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Andes pediatr. 2022;93(3):327-335
DOI: 10.32641/andespediatr.v93i3.3794

ORIGINAL ARTICLE

Monitoring the International Code of Marketing of Breastmilk Substitutes in Santiago, Chile

Monitoreo al Código Internacional de Comercialización de Sucedáneos de la Leche Materna en Santiago, Chile

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Received: April 20, 2021; Approved: October 30, 2021

What do we know about the subject matter of this study?

In Chile, the health team or professionals is partially aware of the extent of the measures suggested by the International Code of Marketing of Breastmilk Substitutes. The companies that market and trade these products, especially the wholesale trade, do not respect the existing laws.

What does this study contribute to what is already known?

It highlights the need for incorporation of missing aspects of the International Code into Chilean law (growing up formula, pacifiers, and bottles), the need for greater oversight and fines for those who do not comply with it, and periodic monitoring to detect violations.

Abstract

In 1981, the WHO and its member countries adopted the International Code of Marketing of Breastmilk Substitutes (CODE) to regulate the marketing of infant feeding products. **Objective:** To evaluate compliance with the CODE in Santiago, identifying the most frequent violations. **Subjects and Method:** The WHO protocol was applied between June and September 2017 to evaluate the CODE compliance in family health centers (CESFAM) and maternity hospitals (MH) by interviewing 451 mothers and 164 healthcare professionals. In addition, advertising of breastmilk substitutes (BMS) and CODE violations in the media, points of sale (small stores n = 70 and large stores n = 10), and labels of these products were evaluated. **Results:** In this study, 21% of mothers of newborn infants, 52% of mothers of infants younger than six months, and 71% of mothers of infants older than six months reported receiving instructions on BMS. Exposure to advertising of BMS exceeded 80%, while 4.7% and 2.9% received free samples or discount coupons, respectively. Among healthcare professionals, 40% from CESFAM and 75% from MH indicated visits from company representatives. During the study period, we found only two television adverts and 59 advertisements on 27 websites. Frequent CODE violations in large stores were offering discounts (70%), special displays (26.5%), and 3,6% promotional gifts. Product label violations were infrequent, however, all labels presented images idealizing product use. **Conclusions:** CODE violations are common in Santiago, Chile. The country would benefit from adopting all the CODE's recommendations, improving oversight, and toughening penalties in case of violations.

Keywords:
Breast Milk Substitutes;
Breast Feeding Barriers;
Breast Feeding Policy

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Edited by:
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How to cite this article: Andes pediatr. 2022;93(3):327-335. DOI: 10.32641/andespediatr.v93i3.3794

Introduction

Breast milk (BM) is the best food that can be offered to infants from birth since it provides energy, all the nutrients, and numerous non-nutritional components[1,2] that protect them from infectious diseases, malnutrition, as well as some chronic non-communicable diseases in adulthood[3,4]. Its possible protective role against obesity stands out since this is a pathology with high prevalence in the country and which is occurring at increasingly younger ages[5].

At the 34th World Health Assembly held in 1981 by the WHO, its member states adopted the International Code of Marketing of Breast-milk Substitutes (hereafter referred to as the "CODE"); which has marked a historical milestone by establishing, in its subsequent resolutions, regulations for the promotion of infant feeding[6,7].

However, even though 194 countries agreed to implement the CODE, only 39 of them have currently enacted laws that include all the resolutions[8]. Chile is among the 136 member countries that have implemented some of the resolutions, where the Food Sanitary Regulation recognizes only 2 types of breast milk substitutes (BMS) : infant formulas (0 to 6 months) and follow- up formulas (6 to 12 months). The national regulation also includes Law 20.869, Article 5 which prohibits all advertising of these products as well as texts or images idealizing them. In relation to labels, these must contain messages indicating the advantages of BM and the recommendation of a health professional for its use[9,10]. Despite these regulations, which restrict sales, the infant formula market in Chile has grown, reaching US$47 million in 2011[11].

In 2014, due to the increase in the BMS market and the scarce regulations in the countries to comply with the CODE's recommendations, the WHO developed a monitoring protocol to support the implementation of the legislation, which has already been applied in several countries[12] also proposing to perform this monitoring periodically to strengthen its implementation[13].

The objective of this study was to monitor compliance with the International Code in Santiago by identifying the most frequent violations. The information obtained will provide evidence to guide policy related to the promotion of BMS in the country.

Subjects and Method

Cross-sectional study for surveying mothers of infants under 2 years of age in family health centers (CESFAM) and mothers of newborns in hospital maternity wards. The professionals of these health services were also surveyed and, additionally, the existence of advertising of infant feeding products in these institutions was investigated.

The study was carried out in the north, south, east, and west areas of Santiago, including 35 CESFAM and 5 hospital maternity wards (*Hospital San José*, *San Juan de Dios*, *del Salvador*, *Barros Luco*, and *Hospital Clínico de la Universidad de Chile*).

In each CESFAM, surveys were randomly applied to 5 mothers of infants under 6 months of age and 5 mothers of children over 6 months of age who attended their regular health check-ups, reaching 351 participating mothers. A professional nutritionist, nurse, physician, and midwife (n = 148) were surveyed in the same centers. In the maternity wards, 100 mothers of, as were four professionals from each hospital (a midwife, a nutritionist, and two neonatologists) were surveyed before discharge. These surveys were conducted between June and September 2017.

This monitoring included only full-term healthy infants, excluding those who were taken for check-ups by someone other than the mother.

Interviews with mothers and professionals in each health facility were conducted by 2 nutritionists who, like the supervisor, attended a 2-day training workshop before the start of the study.

The monitoring also included observation of CODE compliance in the mass media, points of sale, and on the labels of infant feeding products.

In order to collect all advertising found during the study period, the sample size of the media monitoring was not established beforehand. The evaluation of CODE compliance on television was made using a database provided by the Ministry of Health (MINSAL), which made it to monitor compliance with the Food Labeling Law in public and private channels. Internet advertising was also based on MINSAL databases that included websites (blogs and company websites) and social networks (e.g. Facebook and YouTube), which evaluated advertising between January and July 2017. In parallel, a 4-month prospective search (May to August 2017) was conducted on websites of well-known baby food brands and those mentioned by mothers in the surveys, finding 7 sponsored or advertiser websites, 5 points of sales, and 24 from Facebook groups that were evaluated by reviewing advertising for all BMS products included in the CODE.

The availability of BMSs in the outlets was obtained through observation by completing a form detailing the advertising for each type of product and taking photographs of CODE violations. For this purpose, 70 small businesses located near the CESFAMs and 10 supermarket and pharmacy chains in the city were evaluated.

In the analysis of labels, 45 types of milk formulas (infant formula, follow-up, and growing -up formula),

8 complimentary foods (cereals and strained or chopped foods), and 25 types of bottles and pacifiers were studied.

WHO/PAHO recommends that the same monitoring protocol be applied in different countries to compare results. For this reason, the Spanish version was revised and validated by applying a pilot study, and only two questions were reformulated for better understanding. More details regarding the questionnaires and checklists applied are available in "Protocol for periodic CODE monitoring"[13].

The definition of breast milk substitute (BMS) was any food that is advertised or presented as a partial or total replacement for BF, whether or not this is its purpose[6].

Data analysis was univariate, estimating the magnitude of the violations in absolute numbers and percentages (n and %) using SPSS version 22[14].

This study was approved by the Ethics Committee of the University of Chile and the WHO. Each participant signed an informed consent form once the purpose of the study had been explained and anonymity was maintained until the end of the study.

Results

The mean age of the mothers interviewed was 28 years (SD = ± 6), and most of them had completed high school. Only 2.9% of the participants had more than one child and more than half of them worked outside the home. Mean birth weights and lengths of the newborns were within normal ranges (Table 1). Feeding practices was grouped according to the age of the children, with 90% of the mothers of newborns reporting exclusive BF, 62% of those under 6 months of age, and 5% of those older than 6 months (Table 2).

One in five mothers of newborns reported having received a recommendation to use a BMS. This proportion increased to 52% in mothers of infants younger than 6 months and 71% in those of infants older than 6 months (Figure 1). When asked the question "*who recommended it?*", 7% of the mothers of newborns indicated that it was recommended by a health professional (generally a physician), 70.3% of mothers of infants under 6 months of age, and 77.6% of mothers of infants older than 6 months.

Code violations in surveys and visits to Health Centers

The recommendation to feed the infant with a BMS by a "partner, relative, or friend" was mentioned in 13% of the mothers of newborns, in 22.3% of those infants younger than 6 months, and 10.7% of those older than 6 months. formulas were the most frequently mentioned and Nestlé was the most commonly recommended brand (41%).

Less than 6% of the participants indicated having seen BMS in Health Centers, however, 82.9% of them reported having seen or heard advertising for these products in mass media, with television as the most frequently mentioned.

The distribution of free samples or coupons for the purchase of BMS was scarcely mentioned. Of the 3 groups interviewed, one-third of the mothers indicated having received promotional gifts with purchase (Figure 1).

Eight out of ten professionals in the CESFAMs and all those in the hospitals indicated having had training in BF in the three years before the interview. Despite this, they showed little knowledge of the Code (24.3% CESFAMs and 56.3% maternity wards).

40% of the professionals in the CESFAMs and 75% of those in maternity wards indicated that they had been visited by representatives of companies that market BMS in the 6 months before the interview.

Several companies made these visits, but the most frequently mentioned were Nestlé (88.7%) and Abbot (29.6%). During these visits, product information, promotional material, formula samples, and gifts were provided (Figure 2). These professionals also reported having received invitations to attend courses and conferences (9%), promotional presentations (6%), and donations of equipment for the institutions (3%).

During the visit to the facilities, 37.2% of Code violations were detected in the CESFAMs, which included the presence of pencils, calendars, growth charts, formula samples, and stickers with the name of the company they represent and/or its logo. Most of these products were Nestlé products. In one of the hospitals visited, Nestlé had set up and decorated the breastfeeding room in which the company's logo and mascot were clearly displayed.

Code violations in the mass media

In this study, only 2 BMS advertisements on television were observed, both from Nestlé. One referred to the health properties of growing -up formulas (*Nido etapas*) and the other to complementary feeding (*Naturnes*).

Code violations were found in 59 advertisements presented on 27 websites. Of these, 40.7% corresponded to growing – up formulas, 39% to bottles and pacifiers, and 11.7% to infant feeding products. No ads were found for infant formulas and only 2 for follow-up formulas. The most frequently advertised brand name was Nestlé (44%) and it was also the company with the most products for sale. For bottles and pacifiers, Philips and Pigeon accounted for 35% of the ads (Figure 3).

Table 1. General characteristics of mothers and children participating in the monitoring of the International Code of Marketing of Breastmilk Substitutes in Santiago, Chile

	Surveyed in Maternity	Surveyed in Family Health Centers			
	Newborns n = 100	< 6 months n = 181	> 6 months n = 170		
	M (SD)	M (SD)	M (SD)	F	p
Mothers					
Age (y)	27.6 (5.93)	28.0 (6.20)	28.5 (5.80)	0.75	0.472
Years of education	12.5 (2.23)	12.1 (2.43)	12.1 (2.44)	1.09	0.337
Children					
Gestational age (weeks)	39.0 (1.1)	38.9 (1.2)	38.9 (1.3)	0.26	0.769
Birth weight (g)	3.451 (411)	3.426 (446)	3.303 (483)	4.59	0.011
Length at birth (cm)	49.6 (1.98)	49.7 (2.4)	49.7 (2.1)	0.08	0.923

M: Mean. SD: Standard deviation. P value: ANOVA test

Table 2. Occupation of participants, data at birth and type of feeding of their children. Santiago, Chile

	Surveyed in Maternity	Surveyed in Family Health Centers		
	Newborns n = 100	< 6 months n = 181	> 6 months n = 170	
	n (%)	n (%)	n (%)	p
Mothers				
Work outside of home	60 (60.0)	74 (40.9)	66 (38.8)	0.002
Type of work				
• Professionals	4 (4.0)	4 (5.4)	4 (6.1)	0.379
• Mid-level employees	39 (39.0)	51 (68.9)	34 (51.5)	
• Basic level employees	16 (16.0)	16 (21.6)	22 (33.3)	
• Domestic employees	1 (1.0)	3 (4.1)	6 (9.1)	
Children				
Sex				
• Males	52 (52.0)	89 (49.2)	71 (41.8)	0.200
• Females	48 (48.0)	92 (50.8)	99 (58.2)	
Type of delivery				
• Normal	64 (64.0)	116 (64.1)	103 (60.6)	0.794
• Caesarean	36 (36.0)	65 (35.9)	66 (39.2)	
Birth place				
• Public Hospital	80 (80.0)	156 (86.2)	144 (84.7)	0.584
• Private clinic	20 (20.0)	24 (13.2)	25 (14.7)	
• Home	0	1 (0.6)	1 (0.6)	
The newborn was unique	97 (97.0)	179 (99.0)	169 (99.4)	0.171
Feeding				
• Exclusive BF	90 (90.0)	112 (61.9)	8 (4.7)	
• BF +Formula	8 (8.0)	48 (26.5)	2 (1.2)	
• Only Formula	2 (2.0)	13 (7.2)	2 (1.2)	0.001
• BF + solid food	-	4 (2.2)	50 (29.4)	
• Formula + solid foods	-	1 (0.6)	57 (33.5)	
• BF + Formula + solid foods	-	3 (1.7)	51 (30.0)	

BF: Breastfeeding. P value: Chi2

Most of this advertising was on websites (81.4%) whereas 15.3% of the adds appeared on Facebook. Code violations consisted of discounts (76%), invitations to contact companies (19%), and gifts with purchase (5%).

Code violations in small and large businesses

No sales of milk formulas were observed in small stores, but there were strained and chopped infant foods. In 7 of the 10 large businesses analyzed, 83 violations of the Code were found, 37.3% of them in four supermarket chains and 62.7% in 3 pharmacy chains. The most frequent promotions were discounts (70%), of which 28.9% were in supermarkets and 41.0% in pharmacies. In 26.5% of the stores, BMS was prominently displayed in showcases or on shelves, of which 4.8% were in supermarkets and 21.7% in pharmacies.

Code violations on labels for baby food

All the labels analyzed (79%) were in Spanish and included the name of the product, preparation instructions, list of ingredients, nutritional information, serial number, and expiration date. None contained information about health properties. These are all positive aspects that are included in the CODE. The phrases such as "Important: breast milk is the best food for infants" or its equivalent were mentioned on 76% of the labels of infant and follow- up formulas, which were not on growing – up formulas. Many of the labels contained images idealizing the use of the products (72%), including the brand mascot and illustrations on bottles and pacifier packaging.

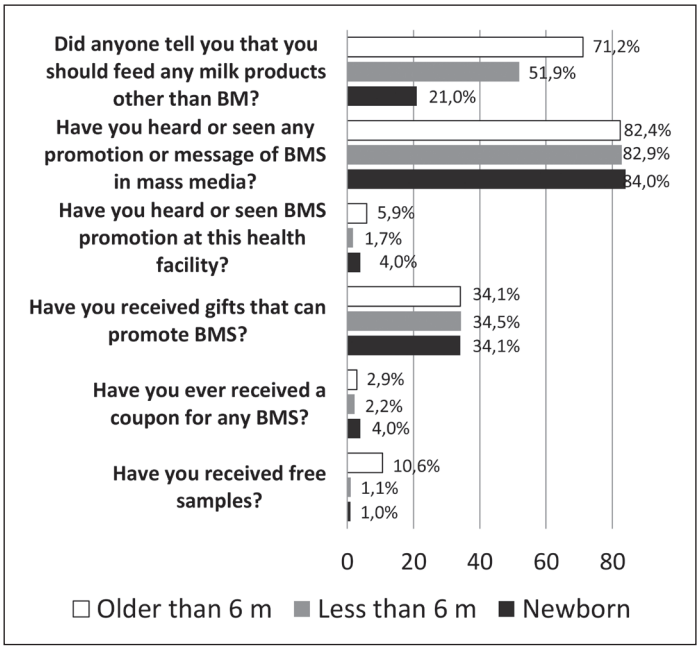
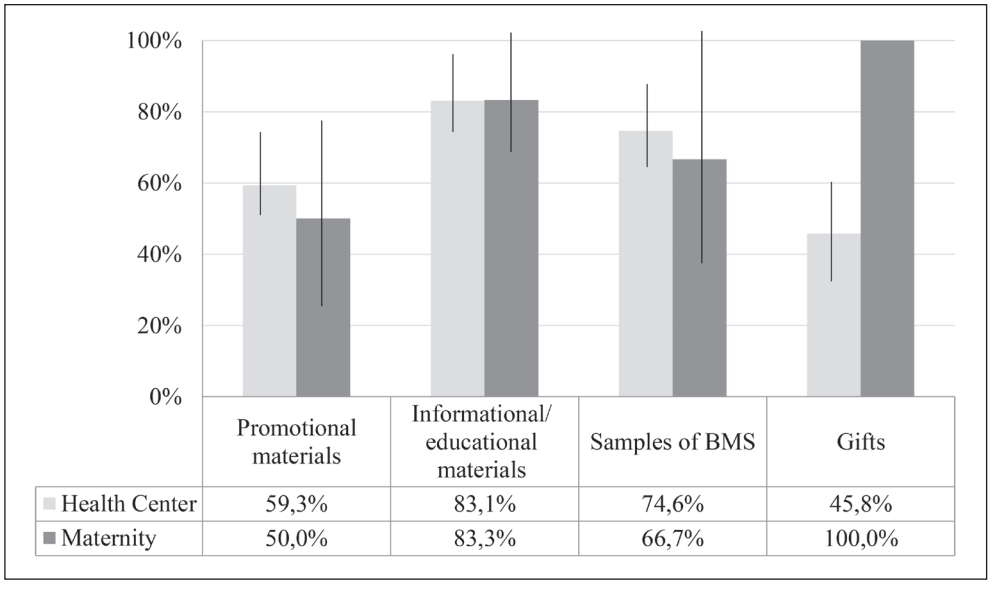


Figure 1. Violations of the CODE, according to mother´s interview. Question: In the last six months. BMS: Breastmilk substitutes.

Discussion

The monitoring of advertising and labeling of infant feeding products confirms that mothers of children under 2 years of age are exposed to advertisements and promotions that violate the CODE in health facilities, commerce and mass media. Professionals working in CESFAMs and maternity wards receive promotional materials and gifts from company representatives which, by being displayed in their offices, generate additional CODE violations.

In this study, recommendations for BMS use in the six months before the interview were even reported by mothers of newborns. It is not surprising that many of



	Promotional materials	Informational/ educational materials	Samples of BMS	Gifts
Health Center	59,3%	83,1%	74,6%	45,8%
Maternity	50,0%	83,3%	66,7%	100,0%

Figure 2. Distribution of the products that Company Representatives have given to the health professionals in the last six months. BMS: Breastmilk substitutes.

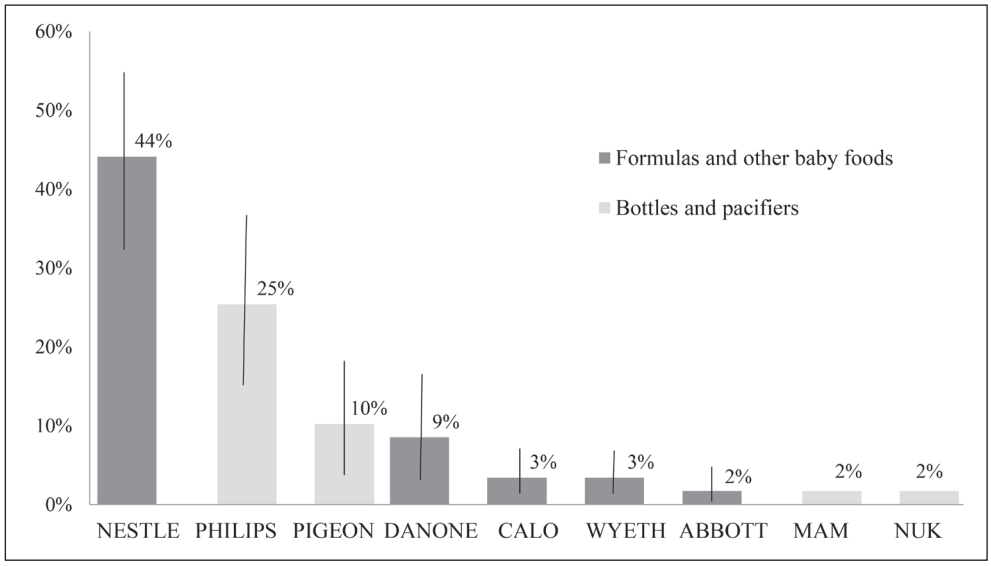


Figure 3. Distribution of the Internet publicity according to brands.

these mothers received these suggestions from family members since providing family advice in Latin America is common, especially in such relevant aspects as the acquisition of feeding habits. In a study of BF practices in low-income communities in Mexico, it was observed that new mothers were influenced by their mothers and mothers-in-law who provided infants with herbal teas and different foods before 6 months of age[15].

Although the recommendations for the use of BMS by health professionals do not constitute a violation of the Code, the high number of mothers who received this recommendation is striking considering that the infants in this monitoring were full-term and healthy. It should be noted that the questionnaire does not include the evaluation of this practice, or reason for the indication by the professionals.

The report of having seen or heard BMS advertising in the mass media was high. Interestingly, it was reported having seen it mostly on television despite that in the country there is a law prohibiting its use. It is known that cable television is widely expanded in the country and that the advertisements shown are probably directed to other Latin American countries where this practice is allowed and where the same formulas are sold. Reducing exposure to this advertising is difficult since regulations apply only to local programming.

The high frequency of exposure to information on infant feeding products online is alarming and difficult to regulate. In Chile, 87.4% of households have Internet access[16] and most mothers have cell phones or computers. The Internet is increasingly being used to advertise and sell BMS as has been reported in the United States[17], highlighting the need for developing new strategies to monitor and enforce the CODE.

Violations of the CODE in commerce, either through discounts on BMSs, display in a prominent place in the store, and/or gifts with the purchase were frequent, especially in pharmacy chains where this type of product is apparently purchased more frequently. Another violation detected was texts and images that idealize the use of BMS on labels, an aspect that has already been reported in Turkey and China[18,19].

As noted above, Chilean regulations define BMS as formulas intended for children under 12 months of age[9]. Therefore, advertising and promotions of growing -up formulas intended for infants older than this age violate the CODE without transgressing Chilean regulations, which was observed mainly in pharmacy chains.

Despite advances in Chile that benefit BF, such as Law 20,869[10] and 20,606, which prohibits advertising for products aimed at children under 14 years of age[20], other BMS such as baby food (strained, chopped, cereals), baby bottles and pacifiers are still excluded.

On the other hand, infant formulas use similar labels for the different products, allowing them to be distinguished only by color and number (e.g., 1, 2, or 3), which can confuse consumers who do not receive an adequate indication from a health professional for their use. This is evidenced by a study carried out in England, in which 16% of mothers used follow- up formulas before 6 months of age because they were unable to differentiate between the different formulas[21]. This points to the need to extend the CODE regulations to labels including product presentation.

It was also noted that there is a growing industry of bottles and pacifiers, whose promotion is based on the characteristics of the products as marketing tools (e.g.,

anti-spill bottles, pacifiers to reduce colic, orthodontics), specifying certain ages of use (0-3 months, 6-12 months, etc.) and thus stimulating the continuation of a certain brand. Therefore, the advertising and sale of these products provide a route for the sale of milk formulas, stimulating and promoting their use without the need to specifically mention them.

The fact that WHO/PAHO recommends a certain protocol for monitoring in different countries facilitates comparisons and allows identifying cultural differences that influence exposure to messages that encourage the use of BMS. In a study conducted in Indonesia[22], 20% of mothers of infants younger than 6 months reported receiving advice to feed their infants with BMS which is similar to our results, but unlike in our study, the recommendation came mainly from family and friends (50.7%). Similar to what was found in this study, monitoring carried out in Mexico[23] found that the proportion of mothers exposed to media advertising reached 80%. Media interest through digital channels has a scope and depth that raises suspicions of increased exposure to BMS, which will result in greater challenges in monitoring and complying with the CODE and laws.

In an assessment of child feeding policies and programs in our country, the experience of a CODE monitoring conducted in 1999 was reported and showed that not all CODE resolutions were yet in force and implemented[24].

Systematic monitoring provides a snapshot of the implementation of the CODE[21]. In addition, as concluded in a study conducted in South Asia[25], it provides information to government authorities to move towards the adoption of measures to enforce the CODE and to establish sanctions when they occur. In this sense, the joint work of Latin American countries, which have made efforts to implement the CODE, generating protection laws similar to those in our country, will undoubtedly help to protect the marketing of BMS in the Region[26-29].

The next step in Chile would be to fully incorporate the aspects contained in the CODE, including periodic monitoring with adequate funding. Expanding the definition of BMS in the Food Sanitary Regulation to extend the regulatory framework to include follow-on formulas, bottles, and pacifiers is a priority.

Among the limitations of this study is that the results correspond to full-term healthy infants and attending public health services. CODE violations may be even more prevalent in the private health system, which was not included in this study. Results may also vary in rural areas or regions far from urban centers where companies marketing BMSs have a more limited presence than in Santiago.

Among the strengths are the feasibility of doing this monitoring in a country where a large part of the population is user of the public health system, where mothers are receptive and provide reliable answers, and where access to the facilities is possible. In addition, we had an extensive retrospective and prospective database of advertising in the mass media, access to small and large businesses, and we were able to generate image databases of violations of the CODE.

Conclusions

This monitoring confirms that mothers of infants under 2 years of age are exposed to violations of the International Code of Marketing of Breastmilk Substitutes.

Periodic monitoring of the national code will provide information that will contribute to building the need to implement all regulations, as well as sanctions for violations.

Ethical Responsibilities

Human Beings and animals protection: Disclosure the authors state that the procedures were followed according to the Declaration of Helsinki and the World Medical Association regarding human experimentation developed for the medical community.

Data confidentiality: The authors state that they have followed the protocols of their Center and Local regulations on the publication of patient data.

Rights to privacy and informed consent: The authors have obtained the informed consent of the patients and/or subjects referred to in the article. This document is in the possession of the correspondence author.

Conflicts of Interest

Authors declare no conflict of interest regarding the present study.

Acknowledgments

To Anna Cristina Pinheiro, who stimulated from MINSAL the realization and dissemination of the results of this Monitoring and to Dr. Hugo Amigo (RIP) who participated in the design, planning of the study and in the preliminary discussion of the data.

Financial Disclosure

This Monitoring was funded by PAHO/WHO (SCON2017-00306), so the results included in this article are the property of these institutions. The opinions expressed in the discussion are the responsibility of the authors and do not necessarily reflect those of PAHO/WHO.

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