

### Support for breastfeeding in health facilities



Helping baby who had difficulty latching on. (Canada)



(Left) Skin-to-skin care. (Right) Tube feeding. (Kuwait)

Infants admitted to a neonatal unit (NNU) are frequently unable to feed by breast or bottle because of ill health or prematurity. These infants require nutritional support until they can start oral feeding. Breastfeeding is advocated for these infants, and mothers are frequently encouraged to express breastmilk and feed it via enteral tube. **6 2** No facility of a health care system should be used for the purpose of promoting infant formula or other products within the scope of this Code. This Code does not, however, preclude the dissemination of information to health professionals as provided in Article 7.2.

**6.3** Facilities of health care systems should not be used for the display of products within the scope of this Code, for placards or posters concerning such products, or for the distribution of material provided by a manufacturer or distributor other than that specified in Article 4.3.



## No promotion of products in health facilities

Articles 6.2 and 6.3 aim to create an environment where breastfeeding is the norm. There must be no product displays in hospitals or clinics. Company materials such as posters, clocks, calendars, desk pads, diaries, stickers, note pads, pen holders, cups, bibs, gift packs, growth charts, health monitoring cards, cot cards and immunisation cards are not permitted in any part of the health care system.

*Why*? Because all such things have been cleverly designed to promote products, instill goodwill for the company and remind health workers of the company name.

Companies are only allowed to provide health professionals with information that is scientific and factual (see Article 7.2) and which complies with all the points set out in Article 4.2.



*Hipp* promotion in health facilities in Central Europe – Social research shows even inexpensive items like these can influence prescribing behaviour.

**6**.4 The use by the health care system of "professional service respresentatives", "mothercraft nurses" or similar personnel, provided or paid for by manufacturers or distributors, should not be permitted.

**6.5** Feeding with infant formula, whether manufactured or home prepared, should be demonstrated only by health workers, or other community workers if necessary; and only to the mothers or family members who need to use it; and the information given should include a clear explanation of the hazards of improper use.

#### No company mothercraft nurses

Company marketing personnel, no matter what they are called, should not be permitted to have contact with mothers. This ban is to stop the infiltration of health facilities by company personnel.

## Formula feeding must become the exception, not the rule

Only parents who need to formula feed their infants should be shown how to prepare formula. They must be warned about the health hazards of formula feeding. There are WHO/FAO Guidelines on safe preparation, storage and handling of powdered infant formula both in hospitals and at home. (see p. 17)

#### WATCH OUT !

Companies claim that their materials are necessary to assist health workers when they instruct mothers. This is not true. Health workers can obtain preparation instructions from product labels without referring to additional company materials which are inherently promotional. Source: BTR 2017/ IBFAN-ICDC



In Singapore a Mead Johnson rep courts new parents with big hamper (right) while health workers look on. **66** Donations or low-price sales to institutions or organisations of supplies of infant formula or other products within the scope of this Code, whether for use in the institutions or for distribution outside them, may be made. Such supplies should only be used or distributed for infants who have to be fed on breastmilk substitutes. If these supplies are distributed for use outside the institutions, this should be done only by the institutions or organisations concerned. Such donations or low-priced sales should not be used by manufacturers or distributors as a sales inducement.

**6.7** Where donated supplies of infant formula or other products within the scope of this Code are distributed outside an institution, the institution or organisation should take steps to ensure that supplies can be continued as long as the infants concerned need them. Donors, as well as institutions or organisations concerned, should bear in mind this responsibility.

#### **Ban on free supplies**

Donations of products within the scope of the Code may only be given to orphanages and similar social welfare institutions – not to hospitals and maternity wards.

There was so much abuse of "free supplies" that the WHA issued several resolutions to stop it. The latest, WHA 47.5 [1994], states that there shall be "no donations ... in any part of the health care system."



Supplies stashed in corners and under hospital beds before the Code-based legislation was adopted in Thailand.

If donations are provided to social welfare institutions such as orphanages, Article 6.7 requires that a sufficient amount be given to last for as long as the baby needs them (i.e. normally, up to one year).

#### WATCH OUT !

There has been considerable controversy and confusion about Article 6.6 and 6.7 of the International Code. When they were drafted, the intention was to allow for charitable donations to orphanages and similar social welfare institutions, not to ordinary health facilities.

Companies, however, were supplying huge amounts of free formula to maternity hospitals and clinics, knowing that this encouraged:

- routine formula feeding of newborns
- using formula instead of solving breastfeeding problems
- the giving of samples to mothers at discharge
- general goodwill towards the company.

Once hospitals have to pay for formula, the use of it will be more carefully managed. But old habits die hard and companies are still trying to get around the ban. Monitoring 'free supplies' remains very important.

#### "Infants who have to be fed on breastmilk substitutes" (Article 6.6):

#### What does it really mean?

This particular phrase has been interpreted widely by companies. Any mother who "has to go back to work" or any mother who "does not have enough milk" was deemed **to have to** formula feed. Other voices said no to this interpretation: the real medical "need" is very small. WHO estimates that less than 3% of mothers are physiologically unable to breastfeed.

By 1985, so many questions were raised about the need for substitutes in hospitals that WHO called in a panel of experts to decide on an interpretation of **"infants who have to be fed on breastmilk substitutes."** The experts concluded that there were so few such infants that maternities did not need free supplies at all. Instead, they should just buy the small amount necessary in the same way as other food and materials are purchased.

Editorial note: The few situations where the use of breastmilk substitutes is medically indicated, can be found in "WHO/UNICEF - Acceptable Medical Reasons for Use of Breastmilk Substitutes", WHO, Geneva, 2009. See http:// www.who.int/child\_adolescent\_health/documents/infant\_ feeding/en/index.html.



(Left) *Dumex* (Danone) decal greets visitors at the entrance of every elevator of a hospital in Phnom Penh. A very large 'open and shut' case of promotion.

(Below) Other than the *Dumex* decal, the hospital also receives regular size formula tins for distribution to mothers of newborn babies. (Cambodia)



#### No more donations !

WHA resolution 39.28 [1986] urges Member States "to ensure that the small amounts of breastmilk substitutes needed for the minority of infants who require them in maternity wards and hospitals are made available through the normal procurement channels and not through free or subsidised supplies."

Eight years later, supplies were still being delivered, more secretly, via doctors' homes, through back doors, or via paediatric wards. Request forms were invented and real invoices were designed to never be paid.

#### WHA resolution 47.5 [1994] finally

clarified Article 6.6 by urging member States "to ensure that there are no donations of free or subsidised supplies of breastmilk substitutes and other products covered by the International Code of Marketing of Breastmilk Substitutes in any part of the health care system." **68** Equipment and materials, in addition to those referred to in Article 4.3, donated to a health care system may bear a company's name or logo, but should not refer to any proprietary product within the scope of this Code.



Nestlé installs an "Allergy Risk Tracker" in a private hospital to reach out to pregnant women and mothers. Even when their assessments show low risk, patients are encouraged to discuss with their doctors on ways to help reduce risk of allergy. The solution given is Nestlé's hypoallergenic formula! (Malaysia)

## No brand names on donated equipment

Although product (i.e. brand) names are not allowed, the name and logo of some companies are the same or very similar to the name of their products.

Article 6.8 is one of the weakest provisions of the Code, as it does not take into account the promotional impact of the company name, nor the possibility of conflicts of interest. When health facilities receive expensive equipment from companies, they may feel obligated to these companies for the material assistance provided and reciprocate in a way that adversely affects the promotion of breastfeeding.

This weakness in the Code is addressed by Recommendation 6 of the **2016 Guidance on ending the inappropriate promotion of foods for infants and young children**. This 2016 Guidance specifically prohibits companies from donating or distributing equipment or services to health facilities.

Health workers can advocate for the implementation of the 2016 Guidance in their work places as a matter of best practice.

See discussion on Recommendation 6 of the 2016 Guidance at pg.50.

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## **BFHI-** Best start for breastfeeding

The **Baby-friendly Hospital Initiative (BFHI)** is a programme launched by WHO and UNICEF in 1991 to designate facilities offering maternity and newborn services that implement evidence-based strategies to become centres of breastfeeding support. The basis of the BFHI is the adherence to the **Ten Steps to Successful Breastfeeding**<sup>7</sup> in the care of mothers and infants and compliance with the Code.<sup>8</sup>

Facilities that demonstrate their full adherence to the **Ten Steps**, as well as their compliance with the Code can be designated "Baby-friendly" after an external audit. BFHI was revised in 2006 and after extensive user surveys, was re-launched in 2009. The revised BFHI implementation tools<sup>9</sup> provided additional recommendations for expansion into other health and community settings.

A new guideline published in 2017<sup>10</sup> reaffirms that to create an enabling environment for breastfeeding, facilities offering maternity and newborn services should have a clearly written breastfeeding policy to underpin the quality standards for promoting, protecting and supporting breastfeeding and these must be routinely

communicated to staff and parents. The policy should incorporate provisions of the Code.

The 2018 BFHI I m p l e m e t a t i o n Guidance<sup>11</sup> includes a revision of the Ten Steps and encompasses for the first time the Code as a distinct step within the Ten Steps.



- 7. The Ten Steps, published two years before the launch of BFHI, summarises the practices and policies necessary to support breastfeeding and laid the foundation of BFHI.
- 8. National Implementation of the Baby-friendly Hospital Initiative, 2017. Geneva: World Health Organization; 2017. Retrieved from http://www.who.int/ nutrition/publications/ infantfeeding/bfhi-national-implementation2017/en/.
- 9. UNICEF/WHO. Baby-friendly Hospital Initiative, revised, updated and expanded for integrated care, Section 1, Background and implementation, January 2009.
- 10. Guideline: protecting, promoting and supporting breastfeeding in facilities providing maternity and newborn services. Geneva: World Health Organization; 2017. Retrieved from http://www.who.int/nutrition/publications/guidelines/breastfeeding-facilities-maternity-newborn/en/.
- 11. Implementation guidance: protecting, promoting and supporting breastfeeding in facilities providing maternity and newborn services the revised Baby-friendly Hospital Initiative. Geneva: World Health Organization; 2018. Retrieved from: http://www.who.int/nutrition/publications/infantfeeding/ bfhi-implementation/en/

## Ten steps to successful breastfeeding

#### **Critical management procedures**

- a. Comply fully with the International Code of Marketing of Breastmilk Substitutes and relevant World Health Assembly resolutions.
  - b. Have a written infant feeding policy that is routinely communicated to staff and parents.
  - c. Establish ongoing monitoring and data management systems.

2. Ensure that staff have sufficient knowledge, competence and skills to support breastfeeding.

#### **Key clinical practices**

3. Discuss the importance and management of breastfeeding with pregnant women and their families.

4. Facilitate immediate and uninterrupted skinto-skin contact and support mothers to initiate breastfeeding as soon as possible after birth.

## 5. Support mothers to initiate and maintain breastfeeding and manage common difficulties.

6. Do not provide breastfed newborns any food or fluids other than breastmilk, unless medically indicated.

7. Enable mothers and their infants to remain together and to practise rooming-in 24 hours a day.

8. Support mothers to recognise and respond to their infants' cues for feeding.

9. Counsel mothers on the use and risks of feeding bottles, teats and pacifiers.

10. Coordinate discharge so that parents and their infants have timely access to ongoing support and care.

**Step 1** on facility breastfeeding policy has been modified to include three components. Application of the Code has always been a major component of the BFHI but was not included as part of the original Ten Steps. This revision explicitly incorporates full compliance with the Code as a step.

Implementation guidance: protecting, promoting and supporting breastfeeding in facilities providing maternity and newborn services – the revised Baby-friendly Hospital Initiative. Geneva: World Health Organization; 2018 at p.14.

## What does it mean to be Code compliant under Step 1?

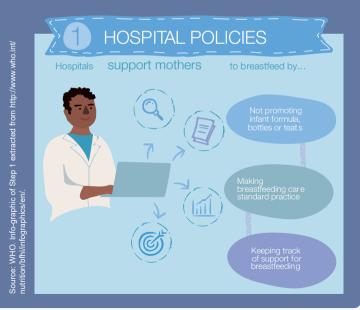
#### Health systems

- must not promote products under the scope of the Code nor allow companies that market foods for infants and young children, or feeding bottles and teats to use health systems for promotion.
- must acquire breastmilk substitutes, feeding bottles or teats through normal procurement channels and not receive free or subsidised supplies.

#### Facility management and staff

- must not engage in any form of promotion or permit the display of any type of advertising of products under the scope of the Code, including the display or distribution of any equipment or materials that refer to a brand name.
- must not give mothers samples of products under the scope of the Code for use in the facility or discharge packs that contain product samples, leaflets, discount coupons or other promotional materials to take home.

- must teach mothers who are formula feeding by necessity or by choice, about safe preparation and storage of formula and ensure the information includes health hazards of improper use.
- must ensure that funding sources do not create conflicts of interest. They must never accept funds, gifts or other incentives from companies that market foods for infants and young children, or feeding bottles and teats.



## International Code Article 7 Health Workers

**7.1** Health workers should encourage and protect breastfeeding; and those who are concerned in particular with maternal and infant nutrition should make themselves familiar with their responsibilities under this Code, including the information specified in Article 4.2.

**7.2** Information provided by manufacturers and distributors to health professionals regarding products within the scope of this Code should be restricted to scientific and factual matters, and such information should not imply or create a belief that bottle feeding is equivalent or superior to breastfeeding. It should also include the information specified in Article 4.2.



Health workers in Bangladesh counsel a new mum on infant feeding. They have the responsibility to protect and promote breastfeeding.

#### No promotion to health workers

The need for health professionals to have product information is often an excuse for companies to advertise. Only scientific and factual information regarding products may be given to health professionals by companies. This information should include the points set out in Article 4.2 including health hazards associated with formula feeding and never imply that their product is the same or better than breastfeeding. Protecting Infant Health-30

# Neither scientific nor factual



The line between promotion and information is crossed here.

In Ethopia, a Liptomil brochure found in a hospital explains how the use of the Liptomil range of formula products will result in "easy digestion, immunity buildup and enhanced brain, eye and neuro-system development". "A Bright Future Needs the Right Start".

This brochure has pop-ups and pullouts to illustrate how the Liptomil range contains all the nutrients needed for healthy growth and development.

In Egypt, a Liptomilk booth at a conference for health professionals attracts the attention of many doctors with goodie bags containing product materials. Whatever 'scientific and factual' information they receive



at the conference will be obliterated by the promotion from companies like Liptis.

(Left) Life-size tins of *Liptomilk* double as counters for delegates. (Right) Goodie bags for delegates who drop by to view *Liptomilk* displays.

**7.3** No financial or material inducements to promote products within the scope of this Code should be offered by manufacturers or distributors to health workers or members of their families, nor should these be accepted by health workers or members of their families.



**Nestlé** power banks and Crocs-styled shoes are donated to health workers in Nigeria. Such gifts are prohibited by the Nigerian law.

### No gifts to health workers

Gifts, whether money, goods or services, should not be offered by companies to health workers, nor should they be accepted. This is to prevent companies from building goodwill with health workers.

Even gifts of little monetary value can influence health workers' advice about infant feeding. They may feel obliged to recommend the donor company's product or do so because they are familiar with the company name, brand or sales representative.

A colleague who wields a lot of influence with the director invited us to a birthday party. When we arrived, a representative from a drug company with a new formula was present. They had financed the celebration. And the next month, that brand was served in the nursery.

**C** 'No strings attached' *still carries some kind of reciprocity*.

JAMA. 2006; 295:429-433

**7**4 Samples of infant formula or other products within the scope of this Code, or of equipment or utensils for their preparation or use, should not be provided to health workers except when necessary for the purpose of professional evaluation or research at the institutional level. Health workers should not give samples of infant formula to pregnant women, mothers of infants and young children, or members of their families.



Surprise in a box - unsolicited formula samples sent by special delivery to homes of health workers. (Canada)

### A ban on samples

Samples may never be passed on to parents. There is only one exception to the ban on samples: **professional evaluation or research at the institutional level**. In most health care settings, this would require protocols and approval by ethics committees.

The very notion of using free samples to conduct professional evaluation and research gives rise to ethical concerns.

Free samples lead to more babies being formula fed rather than breastfed, causing potential harm to both mothers and babies.

Any professional evaluation or research involving infants requires the mothers' written consent and proper counseling on the risks of formula feeding.

Products used for professional evaluation and research should be purchased, not obtained as free samples so as to preserve the independence and integrity of the research. **7.5** Manufacturers and distributors of products within the scope of this Code should disclose to the institution to which a recipient health worker is affiliated any contribution made to him or on his behalf for fellowships, study tours, research grants, attendance at professional conferences, or the like. Similar disclosures should be made by the recipient.

WHA resolution 49.15 [1996] urges Member States to: ensure that financial support for professionals working in infant and young child health does not create conflicts of interest, especially with regard to the WHO/UNICEF Baby Friendly Hospital Initiative.

WHA resolution 58.32 [2005] reiterated that financial support and other incentives for such professionals are likely to create conflicts of interest. Incentives for programmes were added in this resolution.

The need to avoid conflicts of interest was reiterated in the 2008 resolution in the call for Code implementation by scaling up of efforts to monitor and enforce national measures to protect breastfeeding.

### Disclosure

Companies forge links with health workers by providing them with financial support for their professional development. Article 7.5 allows this kind of sponsorship, even though it can create conflicts of interest. The only safeguard provided by Article 7.5 is the need for disclosure but that is insufficient to avoid conflicts of interest because:

- Health workers may have a different understanding of a conflict of interest, and will therefore not disclose all conflicts of interest.
- Declarations of conflict of interest are usually unverified, casting doubts on accuracy.
- Disclosure may be used to "sanitise" a problematic situation, suggesting that no ill effects will follow from the disclosed relationship.

Article 7.5 is a weakness in the Code but there are three WHA resolutions that caution against conflicts of interest, namely resolution WHA 49.15 [1996]; resolution WHA 58.32 [2005] and resolution WHA 61.20 [2008].

See also discussion on Recommendation 6 of the 2016 Guidance at p.50.

### Sponsorship, Conflicts of Interest and Infant and Young Child Feeding

The concept of a **conflict of interest** has its origins in laws used to regulate **fiduciaries**— individuals such as doctors, lawyers and bankers are entrusted to serve the interest of another party or a designated mission. They are held to the highest legal standards of conduct.

The law does not permit fiduciaries to promote their own interests, or the interests of third parties. It requires fiduciaries to be loyal to the party they serve, to act prudently and diligently, and to account for their conduct.<sup>12</sup> Health professionals have specialised knowledge and hold the trust of their patients. As patients are in no position to check whether health professionals are acting solely for their benefit or have been influenced by some personal interest, a duty to avoid conflicts of interest is implied.

Professional associations must also avoid conflicts of interest even though there now exist a **culture of dependency** whereby health professionals believe they cannot carry out activities without sponsorship. Pressure to accept sponsorship for their activities is always present.

Infant formula manufacturers have a duty to their shareholders to maximise sales of their products, which by definition means minimising exposure of infants to breastmilk. Hence, while publicly stating their commitment to breastfeeding, ... infant formula companies are in fact profiting from the failure of breastfeeding ...

Wright C.M., Waterston A.J.R., "Relationships between paediatricians and infant formula milk companies", Archives of Disease in Childhood, 2006; 91: 383-385

<sup>12.</sup> Rodwin, Marc A., Attempts to Redefine Conflicts of Interest (2017). Accountability in Research: Policies in Quality Assurance. In this paper, Rodwin posits that the traditional legal concept of conflict of interest is a practical tool to regulate conduct and warns that attempts to redefine conflicts of interest will result in policies that cannot be implemented effectively and the de-regulation of financial conflicts and overregulation of so-called intellectual conflicts.

#### Protecting Infant Health-35

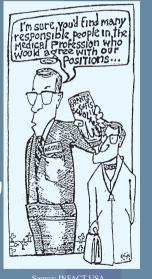
### **Don't break the trust – refuse sponsorship !**

Acceptance of funding or other incentives, however conditional, creates a sense of obligation and loyalty to the company in question. This is exactly what health professional associations ... should avoid. They have a moral obligation to protect

themselves and their members from inappropriate promotion of BMS in all forms, however indirect, and from resulting competing interests in health care settings. Furthermore, health professional associations have a moral obligation to respect and protect women's and children's rights to be free from all forms of inappropriate marketing practices.

Costello, A., Branca, F., Rollins, N., Stahlhofer, M., & Grummer-Strawn, L. (2017). Health professional associations and industry funding. The Lancet, 389(10069), 597-598. Sponsorship by its nature creates a conflict of interests. Whether it takes the form of gift items, meals, or help with conference expenses, it creates a sense of obligation and a need to reciprocate in some way. The "gift relationship" thus influences our attitude to the company and its products and leads to an unconscious unwillingness to think or speak ill of them. Even if individuals are uninfluenced by sponsorship and subsequently act wholly responsibly in relation to breast and formula feeding, by accepting sponsorship or speaking at an infant formula milk company meeting they still lend credibility to the company by the visible association of their name and position with that company.

> Wright C.M., Waterston A.J.R., "Relationships between paediatricians and infant formula milk companies", Archives of Disease in Childhood, 2006; 91: 383-385



# Taking a stand against sponsorship of events

Individual health workers are increasingly faced with the question of whether to participate in industry sponsored events such as seminars, exhibitions and conferences.

In considering whether to attend any such event, it helps to go through the following checklist<sup>13</sup>:

- Have the event's organisers been told why sponsorship of the event is objectionable?
- Have suggestions been provided for alternative sources to fund the event?
- Is the sponsorship in any way directly "benefiting" the participant? (meals, gifts etc.)
- Will health workers compromise their ability to be a critical voice for breastfeeding protection?

If the decision has been made to participate in the event, health workers should consider whether:

- participation is tantamount to endorsing company practices?
- there could be transference of their good image onto the company and/or the event itself?
- participation might be used against them in the future?
- participation would send out mixed messages about their expressed principles?
- the meeting is likely to provide information, contacts, opportunities for learning and interaction with key actors not available elsewhere or in other ways?
- any difference would be made through their technical/strategic presentations?
- any interventions could be made to raise awareness of the sponsorship and conflicts of interest?
- if going as speakers, whether there will be an opportunity to publicly express discontent about the sponsorship in a noticeable manner e.g. in a keynote speech or on a panel?

<sup>13.</sup> Modified from "Guidance for IBFAN groups and members on participation in events sponsored fully or partially by companies with commercial interest in infant and young child feeding", IBFAN-GIFA, 2006.

- speeches/abstracts will be used/published in company materials or in conference announcements or reports, which also contain advertisements for breastmilk substitutes or feeding bottles and teats?
- the sponsoring company is subject to any campaign or boycott for abuses regarding labour, environment or human rights either in the country where the event is taking place or elsewhere in the world?

If the final decision is not to attend the event, the ethical reasons behind the decision should be made known to the organisers.

If the decision is made to attend, there should be an explanation of that decision to the institution the health worker is affiliated to, for accountability and consistency.

Professional associations have to act responsibly on behalf of members. The points which individual health workers must consider apply equally to associations, so the office bearers have a primary duty to question offers of sponsorship. Pressure to accept may be high. Where sponsorship is offered for events that professional associations are themselves organising, alternatives should include the option to scale down the luxury of the event such as using colleges or hospital auditoriums instead of commercial venues like five-star hotels.



*Nan* and *Lactogen* posters serve as an incriminating backdrop for group pictures of delegates at a conference sponsored by Nestlé. (Egypt)

### How the Code Affects Health Workers, Health Facilities and Professional Associations

Code implementation is only one of several important actions required to ensure optimal infant and young child feeding practices. The Code on its own will not improve breastfeeding rates. For that to happen, health authorities must introduce a multi-pronged approach which includes quality breastfeeding education for health workers and women; supportive health services and community programmes and imaginative maternity legislation.

However, by complying with the Code, health workers can do a lot to curb marketing practices that undermine breastfeeding in their work environment. (See also discussion on Recommendation 6 of the 2016 Guidance at p.50) Each major Code provision and relevant WHA resolution has been explained earlier in this booklet. Below is a summary on how the Code impacts on health workers and health care systems.

### What the Code means for health workers:

- Health workers have the responsibility to encourage and protect breastfeeding.
- Health professionals (not health workers in general) may receive only information on scientific and factual matters from companies
- To prevent conflicts of interest, health workers may not receive financial or material inducements from companies.
- Health workers may receive free samples only when they are necessary for professional evaluation or for research at the institutional level. In no case should these samples be passed on to mothers.
- Health workers in both the public and private sector have the same responsibilities under Article 3 of the Code.

### What the Code means for health facilities:

- Health facilities may not promote any product covered by the scope of the Code. This includes the display of products, placards and posters concerning such products and distribution of materials provided by manufacturers and distributors.
- Formula feeding should be demonstrated only to mothers or family members who need to use it; information given should include a clear explanation of risks of formula feeding and hazards of improper use.
- Donated equipment and materials should not display or refer to any brand names.
- Health facilities may not accept supplies of products under the scope free of charge or at low cost (read together with WHA 47.5 [1994]).
- No programmes related to infant and young child nutrition may be sponsored by manufacturers or distributors as this will lead to conflicts of interest (read together with WHA 58.32 [2005]).

### What about professional associations?

Articles 11.2 and 11.4 refer to "professional groups" and accord them the responsibility to monitor the application of the Code and to draw the attention of manufacturers and distributors to Code violations. The responsibilities of professional groups also apply to health workers in their individual capacity.

This interpretation is supported by paragraph 40 of the **Global Strategy on Infant and Young Child Feeding** which states that health professional bodies should observe, in their entirety, their responsibilities under the Code and national measures.



Free gifts (Left) for conference delegates at Mead Johnson booth at a paediatrics conference. (USA)

### **New Marketing Trends**

#### Technological advances influence consumers.

Newgadgetsandelectronicmeansofcommunications, social media and phone apps have become more effective marketing tools than the traditional media such as television, magazines and radio. Companies use social media such as Facebook, Instagram, and YouTube to reach parents and health professionals. Feed algorithm technology and built-in features on social media such as hash-tagging, posting, sharing, liking and commenting are transforming promotion, making it ever more interactive, participatory, and personal. The resulting new 'influencer marketing' can go viral within minutes, reaching hundreds of thousands of people conveniently, freely, and effortlessly.

# Hijacking breastfeeding and public health campaigns.

Besides sponsoring medical conferences for continuing education, companies portray themselves as 'ambassadors of breastfeeding and infant nutrition'. Their activities range from breastfeeding promotion, research on breastmilk to financing breastfeeding rooms. Very often, they involve partnerships with community organisations and governments in public health programmes. Such public-private partnerships have become endemic and exacerbate **conflicts of interest**. This type of industry infiltration compromises the integrity of institutions and programmes whose primary duty ought to be the promotion of breastfeeding and service of public health.



In Mexico under its "United for Breastfeeding", Nestlé opened 20 breastfeeding rooms in public hospitals which carry its formula products slogan *"Start Healthy, Stay Healthy"*.

### Capitalising on prestige of health institutions.

Companies have been building a "health expert" image to gain trust and goodwill from the public. They artfully combine health campaigns to project themselves as health and nutrition champions. They partner with health institutes to conduct studies on infant and young child feeding and capitalise on the prestige of these institutions to burnish their image as a child health expert.

Despite WHA resolutions on conflicts of interest, more health professionals are now being drawn into industry-sponsored programmes which act systemically as conduits between companies and the public, or even between companies and governments.

### Claims and designer formulas.

Non-essential additives such as fatty acids (DHA), pre/pro-biotics, lutein and omega–3, etc. which are not proven to be safe or beneficial continue to be added to formulas which are then promoted aggressively through health and nutrition claims. Claims should no longer be allowed. (WHA 58.32 and 63.23)

Companies are also capitalising on maternal fears and insecurities by calling normal infant behaviour such as colic or regurgitation 'problematic' in order to market new 'designer' formulas at a premium price.

Health workers should try to keep such products out of health facilities, relying on Articles 6.2 and 6.3 of the Code.



Mead Johnson promotes its formula product Enfinitas as the "complete excellent intelligence choice". (China)



A **Friso** LockNutri station in a Singapore supermarket suggests how a supposedly healthy digestive system can be attained= promotion violates the Code

# **Code Watch by Health Workers**

### Code Article 11.4

Nongovernmental organisations, professional groups, institutions, and individuals concerned should have the responsibility of drawing the attention of manufacturers or distributors to activities which are incompatible with the principles and aim of this Code, so that appropriate action can be taken. The appropriate governmental authority should also be informed.

Monitoring is centred on fact-gathering with a view to holding companies to account for their responsibilities under the Code. It is a whistleblowing mechanism which has proven effective in shaming companies into behaving. Health workers have a central role to play in monitoring because they work in settings where companies focus their marketing activities. Monitoring by health workers provides important information for policy makers about marketing practices in health care settings and how these practices affect breastfeeding.

The information can be the catalyst for change in the policies of health facilities in their dealings with companies. Where there are policies already in place, monitoring ensures that they are being observed and achievements are not eroded over time.

Monitoring may even bring about change at the national and international level through legislative reform or the power of shaming.

Health workers can link with local, national and international groups so that information they collect can be systematically collated, analysed and shared. The reports can in turn be adapted as advocacy tools to bring about positive changes in policies for the protection of infants and young children at all levels.

# **Monitoring tools**

The 'Quick and Easy Monitoring Form' in Annex B is a simple format to help in the collection of monitoring data. Health workers who are keen to report on company activities which contravene the Code can use this easy form. If they wish to monitor in a systematic manner, monitoring tools can be built on KoBoCollect or other data collection systems so as to build a database of Code violations.



Online and Smart Phone App Monitoring. Available from www.ibfan-icdc.org In 2017, NetCode (the Network for Global Monitoring and Support for Implementation of the International Code of Marketing of Breastmilk Substitutes and subsequent relevant World Health Assembly Resolutions) developed a toolkit to invigorate and reinforce ongoing monitoring and periodic assessment of the Code and national laws.

This toolkit is ideal for government-run monitoring but can also be used by civil society and other entities to establish a monitoring system.



Available from http://www.who.int/nutrition/netcode/toolkit/en/.

#### What to look for in health facilities

- Free supplies: Companies are prohibited from providing any products to health facilities free or at low cost (less than 80% of the retail price). Remember: the World Health Assembly passed two resolutions (WHA 39.28 [1986] & WHA 47.5 [1994]) which effectively called for an end to all free or low-cost supplies to any part of the health care system.
- *Company materials:* Health facilities should have no posters, literature, crib cards, no equipment or other materials with a name, picture, logo or other reference to any product under the scope of the Code on display. Company literature must be in accordance with Article 4.2 provisions.
- *Gifts:* Companies should not distribute gifts such as pens, note pads, car stickers, bibs or toys, whether or not the item carries a product brand name.
- *Medical representatives, mother craft nurses, etc:* Company marketing personnel, no matter what they are called, should not have contact with mothers or their families.

- If company personnel are in health facilities it is for the purpose of product promotion or for gathering information from the new mothers so as to contact them later.
- *Programmes:* Any planned event or service relating to infant and young child feeding aimed at health workers or mothers.



Finding out why this sample is in a hospital in Laos

# What to look for where health workers are concerned

Health workers should encourage and protect breastfeeding and should not interact with companies. Monitoring health workers should focus on:

- Information materials for health professionals: Information by companies must only contain scientific and factual matters.
- *Free samples:* Health workers can only receive free samples for professional evaluation or for research at institutional level. In no case should these samples be passed on to mothers.
- *Financial or material inducements:* Companies must not provide gifts in the form of money, goods, travel or services to health care workers.
- *Sponsorship:* Contributions by companies for fellowships, study tours, research grants, attendance at professional conferences must be subject to disclosure to the health worker's institution and should not give rise to conflicts of interest.

### **Reporting on Code violations**

Whether a health worker is handling Code violations voluntarily or as part of his or her official duty, the following steps should be considered.

- A time frame for collecting and analysing materials and to prepare a brief report (if possible, via a committee).
- Submission of a report together with selected evidence as exhibits to relevant authorities.
- Dialogue with companies with a view to correcting their conduct (if the relevant authorities so direct). In such event, ensure the meeting has a clear agenda and official minutes are taken. Any statements companies wish to make should be in writing and time must be provided for internal consultation and discussion before a decision is taken. This is particularly important if the monitoring report is being challenged.
- Where a particular practice is an offence under national law, consider lodging a complaint for the initiation of enforcement proceedings against errant companies.

# **Complementary Foods**

The promotion of complementary foods is governed by the **Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children**<sup>14</sup> (the '2016 Guidance'). Promotion of breastmilk substitutes and commercial foods for infants and young children often undermines optimal infant and young child feeding. Only



recommendations relevant to health workers and the Code are highlighted in this chapter.

For details please refer to the Guidance and its **Implementation Manual**.<sup>15</sup>

Technical support for the implementation of the 2016 Guidance (welcomed in Resolution WHA 69.9 [2016])

- 14. Available from: http://apps.who.int/gb/ebwha/pdf\_files/WHA69/A69\_7Add1-en.pdf?ua=1
- 15. Available from: https://www.who.int/nutrition/publications/infantfeeding/manual-ending-inappropriate-promotion-food/en/

#### Scope of the 2016 Guidance (Recommendation 2)

All commercially produced food or beverage products that are specifically marketed as suitable for feeding infants and young children from six months up to 36 months of age are covered under the 2016 Guidance. This include products that:

- are labelled with the words baby/infant/toddler/ young child;
- recommend an age of introduction of less than three years; use an image of a child appearing three years of age or younger or feeding with a bottle; or
- are in any other way presented as suitable for children under the age of three years.



Examples of products covered by the '2016 Guidance'.

# Highlights of Recommendations in the 2016 Guidance:

- reinforces optimal infant and young child feeding practices, such as the emphasis on the use of suitable, nutrient-rich, home-prepared, and locally available foods that are prepared and fed safely; and that complementary feeding should be timely, adequate, safe and appropriate. (*Recommendation 1*)
- clarifies that any milks marketed for feeding infants and young children up to age 3 years (e.g. follow-up formula and growing-up milks) are considered breastmilk substitutes, thus should not be promoted. (*Recommendation 2*)



The debate on whether growing-up milks are covered by the scope of the Code is resolved by Recommendation 2. This Enfa 1,2,3 range shows infant formula, follow-up formula, and growing up milks. (The numbers are a marketing gimmick).

- reiterates that commercial complementary foods should not be promoted if they do not meet all the relevant national, regional and global standards for composition, safety, quality and nutrient levels and are in line with national dietary guidelines. (*Recommendation 3*)
- specifies the types of messages that have to be included when promoting complementary foods, and the kind of messages that are <u>not</u> allowed .(*Recommendation 4*, see **Box 1**)
- forbids **cross-promotion** through similar packaging, design and colour schemes to indirectly promote breastmilk substitutes via complementary foods. (*Recommendation 5*, see **Box 2**)
- identifies situations that could give rise to **conflicts of interest** in the health care system which may result in the **loss of independence**, **integrity and public credibility** of health facilities, health workers and health professional associations and thus should be prohibited. (*Recommendation 6*, see **Box 3**)

#### Box 1.

### **Recommendation 4 - Messages for the promotion of foods for infants and young children**

Although promotion of foods for infants and young children is not completely prohibited, messages should support optimal feeding. Inappropriate messages are prohibited. Messages about commercial products are conveyed in multiple forms, through advertisements and sponsorship via promotion including brochures, online information and package labels.

Irrespective of the form, messages should always:

- include a statement on the importance of continued breastfeeding for two years or beyond and the importance of <u>not</u> introducing complementary feeding before six months of age;
- include the appropriate age of introduction of solids (not less than six months);
- be easily understood by parents and other caregivers, with all required label information being visible and legible.

Messages should <u>not</u>:

- include any image, text or other representation that might suggest use for infants under the age of six months (including references to milestones and stages);
- include any image, text or other representation that is likely to undermine or discourage breastfeeding, that makes a comparison to breastmilk, or that suggests that the product is nearly equivalent or superior to breastmilk;
- recommend or promote bottle-feeding;
- convey an endorsement or anything that may be construed as an endorsement by a professional or other body, unless this has been specifically



approved by relevant national, regional or international regulatory authorities.

Inappropriate messaging includes health and nutritional claims, promotion of bottle-feeding, and suggestions for use of a product before the age of six months.

### Box 2.

# **Recommendation 5 – Avoidance of cross-promotion**

There should be no cross-promotion for breastmilk substitutes indirectly via the promotion of foods for infants and young children.

- The packaging design, labelling and materials of complementary foods must be different from those of breastmilk substitutes so that they cannot be used in any way that also promotes breastmilk substitutes (for example, different colour schemes, designs, names, slogans and mascots; only the corporation name and logo may be used).
- Companies that market breastmilk substitutes should refrain from engaging in the direct or indirect promotion of their other food products for infants and young children by establishing relationships with parents and other caregivers (for example through baby clubs, social media groups, childcare classes and contests).







Promotional elements (e.g. labelling, branding and use of mascots) of a corporation's complementary food products that appear very similar to those of the corporation's range of breastmilk substitutes effectively promote the latter. Here the double heart logo is the common feature in all three Cow & Gate products.

### Box 3

# **Recommendation 6 – Avoidance of conflict of interest**

Companies that market foods for infants and young children should not create **conflicts of interest** in health facilities or health care systems. This includes

- providing free products, samples or reducedprice foods for infants or young children to families through health workers or health facilities, except as supplies distributed through officially sanctioned health programmes.
  Products distributed in such programmes should not display corporation brands;
- donating or distributing equipment or services to health facilities;
- giving gifts or incentives to health care staff;
- using health facilities to host events or contests;
- giving any gifts or coupons to parents, caregivers or families;
- directly or indirectly providing education to parents and other caregivers on infant and young child feeding in health facilities;

- providing any information for health workers other than that which is scientific and factual; and
- sponsoring meetings of health professionals and scientific meetings.

Likewise, health workers, health systems, health professional associations and non-governmental organisations should not accept or allow such activities to take place; and should ensure information given by companies that market foods for infants and young children is scientific and factual.



The Nestlé 'Blue Bear' is paraded along hospital wards inappropriately promoting its complementary foods. Blue Bear' stickers are also seen on new-born baby cots, an indication that Nestlé is encouraging early initiation of complementary feeding. (Singapore)

### **Rationale for Recommendation 6: In brief**

- Provision of free or discounted products and samples through health workers or health care systems creates conflicts of interest that undermine optimal feeding.
- Government or NGO food distribution programmes should ensure meaningful contribution to the diets of children; they

should not just induce families to eat donated food. Government approval and operation of such programmes can ensure oversight on distribution. However, where government approval is not possible, organisations with highlevel oversight on child health (UN organisations or large NGOs)

must determine which products are appropriate for distribution. Individual clinicians or health clinics should not have the authority to decide.

• Donation or distribution of equipment or services to health facilities can lead to conflicts of interest by creating a sense of obligation or

a need to reciprocate by the beneficiary health professional or institution.

- Studies have shown gifts or incentives to health workers by companies can create a sense of obligation; they can influence the judgement or attitudes of health professionals.
  - Health facilities and health workers are responsible for protecting optimal infant and young child feeding, and should not be used by companies to conduct activities that may influence parents and caregivers.
  - Education on complementary feeding provided by employees

of baby food companies creates a conflict of interest, as their primary interest lies with the corporation. This undermines the professional responsibility of health workers to ensure optimal nutrition.

# HIV, Breastfeeding and the Code

# **Risk of HIV Infection in Infants and Young Children**

Mother-to-child transmission of HIV\* can occur during pregnancy, childbirth or breastfeeding.



Mother-to-child / Perinatal Transmission

However, the risk of transmitting HIV in these ways is very low when HIV-positive mothers adhere to antiretroviral treatment.

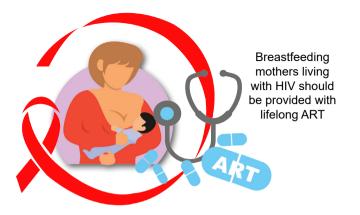
Breastfeeding remains one of the most valuable interventions for improving child survival, health and development, including for babies of mothers living with HIV. Misinformation, such as the false idea that all breastfed babies of mothers living with HIV get infected, can be used by companies to justify their promotional activities to boost their charitable public image (e.g. unsolicited supplies, donations or discounts).

Many changes have been made to WHO Guidelines on infant feeding in the context of HIV over the years. At the time of writing, the global recommendations are contained in the 2010 Guidelines on HIV and Infant Feeding and the 2016 Guideline: Updates on HIV and infant feeding.

# See Annex C for specific recommendations on HIV and infant feeding from WHO and UNICEF.

According to these Guidelines, national health authorities should decide on a strategy that will most likely give infants the highest chance of HIVfree survival given the national context – either support mothers known to be living with HIV to breastfeed (for at least 12 months and even continue breastfeeding for up to 24 months or longer) and be fully supported by antiretroviral therapy (ART); or, avoid all breastfeeding.

<sup>\*</sup> HIV=human immunodeficiency virus



HIV, supplies and the relevance of the Code

The Code and relevant WHA resolutions are of particular relevance in the context of HIV, as it prevents companies from donating supplies of breastmilk substitutes and bottles and teats, or providing them at reduced price to any part of the health care system. Although the International Code does not prevent governments from making breastmilk substitutes available to mothers living with HIV for free or at a subsidised price, it requires that products are procured through normal channels (resolution WHA 39.28 [1986]). This is an important recommendation to control 'spillover' of breastmilk substitutes to the general population and to prevent the undermining of breastfeeding for women living with HIV. The Code also protects babies who are formula-fed by ensuring product labels contain necessary information for safe preparation and consumption. Governments should ensure implementation of the Code as one of the priority actions in relation to the special circumstances created by HIV/AIDS.

### **Preventing spillover effect**

Spillover refers to the unnecessary use of replacement feeding by mothers who are HIV-negative or those whose status is unknown. Such use can be a result of fears of HIV, misinformation or poorly managed distribution of breastmilk substitutes. Effective Code implementation can be used to address spillover:

• In countries where authorities have decided to distribute breastmilk substitutes to mothers living with HIV, health programmes should continue to protect, promote and support breastfeeding as the norm in the general population and emphasise the dangers of artificial feeding.

- Health systems should implement good practices consistent with the 2018 BFHI Implementation Guidance<sup>16</sup>, which includes the Code as a distinct step in its revised Ten Steps.
- Health workers who counsel mothers on infant feeding (including replacement feeding) should have basic knowledge of the Code.
- Instructions on replacement feeding should be given only to mothers living with HIV (and others who are not breastfeeding for other medical reasons or their own decision) and their family members.
- Only health workers should demonstrate feeding with breastmilk substitutes. Group instructions should be avoided.
- Mothers should be taught to use cups to feed their infants, and no bottles should be given out.
- Any commercial infant formula that is used in the health facility for infants of mothers living with HIV should not be displayed to other mothers or pregnant women.

# Role of health workers in the context of HIV and the Code

#### *Health workers must:*

- Make sure Code monitoring takes place in health facilities.
- Ensure there is no donation of supplies of breastmilk substitutes or reduced-price offer to any part of the health care system.
- Ensure the prevalence of HIV is not used to misinform and undermine Code compliance and importance of breastfeeding.
- Not accept financial support and other incentives for programmes and health professionals that create conflicts of interest.
- Raise awareness on the relevance of the Code in the context of HIV to prevent companies from capitalising on the fear of HIV transmission.



<sup>16.</sup> Implementation guidance: protecting, promoting and supporting breastfeeding in facilities providing maternity and newborn services – the revised Baby-friendly Hospital Initiative. Geneva: World Health Organization; 2018. Retrieved from: http://www.who.int/nutrition/publications/infantfeeding/ bfhi-implementation/en/

### **Infant Feeding in Emergencies and the Code**

In emergencies such as droughts, floods, earthquakes, tsunamis, epidemics and wars, emphasis should, be on protecting, promoting and supporting breastfeeding and ensuring timely, safe and appropriate complementary feeding.

However, in times of crisis, large donations of breastmilk substitutes, other baby foods and feeding equipment are often received from various sources. There is, generally a lack of awareness that such donations can do more harm than good. Neither basic infrastructure nor adequate conditions exist to reduce the risks linked to the preparation of these products.

Avoidance of donations will help to prevent situations where excessive availability of donated products results in mothers forsaking breastfeeding when it is in fact a lifeline.



Babies who are breastfed have a secure and safe food supply. With appropriate guidance and support, women were breastfeeding their children in an emergency camp in Botswana in 2016.

Protecting Infant Health-56

# Influx of supplies in emergency camps

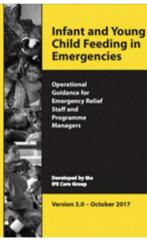
Unsanitary conditions, when there is no electricity, fuel, and clean water pose huge risks to babies' health and survival when they are formula fed. Although donations are sometimes well-intentioned, excessive availability of breastmilk substitutes, other baby foods and feeding equipment can result in mothers forsaking breastfeeding. The Code is important for controlling donations, preventing the distribution of unsuitable products and stopping companies from using emergencies to increase their market share or for public relations.



Donations of breastmilk substitutes and complementary foods can jeopardise optimal infant and young child feeding practices that are critical for health and survival.

**Resolution WHA63.23 [2010]** calls upon governments to ensure that national and international preparedness plans and emergency responses follow the evidence based **Operational Guidance on Infant and Young Child Feeding in Emergencies** (OG-IFE 3.0, updated in 2017, is the most recent version).

### The OG-IFE forbids donations of breastmilk substitutes, complementary foods, and feeding equipment in emergencies.



Useful for emergency preparedness plans and emergency responses Supplies for those who need these products must be purchased through proper channels based on assessed needs, and distributed and used according to strict criteria. The criteria must be compliant with the International Code as well as the WHO Guidance on ending inappropriate promotion of foods for infants and young children. For infants who for one reason or another cannot be breastfed\*, the use of breastmilk substitutes requires a context-specific coordination of care and skilled support to ensure that their nutritional needs are met.

The **OG-IFE** contains guidelines on management of formula feeding, the coordination of a procurement and supply/distribution chain and associated support services that are Code compliant to minimise the risk of formula feeding. (See Sections 5 and 6 of the **OG-IFE** for a full discussion on this topic.)

### \*Situations when infants cannot be breastfed:

- Infants who have become separated from their mothers
- Infants whose mothers are ill or have died, those whose mothers' milk production has become very low, or
- Babies who were already artificially fed prior to the emergency situation.

### HIV and Infant Feeding in Emergencies

HIV adds specific challenges to infant feeding in emergencies where there is a lack of access to HIV testing and counselling, antiretroviral (ARV) drugs, food, safe water and sanitation, breastmilk substitutes (BMS), and support for breastfeeding.

Additional challenges include:

- changes in risk profiles that require re-evaluation of feeding practices
- discordance between policy on HIV and infant feeding and international recommendations in emergency settings
- disrupted ARV supplies
- increased risks of HIV infection and mother-tochild transmission; and
- avoidance of breastfeeding in the absence of testing as a result of fear of HIV transmission among families and health staff.

In 2018, WHO and UNICEF released the **HIV and Infant Feeding in Emergencies: Operational Guidance (the Operational Guidance)**.<sup>17</sup> It emphasises the importance of supporting breastfeeding up to 2 years or beyond and banning BMS donations. Decisions and actions on distribution of supplies need to be in line with the International Code, relevant WHA resolutions, and OG-IFE; for example when procurement and distribution channels for BMS are disrupted or when access to mothers and children is compromised.



This will avoid spillover and ensure appropriate information on BMS use.

Operational guidance, based on a consultation convened by the World Health Organization, the UNICEF and the Emergency Nutrition Network in Geneva in September 2016.

### Annex A

### Summary of the International Code & Resolutions

"...In view of the vulnerability of infants in the early months of life and the risks involved in inappropriate feeding practices, including the unnecessary and improper use of breastmilk substitutes, the marketing of breastmilk substitutes requires special treatment, which makes usual marketing practices unsuitable for these products"

### In brief

The International Code was adopted by the World Health Assembly on 21 May 1981. It is intended to be incorporated in national legislation as a minimum requirement and aims to protect infant health by preventing inappropriate marketing of breastmilk substitutes.

Member States are urged to strengthen implementation of the International Code of Marketing of Breastmilk Substitutes and subsequent relevant Health Assembly resolutions by scaling up efforts to monitor and enforce national measures in order to protect breastfeeding while keeping in mind the World Health Assembly resolutions to avoid conflicts of interest.

### WHA 61.20 [2008] reiterated in WHA 63.23 [2010] & WHA 65.60 [2012]

- Code Preamble

### SCOPE

The Code covers the marketing of the following products:

- Infant formula, including special formulas
- Other milk products, food and beverages that are represented as suitable for use as a partial or total replacement for breastmilk such as bottle-fed complementary foods, therapeutical milks, follow-up milks\* and growing-up milks\* marketed for babies between six months to three years.
- Any other food or beverage that is represented as suitable to be fed to infants less than six months old such as cereals, jarred foods, infant teas, juices and bottled water.
- Feeding bottles and teats.

Art. 2 & WHA 39.28 [1986], WHA 49.15 [1996], WHA 54.2 [2001], WHA69.9 [2016] \*Guidance A69/7 Add.1

### **INFORMATION & EDUCATION**

Infant and young child feeding materials should include clear and consistent information on: (a) benefits and superiority of breastfeeding; (b) maternal nutrition and the preparation for and maintenance of breastfeeding; (c) negative effect on breastfeeding of introducing partial bottle feeding; (d) difficulty of reversing the decision not to breastfeed; and (e) where needed, the proper use of infant formula.

Materials about the use of infant formula should include information on:

- social and financial implications of its use;
- health hazards of inappropriate foods or feeding methods;
- health hazards of unnecessary or improper use.

There should be no idealising pictures or text.

#### Article 4.2

- Health workers, parents and other caregivers must be made aware that powdered infant formula may contain pathogenic microorganisms and must be prepared and used appropriately.
- Governments must avoid conflicts of interest in health programmes, therefore materials sponsored by companies should not be approved.

WHA 49.15 [1996] & WHA 58.32 [2005]

### NO PROMOTION TO THE PUBLIC

There should be no advertising or other form of promotion including point-of-sale advertising, giving of samples or any other promotional device to induce sales directly to the consumer at the retail level. Marketing personnel should not seek direct or indirect contact with pregnant women or with mothers of infants and young children.

#### Article 5

There should be no cross-promotion via promotion of foods for infant and young children.

#### Guidance A69/7 Add.1, WHA 69.9 [2016]



The brand name and logo for **Aptamil** cereal is the same as **Aptamil** formula. (Right) This allows for cross-promotion which is prohibited by Guidance A69/7 Add.1.

### NO GIFTS TO MOTHERS OR HEALTH WORKERS

Companies should not distribute to pregnant women or mothers of infants and young children any gifts which may promote the use of products under the scope of the Code. No financial or material inducements to promote products should be offered to health workers or members of their families.

#### Articles 5.4 and 7.3

Financial support and other incentives for programmes and health professionals working in infant and young child health should not create conflicts of interest. Research on infant and young child feeding which may form the basis for public policies should contain a declaration relating to conflicts of interest and be subjected to independent peer review.

#### WHA 49.15 [1996] & WHA 58.32 [2005]

#### NO PROMOTION IN HEALTH FACILITIES

Health facilities should not be used to promote products. Nor should they be used for product displays or placards or posters concerning such products, or for the distribution of materials bearing the brand names of products.

Articles 4.3, 6.2 & 6.3

### NO PROMOTION TO HEALTH WORKERS

Information provided to health professionals by companies should be restricted to scientific and factual matters, and should not imply or create a belief that bottle-feeding is equivalent or superior to breastfeeding. Samples of products or equipment or utensils for their preparation or use, should only be provided to health workers for professional evaluation or research at the institutional level.

#### Articles 7.2 & 7.4

### **NO FREE SAMPLES OR SUPPLIES**

Product samples should not be given to pregnant women or mothers. Free or low-cost supplies of products are not allowed in any part of the health care system.

National and international preparedness plans and emergency responses need to minimise the risks of formula feeding by ensuring that any required breastmilk substitutes are purchased, distributed and used according to strict criteria which are compliant with the International Code as well as the WHO Guidance on ending inappropriate promotion of foods for infants and young children.

> WHA 63.23 [2010] Operational Guidance on Infant and Young Child Feeding in Emergencies (updated in 2017)

### LABELLING

Labels should provide information about the appropriate use of the product, and not discourage breastfeeding. Infant formula labels should have a clear, conspicuous and easily readable message in an appropriate language on the following points: (a) the words "Important Notice" or their equivalent; (b) a statement about the superiority of breastfeeding; (c) a statement that the product should only be used on the advice of a health worker as to the need for its use and the proper method of use; and (d) instructions for appropriate preparation, and a warning of the health hazards of inappropriate preparation.

Labels should not have pictures of infants, or other pictures or text which may idealise the use of infant formula.

Articles 9.1 & 9.2

Nutrition and health claims are not permitted, except where specifically provided for in relevant Codex Alimentarius standards or national legislation.

#### WHA 58.32 [2005] & WHA 63.23 [2010]

Where applicable, information is to be conveyed through an explicit warning on packaging that powdered infant formula may contain pathogenic microorganisms and must be prepared and used appropriately.

WHA 58.32 [2005]

### NO PROMOTION OF COMPLEMENTARY FOODS BEFORE THEY ARE NEEDED

Where promotion of foods for infants and young children is not prohibited, messages used to promote such foods should support optimal feeding. These messages should include a statement on the importance of continued breastfeeding for up to two years or beyond and the importance of not introducing complementary feeding before six months of age.

#### WHA 39.28 [1986], WHA 49.15 [1996], WHA 54.2 [2001] WHA 63.23 [2010] Guidance A69/7 Add.1, WHA 69.9 [2016]



"Supported Sitter" on this label means younger than 6 months !!!

### FOOD SAFETY & QUALITY

Member States, as a matter of urgency, should ensure that the introduction of micronutrient interventions and the marketing of nutritional supplements do not replace or undermine support for the sustainable practice of exclusive breastfeeding and optimal complementary feeding.

### WHA 55.25 [2002]

WHO/FAO guidelines on safe preparation, storage and handling of powdered infant formula\* should be applied and widely disseminated in order to minimise the risk of bacterial infection and, in particular, ensure that the labelling of powdered formula conforms with the standards, guidelines and recommendations of the Codex Alimentarius Commission.

Member States must implement food safety standards including regulatory measures to reduce the risk of intrinsic contamination.

WHA 61.20 [2008]

\*Obtainable from http://www.who.int/foodsafety/ publications/micro/pif2007/en/index.html

### **CORPORATE COMPLIANCE**

Independently of any other measures taken for implementation of the Code, companies should be responsible for monitoring their marketing practices according to the principles and aim of the Code and take steps to ensure that their conduct at every level conforms to all its provisions.

### (Article 11. 3)

Monitoring the application of the International Code and resolutions should be carried out in a transparent, independent manner, free from commercial influence.

#### WHA 49.15 [1996]

Companies should comply fully with their responsibilities under the Code and resolutions.

#### WHA 63.23 [2010]

Note: For the full text of Code and resolutions, see: http://www.who.int/nutrition/publications/code\_english.pdf http://www.who.int/nutrition/topics/wha nutrition iycn/en/

### Annex **B**

### 

### **Description of Code violation** (please answer all questions)

1. Short description (include heading or slogan found on company materials)

- 2. When was the violation observed? (dd/mm/yyyy)
- 3. Where? (place, city and country)
- 4. Who is violating the Code and how?

Company	Brand	Type of product <sup>a</sup>	Type of violation <sup>b</sup>

### <sup>a</sup> Type of product

Breastmilk substitutes: a. infant formula (including special formula), b. follow-up formula, and c. growing-up milk

d. Complementary food<sup>1</sup>: Cereal, fruit/vegetables/meat puree, juice, tea, and mineral water

e. Bottle

f. Teat

g. Other (specify the product)

### <sup>b</sup> Type of violation

- a. Advertisement television/in print/online/social media
- b. Promotion in health facility
- c. Company contact with mothers in person/via internet/social media/phone app
- d. Donation of product to health facility
- e. Free sample
- f. Gift to health worker
- g. Gift to mother
- h. Inappropriate labelling
- i. Promotion in shop
- j. Sponsorship
- k. Other

Is specimen or picture attached? Yes \_\_\_\_ No\_\_\_\_

5. Additional observation/details (please use another sheet of paper if necessary)

1. For complementary food, it is a violation if :

- the product is marketed or represented as suitable for below 6 months
- the product is promoted in health facilities, regardless of age indication
- the labelling and packaging look similar to its breastmilk substitute products (cross-promotion)

(Any one of the above constitutes a violation of the 2016 WHO Guidance on ending inappropriate promotion of foods for infants and young children)

### Annex C

### **Recommendations on HIV and Infant Feeding**

The **2010 Guidelines on HIV and Infant Feeding**<sup>i</sup> recognised the importance of antiretroviral (ARV) drug interventions to prevent postnatal transmission of HIV during the breastfeeding period, and recommended a public health approach. Subsequently WHO updated the guidelines on the use of ARV drugs<sup>ii</sup>, and the recommendations of **lifelong ART** for everyone from the time of HIV diagnosis is reflected in the **2016 Guideline: Updates on HIV** and infant feeding<sup>iii</sup> (2016 Guideline).

The 2016 Guideline aims to improve the HIVfree survival of HIV-exposed infants. The new recommendations and best practice statements have updated some of the principles and recommendations previously put forth in 2010<sup>iv</sup>.



The 2010 Guidelines recognised the important impact of ARVs during the breastfeeding period. This 2016 Guideline addresses questions that have arisen following the implementation of the 2010 Guidelines at country level.

- i. Guidelines on HIV and Infant Feeding: Principles and Recommendations for Infant Feeding in the Context of HIV and a Summary of Evidence. World Health Organization. 2010. Retrieved from http://www.who.int/maternal\_child\_adolescent/documents/9789241599535/en/
- ii. WHO Consolidated Guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Retrieved from http://www.who.int/hiv/pub/arv/arv-2016/en/
- iii. WHO & UNCEF. Guideline: Updates on HIV and infant feeding: the duration of breastfeeding, and support from health services to improve feeding practices among mothers living with HIV. Geneva: World Health Organization; 2016. Retrieved from http://www.who.int/maternal\_child\_adolescent/documents/hiv-infant-feeding-2016/en/
- iv. Except those noted as updated and superseded by the 2016 Guideline, principles and recommendations from 2010 Guidelines remain valid.

# Key points from the 2010 Guidelines on HIV and Infant Feeding

- 1. National health authorities should decide on a national strategy that will most likely give infants the highest chance of HIV-free survival either to counsel and support mothers living with HIV to breastfeed with ARV drug interventions, or avoidance of all breastfeeding.
- 2. Where the authorities recommend breastfeeding with antiretroviral interventions as national policy, mothers known to be living with HIV should be provided with lifelong ART.
- 3. Necessary conditions for replacement feeding are:
  - (i) safe water and sanitation at household level;
  - (ii) caregiver's ability to reliably provide sufficient infant formula to support infant's normal growth and development;
  - (iii)caregiver's ability to prepare it cleanly and frequently enough to ensure it does not pose risks of diarrhoea and malnutrition;
  - (iv) caregiver's ability to give infant formula exclusively for the first six months;

- (v) family support; and
- (vi) access to health care that provides comprehensive child health services.
- 4. If infants are known to be living with HIV, mothers are encouraged to breastfeed them according to the global recommendations for all children: exclusively for the first six months and continued breastfeeding, with safe and age appropriate complementary feeding up to 2 years or beyond.

### Key points from the 2016 Guideline: Updates on HIV and Infant Feeding

- 1. Mothers living with HIV should breastfeed for at least 12 months and may continue breastfeeding for up to 24 months or beyond (similar to the general population) while being fully supported for ART adherence.
- 2. National and local health authorities should actively coordinate and implement services in health facilities and activities in workplaces, communities and homes to protect, promote and support breastfeeding among women living with HIV.

- 3. ARV treatment reduces the risk of postnatal HIV transmission in case of mixed feeding. Although exclusive breastfeeding is recommended, mixed feeding is not a reason to stop breastfeeding in the presence of ARV drugs.
- 4. A duration of breastfeeding of less than 12 months is better than never initiating breastfeeding.

**Editorial note**: The focus in this guide is Code-centric and aimed at helping health workers to incorporate Code principles. The above recommendations have bearings on breastfeeding and the Code in the context of HIV. For further guidance on HIV and infant feeding, readers should refer to the original WHO documents for the complete set of recommendations and best practice statements. NOTES

NOTES



The International Baby Food Action Network (IBFAN) was founded in October 1979 and is now a coalition of 273 citizen groups in 168 developing and industrialised nations.

- IBFAN works for better child health and nutrition through the promotion of breastfeeding and the elimination of irresponsible marketing of infant foods, bottles and teats.
- The Network helped to develop the WHO/UNICEF Code of Marketing of Breastmilk Substitutes and is determined to see marketing practices everywhere change accordingly.
- IBFAN has successfully used boycotts and adverse publicity to press manufacturers and distributors into more ethical behaviour. IBFAN also helps to promote and support breastfeeding in other ways.



The International Code Documentation Centre (ICDC) was set up in 1985 to keep track of Code implementation worldwide.

- ICDC collects, analyses and evaluates national laws and draft laws.
- ICDC also conducts courses on Code implementation and Code monitoring and maintains a database on Code violations worldwide.
- From 1991 to 2018, ICDC trained over 2000 government officials from 148 countries in drafting sound legislation to protect breastfeeding.
- ICDC publishes a global monitoring report, Breaking the Rules, Stretching the Rules and a State of the Code by Country chart every three years.

**IBFAN-ICDC** 

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