

The International Code of Marketing Breast-Milk Substitutes, national legislation and endorsement practices; violations of selected breastfeeding regulation in Greece

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Abstract

Present study provides an exploratory, descriptive account of the extent to which selected provisions of the International Code of Marketing Breast-Milk Substitutes and relevant national legislation are violated in maternity clinics and hospitals in Greece. Findings are based on a convenience sample of 193 midwives working in public and private maternity clinics and hospitals in various parts of the country. Data were collected through an anonymous closed-end questions survey. Participants reported their personal observations and experiences of BMS companies' representatives' direct contact and gift offering to health care professionals, maternity facilities and post-partum women. Reported frequencies of health care professionals' redistribution of BMS products to post-partum women were also noted. Our study shows that violations of the Code and national legislation is a frequently observed phenomenon within maternity facilities in Greece. Our study further points to need for a) establishment of a mechanism monitoring and documenting compliance to legislation and b) extensive research on the subject in order to collect internationally comparable data and results which can further inform policies to support breast-feeding at the national level.

Keywords: breastfeeding, compliance to the International Code of Marketing Breast-Milk Substitutes, Greek legislation on milk substitutes, BMS endorsement practices, health care professionals' behavior.

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1 Introduction

Breastfeeding's positive impact on the individual physical and psychological health and wellbeing of mothers and newborns, its benefits for individual health in puberty and adulthood and its overall significance for public health has been amply documented in research and international experience [1-8]. Infant feeding decisions, however, including the decision to breast-feed, are complex and influenced by state regulation and policies, policies and procedures followed by health care facilities, the overall attitudes, behaviors and advice provided by health care professionals (HCPs) to expectant mothers and mothers of newborns and significantly, by endorsement practices of Breast-Milk Substitutes (BMS) companies [9-13]. It follows then, that informed decisions to breastfeed require an environment free of undue pressures especially those initiated by BMS endorsement practices.

To safeguard an environment free of undue pressure and curb adverse impacts on breastfeeding decisions numerous initiatives, with the International Code of Marketing Breast-Milk Substitutes (the Code) [14] as a flagship, have been undertaken at the international level. These in turn, have been adopted and implemented at varying degrees and with varying results at the transnational and national level [15-18]. Until 2014, only 39 countries had fully implemented the Code in their national legislation and only 47 implemented some Code provisions. Also, only 45 countries have functioning monitoring and enforcement systems in place [19]. Nevertheless, the aims, content and effective implementation and monitoring of regulation and policies are of paramount importance for promotion, support and continuance of breast-feeding. Research shows that regulation and policies which consistently and persistently support breastfeeding and are adequately implemented and enforced have a positive impact on initiation and continuance of breastfeeding [20-25]. On the contrary, inconsistent policies and even more so, inadequate implementation and observance of relevant regulation negatively impact upon the decision to breastfeed [13, 21, 24, 26, 27]. Consequently, the state of affairs with regard to adherence to regulation is of paramount importance [9, 27-29].

Greece is among the countries which have adopted the Code and harmonized its national legislation to trans-national (i.e. European Union) regulation albeit with several regulatory and structural limitations. Furthermore, relevant monitoring and research data are lacking and thus, compliance to the Code's and national legislation's provisions are not assessed consistently, comprehensibly and reliably. The present study aims at filling this gap by providing an initial, exploratory, descriptive account of the extent to which the provisions of the Code and of the national legislation are observed within the context of maternity hospital and clinics in Greece. Results are based on midwives' reports of their observations and experiences concerning BMS representatives' and other HCPs' actions and behaviors which may violate the Code and national legislation.

Despite its exploratory, descriptive nature, the current study provides useful results which can serve as a basis for further research and potentially inform future policies and regulation.

Regulatory framework and BMS endorsement practices

During the late 60s BMS companies' aggressive marketing practices, which in developing countries were linked to a number of preventable infant deaths gave rise to an international opposition which led to several international initiatives promoting and protecting breastfeeding [30]. Pivotal among them, the International Code of Marketing of Breast-Milk Substitutes, was adopted in 1981 [14] and aimed primarily at "...the provision of safe and adequate nutrition for infants..." (art. 1) "...through the protection of breastfeeding and the regulation of promotion, marketing and distribution of products such as infant formula..." (art. 2). The Code, thus, can be understood as a minimum, albeit necessary framework providing guidelines which, when implemented by national legislations, have the potential to safeguard and promote an environment free of undue interferences caused by BMS companies' aggressive advertisement and allow women to freely choose between breastfeeding and bottle-feeding.

At the EU level, many provisions of the Code were adopted in 1991 and 1992 (Directives 91/321/EC and 92/52/EEC). However, compared to the goals, aims and provisions of the Code, the relevant EU legislative framework, on the one hand, is more permissive to BMS' advertisement and promotion practices and on the other, more restrictive as to the spectrum of products covered under its regulations [31].

Greece, an EU member state, adopted the Code in 1983 and in 1993 harmonized its national legislation to the relevant EU regulation. Specifically, Greek legislation states that: a) advertisement of infant food is allowed only in scientific publications and publications specializing in baby care, b) point-of-sale advertising and direct advertisement of infant formula to consumers in the form of distribution of free samples or any other promotional material is not allowed, c) distribution of free samples of infant formula or sale of products at reduced prices as well as offering of promotional gifts either directly to the public or indirectly through the health care system or health care professionals is not allowed. However, infant formula may be donated or sold at reduced prices to institutions or organizations either for use within the institution or organization or for distribution outside them. Overall, then, it can be argued that, in accordance with EU regulation, Greek legislation concerning the promotion and advertising of BMS substitutes is more permissive than the Code.

Additional characteristics of the Greek legislation, policies and practices, however, call for attention. Specifically, despite legally prescribed prohibitions and obligations for individuals, companies and organizations, no penalties are defined for their violation. Enforcement thus, is curtailed. Moreover, a system monitoring compliance to the Code's provisions has not been established in

Greece despite being obligatory for countries ratifying the Code. As a result, official data as to the extent legally prescribed behaviors and practices are observed or bridged in everyday practice by BMS companies, HCPs and health care facilities, are not available. In parallel, research data directly addressing compliance to the Code's and national legislations' provisions are also lacking. It is conceivable thus, that within this context, violations of the provisions of the Code and of national legislation can and do occur as can be inferred by studies addressing related issues [32-35]. Consequently, they remain undocumented and their impact cannot be assessed.

The negative implications of inadequate regulation and policies, however, and in particular the lack of monitoring mechanisms [36] have been documented in various studies. Such studies show that in countries where monitoring mechanisms are lacking, compliance to the Code's provisions is minimal. Thus, it is not unusual to observe and document explicit violations of the Code and respective national regulations such as prohibition of direct advertisement to the general public, pregnant women, mothers of newborns, HCPs and maternity hospitals and clinics through the distribution of free BMS samples and nutritional information material [9, 37-42]. Nevertheless, even when monitoring mechanisms are in place, violations of the Code are not lacking and are significantly linked to strategies of marketing and promotion of BMS directly to HCPs and health care facilities and through them to pregnant women and mothers of newborns [9, 13, 30]. The latter is of significance since capitalizing upon HCPs' privileged relation with pregnant women and mothers of newborns and their influence on parent's feeding decisions, BMS manufacturers consistently engage them in the endorsement of BMS products through feeding guidance and advice, product referrals, distribution of free samples of baby milk and/or baby food and BMS discharge gift packs [30, 39-41]. Inducements such as sponsoring of, and directly financing participation in professional activities (e.g. scientific/medical conferences), offering free gifts with company logos and even financial incentives are only few of the BMS marketing strategies targeting HCPs [9, 31, 37-41].

Providing free infant formula and other BMS products upon hospital discharge, however, supplying women with infant formula prescriptions or referrals and offering bottle-feeding advice by HCPs tend to inhibit initiation and duration of breastfeeding [13, 34-35] while at the same time, violate provisions of the Code as well as national legislations, including Greek legislation.

Given the significance of enactment, compliance and enforcement of international and national legislation for abating BMS marketing, Greece's permissive and incomplete national legislation (i.e. absence of penalties for violations), the lack of relevant monitoring mechanisms and the limited research on the subject, the goal of the present study is to provide an initial, exploratory account of the perceived extent and frequency of BMS representatives' and HCPs violations of the Code and country regulations.

2 Material and Method

To address the goals of the present study we documented manifest, observable and reported behaviors and practices which relate to BMS representatives' endorsement practices and HCPs promotion of BMS. Specifically: to document BMS company representatives' endorsement practices, we asked respondents to report a) on the frequency they perceive BMS representatives come in direct contact with HCPs professionals and post-partum women, b) on the frequency they perceive BMS representatives offer gifts to HCPs, hospitals and post-partum women. To document HCPs' promotion of BMS products we asked our participants to provide their estimate of the frequency with which HCPs offer free samples to post-partum women. Direct contact between BMS and HCPs although not explicitly forbidden by the Code or national legislation has been prohibited by at least one policy initiative⁴ because it has been considered as a form of direct advertisement with potential adverse impact on breastfeeding [43]. Direct advertisement of BMS products however, is explicitly prohibited by the Code and national legislation. In our study, we use direct contact between BMS and HCPs as a proxy for direct advertisement.

We chose to depend on the relevant experiences and reports of a sample of midwives instead of any other category of HCPs since midwives in Greece who work in maternity hospitals and clinics are more likely to be closer to, and provide care to women throughout pregnancy, delivery, birth and the post-natal period. Additionally, on the one hand by training and on the other by duty and competence, midwives in Greece carry the responsibility for promoting and supporting women to maintain breastfeeding. We considered thus, midwives to be HCPs with higher sensitivity, knowledge and awareness regarding professional and regulatory compliance to supporting breastfeeding. Furthermore, given their close collaboration and contact with other HCPs, we considered that midwives would be well aware of the manifest and latent everyday routines, functions and operations of HCPs, hospitals and clinics, BMS representatives' presence and practices included.

Study participants were recruited during the 10th Pan-Hellenic Midwife Conference. A total of 310 conference participants were approached, informed of the purpose of our study and asked to participate. Of these, 193 agreed to participate and after signing an informed consent form they were asked to fill an anonymous questionnaire (no information leading to the respondent was marked on the body of the survey) containing a total of 26 closed-end questions survey.

⁴ Considering the potential adverse impact of this type of advertising the Greater Glasgow National Health Service as early as 2003 explicitly prohibited BMS representatives to come in direct contact with health care professionals [43].

Survey questions asked for participants' demographics (e.g. age, years of professional experience, employment status, type and location of facility, unit of work) and their estimates on the frequency and patterns of BMS representatives endorsement practices (e.g. direct contact with HCPs, post-partum women and gift offering) and HCPs gift offering to post-partum women⁵.

The type (public vs private) maternity facilities was taken into consideration in our study in order to record any potential differences between profit oriented (private) and non-profit oriented (public) facilities. The location of maternity facilities was also considered in our study. Provincial maternity facilities, tend to be smaller in size, HCPs may have closer relations and be more aware of the everyday functions of their place of work and the whereabouts of the personnel. Along these lines, 'outsiders' such as BMS representatives would be more likely to be 'spotted' and observed by mere size alone. On the contrary, maternity facilities in Athens, tend to be large in size, employ large numbers of HC and administration personnel, provide care to significant larger numbers of persons while at times the various units may be located in different buildings one away from the other. Thus, it is likely difficult for HCPs and other staff and personnel for that matter to be fully aware of daily routines and practices. Finally, for descriptive purposes our respondents' years of professional experience as well as the type of unit in which they worked were considered. Statistical analysis was performed employing SPSS 23. The chi-square criterion was applied to test for the significance of differences between pairs of independent samples.

3 Main Results

3.1 Sample Description

A total of 193 midwives, all women, with a mean age of 38.27 years were included in our sample. Most of them (77%) worked in public facilities, in the country's province (79.8%) and in post-natal units (80.3%) (Table 1). Approximately two thirds of our sample was comprised by experienced (33.7%) and highly experienced (33.1%) professionals or in other words with professionals who had over 10 years of experience (Table 1). Furthermore, highly experienced midwives, that is those having over 19 years of professional experience, tended to work in public (89,8%), provincial facilities (71.7%) and in post-natal units (88.1%) (Table 1).

⁵ The survey was developed in the context of a broader project documenting the extent of compliance to provisions of the *Innocenti Declaration* (including the *International Code of Marketing of Breast-Milk Substitutes* and *Ten Steps to Successful Breastfeeding*) in Greece. In the context of the broader project the experiences of mothers of newborns and infants were also analyzed [32]. Here, we report part of the project findings which address compliance to provisions of the Code as reported by the sample of midwives.

3.2 BMS representative's endorsement practices

Our findings show that BMS direct contacts with HCPs (obstetricians/gynecologists, pediatricians) are a rather frequent occurrence in maternity hospitals and clinics in Greece. Approximately 64.7% of the midwives in our sample report that overall, BMS representatives come in direct contact with HCPs either often (32.6%) or sometimes (32.1%). They are more likely to be seen visiting HCPs 'often' (25.3%) in public rather than private (7.4%) maternity facilities located in the province (36.2%) rather than in Athens (Table 2). Midwives report that they are rarely directly contacted by BMS representatives (65.9%), but the frequency of direct contacts differs in statistically significant ways between facilities located in the province and those in Athens ($p=.012<.05$) (Table 2). Nevertheless, our respondents' claim that they are rarely contacted directly by BMS representatives is in contradiction with their response in another question which asked participants to identify the specializations of HCPs more frequently visited by BMS representatives. Based on responses to this question (not shown here in a table) midwives rank second after pediatricians and before obstetricians and other nursing personnel. Finally, based on our findings, it appears that BMS representatives rarely (91.5%) come in direct contact with post-partum women (Table 2).

In their majority, our respondents report that they aware that HCPs and maternity facilities (56.5% and 45.5% respectively) receive gifts from BMS representatives. HCPs in public (40.5%) and provincial (44%) facilities are more likely to receive such gifts. Furthermore, higher awareness of gift offering to hospitals and clinics is reported by respondents in public facilities (33.3%) compared to private facilities (12.1%) while reported frequencies for facilities in the province (37%) differ in statistically significant ways than the equivalent for facilities located in Athens (8.5%) ($p=.009<0.05$) (Table 3). Reported awareness of gift offering to post-partum women differs in statistically significant ways between public and private facilities ($p=.006<.05$) and between facilities in the province and those in Athens ($p=.013<.05$). Based on our findings, BMS representatives tend not to offer gifts to post-partum women (28.3%) although women in public facilities (16.2%) and those who deliver in the province (20.8%) appear to be receiving such gifts more frequently than their counterparts in private (11.9%) facilities and facilities in Athens (7.5%). Nevertheless, a large proportion of our respondents report that they do not know whether such gifts are offered to post-partum women (between 35.8% and 38.2%) (Table 3).

The frequency of gift offering was also assessed by survey respondents. Maternity facilities (73.6%), especially public (57.5%) and provincial ones (74.3%) were identified by our sample as frequently receiving gifts (Table 4). HCPs also receive gifts frequently (44.1%). However, HCPs in public hospitals (36.6%) and in the province (36.6%) were reported as receiving gifts more frequently than HCPs in private facilities (7.5%) and facilities in Athens (7.5%). Reported frequencies of gift offering to HCPs differed in statistically significant ways between public and private hospitals ($p=.001<.05$) (Table 4). As for the kinds of

gifts offered in addition to artificial milk samples and boxes which were provided to post-partum women as well, HCPs receive promotional gifts, financed trips and even (very rarely) financial incentives such as money (Table 5).

3.3 HCPs promotion of BMS

Our respondents report that they rarely (66.1%) observe HCPs supplying post-partum women with free BMS products regardless of the type or the location of the facility (Table 6). Midwives working in public hospitals are more likely than midwives working in private facilities to report that HCPs rarely supply post-partum women with BMS products (53.9% and 12.2% respectively; $p=.000<.05$). Nevertheless, other Greek study [34] has found that upon release from the hospital mothers of newborns are provided by a BMS prescription which mainly serves as a brand name suggestion⁶.

Overall then, our findings show that BMS representatives frequently come in direct contact with HCPs, supply maternity facilities with free samples and boxes of BMS and offer gifts (samples and boxes of infant formula, promotional gifts, support for professional activities such as trips etc) to HCPs. The above patterns of endorsement practices tend to be more noticeable in public facilities and in facilities located in the province. Post-partum women are less likely than any other group to be directly contacted by BMS representatives or receive gifts from them and according to midwives, HCPs rarely re-distribute BMS products to post-partum women.

⁶ Since its enactment, Greek law placed the production, supply and marketing of infant formula, follow-up formulae and other relevant products under the responsibility of the *National Organization of Medicines* (NOM). Arguably, regulation of BMS products falls under the heightened control provisioned for medicines and pharmaceuticals. To that extent, infant formula is sold exclusively by licensed pharmacies and typically requires a medical prescription explaining the reasons necessitating bottle-feeding. Follow-up formulae and/or other milk substitutes or infant food on the other hand are sold in supermarkets. In practice however, infant formula can be bought at any pharmacy without a prescription. Thus, the prescription provided to post-partum women upon release from the hospital serves as a brand name suggestion [34].

4 Labels of tables

Table 1: Description of sample

Level of experience*	Type of Facility			Location of facility			Unit of work			
	Public	Private	Total	Province	Athens	Total	Post-natal care	Delivery room	Other unit	Total
	n % (row) % (column)									
Moderately experienced	36 <i>61.0</i> 20.2	23 <i>39.0</i> 12.9	59 33.1	44 <i>74.6</i> 24.7	15 <i>25.4</i> 8.4	59 33.1	42 <i>77.8</i> 24.3	2 <i>3.7</i> 1.2	10 <i>18.5</i> 25.8	54 31.2
Experienced	48 <i>80.0</i> 27.0	12 <i>20.0</i> 6.7	60 33.7	43 <i>71.7</i> 24.2	17 <i>28.3</i> 9.6	60 33.7	45 <i>75.0</i> 26.0	5 <i>8.3</i> 2.9	10 <i>16.7</i> 5.8	60 34.7
Highly experienced	53 <i>89.8</i> 29.8	6 <i>10.2</i> 3.4	59 33.1	55 <i>93.2</i> 30.9	4 <i>6.8</i> 2.2	59 33.1	52 <i>88.1</i> 30.1	5 <i>8.5</i> 2.9	2 <i>3.4</i> 1.2	59 34.1
Total	137 77	41 23	178 100.0	142 79.8	36 20.2	178 100.0	139 80.3	12 6.9	22 12.7	173 100.0

Age: $M=38.27$ $SD=8.64$, Range=23-60

Gender: All Women

Years of professional experience: $MD=13.59$, $SD=8.53$, Range= 1-38.

*Measured in years of professional experience. Moderately experienced: 1-9 years, Experienced: 10-19 years, Highly experienced: 19-38 years

Table 2: Reported frequency of BMS representatives' direct contact with health care professionals and post-partum women per type and location of facility

		Often n % (row) % (column)	Sometimes n % (row) % (column)	Rarely n % (row) % (column)	Total n % (row) % (column)	χ^2	<i>p</i> -value
Health care professionals: Obstetricians/Gynecologists, Pediatricians, etc							
Type of facility	Public	48 33.6 25.3	47 32.9 24.7	48 33.6 25.3	143 75.3	0.732	0.694
	Private	14 29.8 7.4	14 29.8 7.4	19 40.4 10.0	47 24.7		
	Total	62 32.6	61 32.1	67 35.3	190 100.0		
Location of facility	Province	54 36.2 28.4	47 31.5 24.7	48 32.2 25.3	149 78.4	4.645	0.098
	Athens	8 19.5 4.2	14 34.1 7.4	19 46.3 10.0	41 21.6		
	Total	62 32.6	61 32.1	67 35.3	190 100.0		
Health care professionals: Midwives							
Type of facility	Public	20 14.6 11.4	30 21.9 17.0	87 63.5 49.4	137 77.8	1.868	0.393
	Private	5 12.8 2.8	5 12.8 2.8	29 74.4 16.5	39 22.2		
	Total	25 14.2	35 19.9	116 65.9	176 100.0		
Location of facility	Province	23 16.5 13.1	32 23.0 18.2	84 60.4 47.7	139 79.0	8.832	0.012
	Athens	2 5.4 1.1	3 8.1 1.7	32 86.5 18.2	37 21.0		
	Total	25 14.2	35 19.9	116 65.9	176 100.0		
Post-partum women							
Type of facility	Public	6 4.2 3.2	7 4.9 3.7	129 90.8 68.6	142 75.5	0.444	0.801
	Private	1 2.2 .05	2 4.3 1.1	43 93.5 22.9	46 24.5		
	Total	7 3.7	9 4.8	172 91.5	188 100.0		
Location of facility	Province	7 4.7 3.7	8 5.4 4.3	133 89.9 70.7	148 78.7	2.648	0.266
	Athens	0 0.0 0.0	1 2.5 0.5	39 97.5 20.7	40 21.3		
	Total	7 3.7	9 4.8	172 91.5	188 100.0		

Table 3: Reported frequency of midwives' awareness of gift offering to health care professionals, maternity facilities and post-partum women

		Yes n % (row) % (column)	No n % (row) % (column)	Don't know n % (row) % (column)	Total n % (row) % (column)	χ^2	p-value
Health care professionals (Obstetricians/Gynecologists, Midwives, Pediatricians, etc)							
Type of facility	Public	68 53.5 40.5	8 6.3 4.8	51 40.2 30.4	127 75.6	2.274	0.321
	Private	27 65.9 16.1	1 2.4 0.6	13 31.7 7.7	41 24.4		
	Total	95	9	64	168		
Location of facility	Province	74 57.4 44.0	8 6.2 4.8	47 36.4 28.0	129 76.8	1.208	0.547
	Athens	21 53.8 12.5	1 2.6 0.6	17 43.6 10.1	39 23.2		
	Total	95	9	64	168		
Maternity facilities (hospitals and clinics)							
Type of facility	Public	55 43.7 33.3	21 16.7 12.7	50 39.7 30.3	126 76.4	0.726	0.696
	Private	20 51.3 12.1	6 15.4 3.6	13 33.3 7.9	39 23.6		
	Total	75	27	63	165		
Location of facility	Province	61 46.9 37.0	26 20.0 15.8	43 33.1 26.1	130 78.8	9.426	0.009
	Athens	14 40.0 8.5	1 2.9 0.6	20 57.1 12.1	35 21.2		
	Total	75	27	63	165		
Post-partum women							
Type of facility	Public	26 22.4 16.4	49 42.2 30.8	41 35.3 25.8	116 73.0	10.174	0.006
	Private	19 44.2 11.9	8 18.6 5.0	16 37.2 10.1	43 27.0		
	Total	45	57	57	159		
Location of facility	Province	33 27.10 20.8	51 41.8 32.1	38 31.1 23.9	122 76.7	8.708	0.013
	Athens	12 32.4 7.5	6 16.2 3.8	19 51.4 11.9	37 23.3		
	Total	45	57	57	159		

Table 4: Reported frequency of BMS gift offering to health care professionals, maternity facilities and post-partum women per type and location of facility

		Often n % (row) % (column)	Sometimes n % (row) % (column)	Rarely n % (row) % (column)	Total n % (row) % (column)	χ^2	p-value
Health care professionals (Obstetricians/Gynecologists, Midwives, Pediatricians, etc)							
Type of facility	Public	34 47.9 36.6	28 39.4 30.1	9 12.7 9.7	71 76.3	14.069	0.001
	Private	7 31.8 7.5	4 18.2 4.3	11 50.0 11.8	22 23.7		
	Total	41 44.1	32 34.4	20 21.5	93 100.0		
Location of facility	Province	34 43.6 36.6	30 38.5 32.3	14 17.9 15.1	78 100.0	5.180	0.075
	Athens	7 46.7 7.5	2 13.3 2.2	6 40.0 6.5	15 100.0		
	Total	41 44.1	32 34.4	20 21.5	93 100.0		
Maternity facilities (hospitals and clinics)							
Type of facility	Public	50 75.8 57.5	8 12.1 9.2	8 12.1 9.2	66 100.0	3.692	0.158
	Private	14 21.9 16.1	1 4.8 1.1	6 28.6 6.9	21 100.0		
	Total	64 73.6	9 10.3	14 16.1	87 100.0		
Location of facility	Province	55 74.3 63.2	9 12.2 10.3	10 13.5 11.5	74 85.1	3.666	0.160
	Athens	9 69.2 10.3	0 0.0 0.0	4 30.8 4.6	13 100.0		
	Total	64 73.6	9 10.3	14 16.1	87 100.0		
Post-partum women							
Type of facility	Public	15 34.9 24.6	13 30.2 21.3	15 34.9 24.6	43 70.5	1.636	0.441
	Private	6 33.3 9.8	3 16.7 4.9	9 50.0 14.8	18 29.5		
	Total	21 34.4	16 26.2	24 39.3	61 100.0		
Location of facility	Province	18 35.3 29.5	13 25.5 21.3	20 39.2 32.8	51 83.6	0.134	0.935
	Athens	3 30.0 4.9	3 30.0 4.9	4 40.0 6.6	10 16.4		
	Total	21 34.4	16 26.2	24 39.3	61 100.0		

Table 5: Rank order of types of BMS representatives' gifts offered to HCPs and post-partum women

	Rank order or types of gifts offered	%
Health care professionals	Samples of BMS	61.5
	Promotional gifts (e.g. diaries etc)	42.3
	Boxes of BMS	39.4
	Boxes of baby food	34.6
	Sponsored trips	30.8
	Financial incentives	8.7
Post-Partum Women	Samples of BMS	71.4
	Boxes of baby food	26.5
	Boxes of BMS	24.5
	Promotional gifts (e.g. diaries etc)	4.1

Table 6: Reported frequency of HCPs BMS distribution to post-partum women per type and location of facility

		Often n % (row) % (column)	Sometimes n % (row) % (column)	Rarely n % (row) % (column)	Total n % (row) % (column)	χ^2	<i>p</i> -value
Type of facility	Public	22 16.4 12.2	15 11.2 8.3	97 72.4 53.9	134 74.4	16.124	0.000
	Private	21 45.7 11.7	3 6.5 1.7	22 47.8 12.2	46 25.6		
	Total	43 23.9	18 10.0	119 66.1	180 100.0		
Location of facility	Province	33 23.2 18.3	12 8.5 6.7	97 68.3 53.9	142 78.9	2.225	0.329
	Athens	10 26.3 5.6	6 15.8 3.3	22 57.9 12.2	38 21.1		
	Total	43 23.9	18 10.0	119 66.1	181 100.0		

5 Discussion

This study, aimed at providing a preliminary, descriptive assessment of the implementation of the Code and the relevant Greek legislation in effect. The basic premise in this study is that women have the right to autonomously choose what they consider to be the ultimate feeding method for their newborns, infants and children. An additional premise in this study is that the right to make informed feeding decisions can be exercised only within an environment which actively supports autonomous decision making and safeguards against undue pressures. For decisions about breast-feeding such an environment necessitates an appropriate regulatory framework, effectively implemented and monitored which on the one hand facilitates independent decision making and on the other limits and restricts actions and conduct with known negative impact such as BMS companies' product endorsement strategies and practices. Based on the above, in our study we concisely examined the current Greek regulatory framework and focused on selected BMS endorsement practices.

The Greek regulatory framework as explained above, is more permissive to BMS marketing practices than the Code. Furthermore, the Greek regulatory framework suffers two significant deficiencies: a) does not define penalties for violations of its provisions and b) has not established a monitoring mechanism to oversee and monitor (and in turn promote) compliance. As a result of the regulatory system's first deficiency, enforcement of the law is curtailed. Although not unlike the situation in other countries and parts of the world, lack of concrete legal sanctions leads to ineffective implementation of regulations; a state of affairs with empirically documented adverse impact on breastfeeding [13, 20, 21, 26]. Because of the Greek regulatory framework's second deficiency, that is, the lack of a monitoring mechanism, data on the level and extent of compliance to the Code are not available. The significant shortcomings of the lack of data on compliance with the Code can be better appreciated taking into consideration that in Greece only a limited number of Baby Friendly Hospitals are in operation while at the same time, breastfeeding rates tend to be rather low [34, 35, 44]. In other words, accurate measurements of what appears to be a rather unfriendly to breastfeeding environment⁷ are not available. Moreover, estimates on the impact that BMS practices may potentially have on breastfeeding decisions cannot be made. Our study cannot by any means, fill this official monitoring gap. It can

⁷ It has to be noted however, that since 2014 the enactment of Law 4316 attempts to initiate improvements in perinatal care including actions supportive of breastfeeding such as: provisions for the establishment of breastfeeding areas in work places and other public places, development of *Baby Friendly hospitals*, establishment of breast-milk banks, initiatives and actions supporting and promoting breastfeeding after hospital discharge etc. Although some inroad has been made, it remains to be seen how and to what extent the provisions of the new law will be implemented and sustained. Nevertheless, this new law has not made any changes in the existing one in relation to marketing of BMS, the main focus of the Code and the current research.

however serve as a documentation of violations of the Code and relevant Greek legislation.

Based on our study thus, it appears that, similarly to the situation in other countries [37-41, 44-48], BMS representatives are often sighted in maternity hospitals and clinics in Greece visiting and directly contacting HCPs (e.g. obstetricians/gynecologists, pediatricians, etc) and less often midwives and post-partum women. BMS representatives' direct contact with HCPs rather than post-partum women or the general public is assessed as a BMS preferred strategy which circumvents limitations and counterbalances losses caused by marketing restrictions in various countries. It is further preferred by BMS companies as an effective practice to the extent that such professionals enjoy privileged and often authoritative relations with pregnant women and mothers of newborns and thus are more likely to exert an influence on the latter's feeding decisions; bottle-feeding included [13, 30, 43, 49-50].

Gift offering to HCPs was also found to be a frequent occurrence. In other words, similarly to other studies, our study concurs gift offering to HCPs as a usual BMS endorsement practice [31, 37-38, 45-48, 50]. This practice, however, constitutes a direct violation of the Code as well as Greek national legislation. Offering of BMS products to maternity facilities was a phenomenon of very high prevalence. Our sample was not only highly aware of the distribution of free or at reduced prices samples of infant formula and other similar products in all types of maternity facilities, but they also considered these to be occurring rather frequently. Such practices are not unique in the context of Greek maternity facilities [51]. Nevertheless, they constitute a direct violation of the Code and under conditions of Greek legislation. They have further been found to adversely impact upon breast-feeding decisions [52].

The significant implications of the extensive BMS product offering to Greek maternity facilities can on the one hand be better appreciated in light of empirical research on breastfeeding decisions in Greece and on the other, potentially explain some of our findings. Contrary to the findings of other study [50], our study finds that HCPs in Greece are rarely observed distributing BMS samples to post-partum women. Nevertheless, this finding may be a function of the specifics of clinical practices mainly those related to feeding practices. After delivery, women are required to stay in the hospital for several days during which HCPs frequently visit, examine and overall are in close contact with them; hence, have more time and opportunity to discuss feeding options. Furthermore, research has shown that hospitals fail to apply the practices of 'rooming in' or 'feeding on demand' [34], while at the same time they consistently offer mixed diet to infants [35, 44]. The prevalence of the latter practice is such that in a study on a sample of 140 mothers who had recently delivered 68.3% of them reported that they were offered a bottle of formula every time their neonate was brought to them to be fed. Furthermore, 63.6% of mothers who had already decided to breastfeed believed that formula was offered to their children without their knowledge [32]. Practices such as the above have been found to significantly relate to disparities between initiation and

continuance of breastfeeding. That is, in Greece, although initiation rate of breastfeeding is high, exclusive breastfeeding is relatively low [34-35, 44, 53]. These findings are further corroborated by a study [35] showing that after hospital discharge exclusive breastfeeding increased among mothers in their sample⁸.

It is likely then, that in Greek maternity facilities, distribution of BMS products in the form of samples or boxes of infant formula by HCPs is redundant and thus unnecessary. Consistently offering formula supplements, abundantly available in maternity hospitals and clinics and providing mothers of newborns with formula prescriptions [32-33] HCPs and maternity facilities on the one hand inhibit rather than promote breastfeeding and on other consistently, direct and indirect advertise BMS products in clear violation of the Code and Greek law.

BMS endorsement practices, were perceived in our sample to differentiate in statistically significant ways between public and private facilities and facilities located in the province and those located in Athens. Overall, it can be argued that BMS practices in violation of the Code and/or the national legislation were more frequently observed in maternity facilities located in the province rather than in Athens and in public rather than in private ones. Although causal explanations cannot be established through our study, the observed prevalence of BMS representatives' violations in provincial maternity facilities could indeed signify differential endorsement practices. On the other hand, given that our results represent estimates of frequency of observation behaviors, this differentiation could be a function of the facilities' size and relations between health care personnel and hospital employees. That is, provincial maternity facilities tend to be smaller in size while workers and personnel have closer relations-by mere numbers alone. Thus, midwives working in provincial maternity facilities may indeed be more aware than midwives working in maternity hospitals and clinics in Athens, of the daily functions and routines occurring in their place of work as well as the whereabouts of its personnel. Still, however, our findings do point to differences between types and location of maternity facilities which should probably be taken into consideration in any future research.

6 Conclusion

After almost four decades of its adoption, the International Code of Marketing Breast-Milk Substitutes continues to be challenged, mainly, by aggressive BMS advertisement and endorsement practices, inadequate and insufficient regulations and policies. In Greece, a permissive and incomplete law,

⁸ Currently, three public and one private maternity hospitals have been certified as Baby friendly hospitals. In these hospitals, such practices are no longer allowed. It remains to be seen whether the practices of these hospitals will have an effect in practices of other hospitals as well and reduce or even reverse negative effects on breastfeeding.

the lack of appropriate monitoring mechanism and HPCs' and hospital practices on the one hand directly violate the Code and the national legislation and on the other impede women's informed and autonomous decisions about breastfeeding. Given the importance of breastfeeding for public and individual health and even more so the importance of citizens' free and autonomous decisions it is important for Greece (and other countries as well) to take all necessary measures to apply the Code and the national legislation. Furthermore, research needs to address the issue of compliance with breastfeeding regulations in order for the current situation to be appreciated and future practices to be informed.

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Appendix Extracts from the International Code of Marketing Breast milk Substitutes

Article 2 (products covered by the code)

The code applies to the marketing, and practices related thereto, of the following products: breast milk substitutes, including infant formula; other milk products; foods and beverages, including bottle fed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast milk; feeding bottles; and teats. It also applies to their quality and availability, and to information concerning their use.

Article 4.1 (governments' responsibility)

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.

Article 5.1 (advertising to public)

There should be no advertising or other form of promotion to the general public of products within the scope of this Code.

Article 5.2 (provision of sample)

Manufacturers and distributors should not provide, directly or indirectly, to pregnant women, mothers, or members of their families, samples of products within the scope of this code.

Article 7.2 (provision of information to health workers)

Information provided by manufacturers and distributions to health professionals regarding products in 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 breast feeding. It should also include the information specified in article 4.2.

Article 7.3 (provision of inducements to health workers)

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.

Article 7.4 (provision of samples to health workers)

Samples of infant formula or other products within the scope of this code ...should not be provided for 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.

Article 11.1 (the governments' role)

Governments should take action to give effect to the principles and aim of this Code, as appropriate to their social and legislative framework, including the adoption of national legislation, regulations or other suitable measures.