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In-Country Assessments of BMS Companies' Compliance with the International Code of Marketing of Breast-milk Substitutes

India Report

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Disclaimer

Westat, with its local subcontractor in India, was responsible for the collection of data related to company compliance with the International Code of Marketing of Breast-milk Substitutes and any additional country-specific regulations related to marketing of these products. Westat is responsible for the analysis of the data related to compliance with the BMS marketing standards and for preparation of summary reports that have been incorporated by ATNF into the scoring of company performance for the 2016 India Access to Nutrition Index. Westat and its local subcontractor engaged with health facilities, pregnant women and mothers of infants who attended those facilities, health workers at the facilities, and retailers as part of the data collection and analysis process.

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Acronyms

ATNF	Access to Nutrition Foundation
BMS	Breast-milk Substitute
BPNI	Breastfeeding Promotion Network of India
CMS	Center for Media Studies
FOF	Follow-on Formula
GUM	Growing-up Milk
IF	Infant Formula
IBFAN	International Baby Food Action Network
IGBM	Interagency Group on Breastfeeding Monitoring
IMS	The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 as Amended in 2003 (IMS Act)
UNICEF	United Nations Children's Fund
WHA	World Health Assembly
WHO	World Health Organization

Executive Summary

In the spring of 2016, the Access to Nutrition Foundation (ATNF) commissioned a population-based survey in Mumbai, India to systematically assess breast-milk substitute (BMS) manufacturers' compliance with the International Code of Marketing of Breast-milk Substitutes (The Code) and subsequent World Health Assembly (WHA) Resolutions, as well as the extent to which companies comply with The India Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 as amended in 2003 (IMS Act), in areas where the regulation goes beyond the provisions of The Code. The purpose of this pilot study was to provide analysis for the first Access to Nutrition India Index, due to be published at the end of 2016. The definition of BMS products included in the study is derived from both The Code and subsequent guidance issued by World Health Organisation (WHO) in 2013.[1] The Code is considered applicable to any product when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast-milk. Products considered to be breast-milk substitutes and included in this study include infant formula (a formula designed to satisfy the normal nutritional requirements of infants up to 6 months of age); follow-on formula (for infants from six months of age); growing-up milk (products generally marketed for use by infants and young children from 12 to 24 months); and complementary foods recommended for infants less than 6 months of age. The Code also applies to the marketing of bottles and teats but they were not included in this study.

Although the IMS Act also extends to complementary foods for infants between 6 and 24 months, this study did not include those products, as it focuses only on the marketing of breast-milk substitutes and not on complementary foods that may be introduced as supplements at 6 months of age. Moreover, ATNF retained this definition of a BMS product to ensure that the three pilot studies conducted for ATNF are consistent (i.e., this study and two conducted in Vietnam and Indonesia in 2015 that fed into the ATNI Global Index 2016).[2]

This report presents findings from the India study, carried out in Greater Mumbai. This city was selected by ATNF, with advice from its Expert Group, because it has one of the highest population

[1] http://www.who.int/nutrition/topics/WHO_brief_fufandcode_post_17July.pdf.

[2] Further, although the May 2016 WHA resolution extended the definition of infant formula considered to be breast-milk substitutes to products marketed for up to 36 months of age, for purposes of consistency, the same definition was used as in the other two pilot studies. http://www.who.int/mediacentre/news/releases/2016/wha69-28-may-2016/en/

densities in India and high gross domestic product (GDP) per capita, likely making it an appealing market for infant foods companies. Moreover, a similar study had previously been carried out in Delhi by PWC on behalf of FTSE4Good.[3] The results of this study should be representative for these areas, but they should not be interpreted to apply to all of India.

The design of the survey was based, with permission from the United Nations Children's Fund (UNICEF) in New York, on a Protocol developed by the Interagency Group on Breastfeeding Monitoring (IGBM) entitled Estimating the Prevalence of Violations of The Code and National Measures. This Protocol was last updated in August 2007, and ownership of the Protocol currently rests with UNICEF.[4] The IGBM Protocol calls for data collection at multiple levels to examine different aspects of Code compliance, including interviews with pregnant women and mothers of infants in health facilities, interviews with healthcare workers in health facilities, identification of informational materials produced by BMS manufacturers available in health facilities and retail stores, identification of sales promotions by BMS manufacturers in retail stores, analysis of product labels and inserts of all available products on the local market, and monitoring of media advertising. These channels of promotion were fully examined in the conduct of the survey.

The IGBM Protocol also requires that compliance with national measures (the IMS Act) be assessed, if they go beyond the requirements of The Code. Our BMS Code expert determined that the IMS Act expands on The Code in several ways, particularly in respect of product labelling and informational and educational materials. It also sets out its own definitions of some terms.

The methodology and procedures that were followed include:

- Field-level training of 17 interviewers and their 3 supervisors conducted in July 2016;
- Field data collection of interviews with 808 women and 120 healthcare workers in 40 health facilities conducted in July 2016;
- Monitoring advertising or product promotion in various media conducted during July and September 2016;
- Monitoring 120 retail outlets for observation of product promotion in July 2016; and

[3] http://www.ftse.com/products/indices/F4G-BMS. The FTSE4Good Index Series is designed to measure the performance of companies demonstrating strong Environmental, Social and Governance (ESG) practices. Companies that market breast-milk substitutes have to meet FTSE4Good's BMS marketing inclusion criteria to be admitted into the FTSE4Good Index.

[4] Permission to base the survey on the IGBM protocol does not imply any endorsement of the resulting report by UNICEF

- Purchasing and systematic analysis of the labels and inserts of 44 relevant BMS products from June through October 2016.

This work builds on and is intended to complement other monitoring exercises carried out by the Breastfeeding Promotion Network of India (BPNI).

The principal findings of the pilot study are:

- **Sub-article 4.2 of The Code. Informational and educational materials dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children**. The study team identified 8 items in 4 of the 40 health facilities that appeared to be informational or educational materials about infant feeding. These represented 5 unique items pertaining to infant formula, follow-on formula, or growing-up milk. They were produced by 2 BMS manufacturers. The IMS Act does not allow the distribution of these types of materials.

- **Sub-article 4.3 of The Code. Equipment or materials donated to health facilities 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**. None of the 120 healthcare workers interviewed reported knowing of any non-compliance.

- **Sub-article 5.1 of The Code. No advertising or other form of promotion to the general public of products within the scope of this Code.[5] Provision 3 (a,b) of the IMS Act. Prohibits all persons from promoting to the public through advertising.** Overall, the media monitoring identified no television, newspaper, magazine or social media advertising. The women interviewed most frequently recalled seeing ads for covered products on television (3.6%) with fewer mentions of the internet (1.0%), social media (0.9%), and shop or pharmacy (0.6%). Since the media monitoring identified no advertisements, they could be remembering ads from some time ago or for products for children 2 years or older. As a secondary exercise, a set of 12 online stores were monitored weekly over a four-week period to search for any promotions of covered products, such as price discounts. These are more akin to point-of-sale promotions than traditional advertisements. The findings are discussed under Sub-article 5.3.

- **Sub-article 5.2 of The Code. 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**. Only 1 woman interviewed remembered receiving samples of a BMS product but could not remember the company or product name.

- **Sub-article 5.3 of The Code. For products within the scope of this Code, there should be no point-of-sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level.** No point-of-sale promotions were identified in any of the 120 retail outlets. Of the 12 online stores that

[5] Covered products are those formulas designed for children 0-24 months of age and complementary food designed for infants of 0-6 months of age as these are breast-milk substitutes.

were monitored, we identified sales promotions on 2 of them. One had sales promotions for 7 products, but when we attempted to order them through an Indian IP address, they were all listed as out of stock. Another had promotions for 6 different products. It is not possible to determine whether these promotions were offered by the BMS companies or by the retailers themselves without manufacturer involvement.

- **Sub-article 5.4 of The Code. Manufacturers and distributors should not distribute to pregnant women or mothers of infants and young children any gifts of articles or utensils which may promote the use of breast-milk substitutes or bottlefeeding**. Of the 808 women interviewed, 4 (0.5%) reported receiving a gift from someone other than a family member or friend. None of the gifts was from a BMS manufacturer.

- **Sub-article 5.5 of The Code. Marketing personnel, in their business capacity, should not seek direct or indirect contact of any kind with pregnant women or with mothers of infants and young children.** Of the 808 women interviewed, none reported having been spoken to by a company representative.

- **Sub-article 6.2 of The Code. 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.** Overall, 33 (4.1%) of the 808 women reported being spoken to by a health professional about using BMS products, and 23 (69.7%) of those professionals reportedly recommended a specific product. The companies most frequently mentioned were Nestlé (16) and Abbott (4).

- **Sub-article 6.3 of The Code. 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 specified in Article 4.3. Provision 8 (1) of the IMS Act. No person shall use any health care system for the display of placards or posters relating to, or for the distribution of, materials for the purpose of promoting the use or sale of infant milk substitutes or feeding bottles or infant foods.** Five (5) informational materials were found on public display in 4 of the 40 health facilities, thus not complying with the IMS Act.

- **Sub-article 6.8 of The Code. 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**. There were no instances of donations reported or observed in open areas of the 40 health care facilities.

- **Sub-article 7.2 of The Code. 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**. Twenty-one (21) of the workers from 14 of the 40 facilities reported that a BMS company representative had visited to give product information to health professionals. However, as the IGBM Protocol does not call for information to be

collected on the content of these materials, no further insights are available about the nature of these visits or the information imparted.

- **Sub-article 7.3 of The Code. 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. Provision 9.2 of the IMS Act. No contribution or pecuniary benefit to a health worker or any association of health workers, including funding of seminar, meeting, conferences, educational course, contest, fellowship, research work or sponsorship.** One (1) of the 120 workers interviewed mentioned a gift – snacks, provided by Nestlé, for a breastfeeding class. As with other items that a worker might consider inappropriate, it is possible that there could be some underreporting.

- **Sub-article 7.4 of The Code. 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, and health workers should not give samples of infant formula to pregnant women, mothers of infants and young children, or members of their families.** None of the 120 healthcare workers who were interviewed mentioned receiving samples from a BMS manufacturer.

- **Sub-article 9.2 of The Code. Manufacturers and distributors of infant formula should ensure that each container has a clear, conspicuous, and easily readable and understandable message printed on it, or on a label which cannot readily become separated from it, in an appropriate language, which includes all the points in Sub-article 9.2. Provision 6(1a) of the IMS Act also requires the statement "IMPORTANT NOTICE:" and "MOTHER'S MILK IS BEST FOR YOUR BABY" in capital letters on the central panel of every container in letters not less than five millimeters, and that several other statements must be included on labels. Provision 6 (2a,b) of the IMS Act also prohibits pictures of an infant or a woman or both, or pictures or other graphic material or phrases designed to increase the saleability of infant milk substitutes or infant food.** Overall, the labels, and inserts if any, of 44 formula and complementary food products marketed by 8 BMS companies were analyzed. Compliance was good. There were no incidences of non-compliance found on labels of any products other than seven parallel imports, i.e., products not intended for the Indian market.

- **Sub-article 9.4 of The Code. The label of food products within the scope of this Code should also state all of the required information relating to ingredients used, composition analysis, storage conditions required, the batch number and date by which the product is to be consumed. Provision 6 (1h) of the IMS Act also requires the date of manufacture on all labels.** Of the 44 product labels analyzed, the label of only one was missing "storage conditions" and another "date of manufacture."

A summary of observed non-compliance for all producers of covered formula and complementary food products found in Mumbai is presented below. This is presented for descriptive purposes only.

Executive summary table: Observations of non-compliance by article and source

Company	Number of formula and complementary food products in study	Total observations	Relevant Code sub-article			
			4.2 Facility/ store observation	5.1 Media monitoring	5.3 Store observation (including online stores)	9.2 and 9.4 Label analysis (total number of non-compliances on all labels)
Danone	13	1	0	0	1	0
Nestlé	11	13	2	0	7	4
Mead Johnson	5	9	0	0	1	8
Abbott	7	3	3	0	4	0
Heinz	2	11	0	0	0	11
Hain Celestial	1	5	0	0	0	5
Raptakos Brett	4	0	0	0	0	0
Amul	1	3	0	0	0	3
Total	44	45	5	0	13	31

Important conclusions and recommendations include:

- Public advertising of BMS products was virtually non-existent in Mumbai. Likewise, there were no point-of-sale promotions in any of the observed brick-and-mortar retail outlets. There appears to be little contact by BMS company representatives with the women or health care workers. Labelling of products intended for the Indian market is nearly fully compliant with the requirements of the IMS Act. This implies that voluntary compliance by companies is relatively good and/or enforcement of the IMS Act by the national and state governments of India with the support of the authorized organizations and the health care profession is very strong.

- The main instances of non-compliance with the IMS Act provisions for labelling were related to parallel imports. This may be an area for more enforcement activity.

- While public advertising and point-of-sale promotions in physical retail stores appears to have been successfully controlled by the Indian government, we identified a new concern with online store sales promotions. This may be a challenge for regulators, but an effort should be made to understand it and develop appropriate strategies to limit it.

- There was little reported company contact with the pregnant women or mothers. However, two potential avenues of contact were identified. Some online magazines and marketing websites invite mothers to "sign-up" to access information and engage in exchanges with other members. While there were no reports of non-compliance, these could be avenues through which to establish brand awareness for formula products. Also, there was documentation of a Nestlé representative providing snacks for a

breastfeeding class at a healthcare facility. These could perhaps be considered to be a "gift."

These findings appear to accord with the findings and reports of BPNI which monitors compliance with the IMS Act on an ongoing basis.[6]

Limitations of this pilot study include:

- Much of the information needed to assess compliance comes from interviews with women and with health care workers. Self-reported events or information can be misreported for various reasons, as described in Chapter 7.
- Health care workers were selected by the interviewers within each health facility following the IGBM Protocol, but they might or might not have been the best workers to interview with respect to facility-related issues. The most knowledgeable respondents might be the facility manager and the facility financial manager but the Protocol does not indicate that such persons should be selected for interview in each facility.
- The selection of retail outlets to observe point-of-sale promotions was purposive, not representative. The convenience of selection does not allow the results to be extrapolated to the universe of stores in Mumbai. Additionally, observations were made only on one day rather than over a period of time.
- The study sample was limited to mothers with children only up to 6 months old. This does not allow the assessment of the promotion of breastfeeding up to 24 months of age for children and may underestimate the promotion of BMS products for children between 6 and 24 months.
- The IMS Act restricts advertising and promotion of complementary foods up to 24 months, while The Code originally covered complementary foods only up to 6 months. As this study did not extend to such products to keep it in line with The Code's definition of BMS (and subsequent WHA resolutions) and the other two pilot studies, other organizations/studies may provide useful additional information on marketing activities relating to complementary food products for infants of 6 to 24 months of age, or up to 36 months, in accordance with the most recent guidance issued by the WHO in May 2016.

[6] http://www.bpni.org/IMS-ACT/BTL-7-24022016-low-res.pdf and http://www.bpni.org/IMS-ACT/BTL-6.pdf

Background 1

A. Rationale for Conducting the India Pilot Study

The Access to Nutrition Foundation (ATNF) is a not-for-profit organization, based in The Netherlands, that was established in 2013 to develop and publish the Access to Nutrition Indexes (ATNIs). The first Global Index, launched in 2013, scored and rated 25 of the world's largest food and beverage manufacturers on commitments, performance and disclosure on addressing obesity and under-nutrition. The second edition of the Global Index was introduced in January 2016 and rated 22 companies similarly. More information is available at www.accesstonutrition.org. The Indexes are intended to: (1) enable companies to benchmark their own performance against international standards and best practice and compare themselves to their peers; and (2) provide an objective source of information for all stakeholders to use to evaluate companies' responses to two of the world's most pressing public health challenges.

ATNF and Westat first piloted the methodology for this survey during 2015 in Vietnam and Indonesia. This report builds on that experience plus the work by the Breastfeeding Promotion Network of India (BPNI) (which monitors compliance with The India Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 as amended in 2003 (IMS Act) on an ongoing basis) and that of FTSE4Good (for whom PWC conducted a study of Nestlé's marketing activities in 2011). BPNI cited examples of non-compliance and encouraged the Government of India to take action against breast-milk substitute (BMS) manufacturers who are not in compliance.[7] The PWC report was confidential but letters from FTSE4Good to Nestlé outlining its areas of concern (and the company's response) are available on FTSE's website.[8]

ATNF and Westat collaborated again on the third pilot study in India. The results will be used to inform the first 2016 India ATNI in the same way that the studies in Vietnam and Indonesia fed into the 2016 Global Index.

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[7] http://www.bpni.org/protecting-breastfeeding

[8] http://www.ftse.com/products/indices/F4G-BMS

Mumbai was chosen as the geographical location for this subsequent pilot study. This city was selected by ATNF, with advice from its Expert Group, because it has one the highest population densities in India and high gross domestic product (GDP) per capita, likely making it an appealing market for infant foods companies. Moreover, a similar study had previously been carried out in Delhi by PWC on behalf of FTSE4Good.

The assessment was designed to determine whether those companies whose BMS products were for sale in the study area conform fully with the provisions of the International Code of Marketing of Breast-milk Substitutes (The Code), subsequent World Health Assembly (WHA) resolutions and national regulations (IMS Act), in order not to undermine optimal infant and young child nutrition, which is a major contributor to combating obesity, under-nutrition and related morbidity and mortality.

B. The Importance of Breastfeeding for Infant and Child Health

It is estimated that 830,000 deaths globally could be avoided if every baby were breastfed within the first hour of life.[9] Moreover, the World Health Organization (WHO) advocates that to achieve optimal growth, development and health:

- All children should be breastfed exclusively for the first six months;
- Breastfeeding should continue until the age of two or beyond; and
- At six months old, and not before, safe and appropriate complementary foods should be introduced to infants' diets to meet their evolving nutritional requirements.

In India, which has a high level of national commitment for reducing neonatal and infant mortality, the promotion of appropriate breastfeeding practices has been accorded a very high priority by the Ministry of Health and Family Welfare, Government of India.[10] This is evident from the fact that in the seven northern states of India, where over 50% of infants are born and where most infant deaths occur, the rates of early initiation of breastfeeding within the first hour of birth increased significantly from 12.4% in 2006 to 42.1% in 2011.[11] In a recent 2013-14 national report, 46.4% of infants were reported to be breastfed within one hour and 65% of infants were reported to be

[9] Save the Children (2013).

[10] Home Based Newborn Care, Operational Guidelines (revised 2014), MoHFW, GoI

[11] ibid

exclusively breastfed for the first 6 months of life, compared to corresponding rates of 25% and 46% in the earlier national survey findings of 2005-06.[12,13] Introduction of complementary feeding between 6 to 8 months continues to be poor with one in two children in 2006, as well as 2013, reported as receiving complementary feeding at this age.[14]

Breastfeeding confers a range of health and other benefits, as extensive evidence has demonstrated.

Babies who breastfeed are at a lower risk of:

- Gastroenteritis;
- Respiratory infections;
- Sudden infant death syndrome;
- Obesity;
- Type 1 and 2 diabetes; and
- Allergies (e.g., asthma, lactose intolerance).[15]

Breastfeeding also reduces the need for antibiotics and other medicines.[16] Evidence is also mounting that the initiation and duration of breastfeeding may influence obesity in later life.[17]

Several benefits to mothers have been identified, which include greater protection against breast and ovarian cancer, and hip fractures in later life. Recent evidence has demonstrated an association between prolonged breastfeeding and postmenopausal risk factors for cardiovascular (CV) disease. These illnesses all represent the greatest threats to women's health across all ages.[18]

Extensive breastfeeding, therefore, also contributes to health service cost savings.

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[12] Ministry of Health and Family Welfare (2013-14) National Health Family Survey 4, International Institute for Population Sciences (HPS), Mumbai, India.

[13] Ministry of Health and Family Welfare (2003-4) National Health Family Survey 3, International Institute for Population Sciences (HPS), Mumbai, India.

[14] Government of India. Ministry of Women and Child Development: Rapid Survey on Children 2013-2014

[15] https://www.unicef.org.uk/babyfriendly/news-and-research/baby-friendly-research/infant-health-research/

[16] http://www.who.int/features/factfiles/breastfeeding/en/

[17] http://www.hsph.harvard.edu/obesity-prevention-source/obesity-causes/prenatal-postnatal-obesity/

[18] ibid

Nutrition and health specialists, therefore, encourage as many women as possible to breastfeed. In the poorest countries particularly, breastfeeding can prevent hundreds of thousands of infant deaths and protect children throughout their lives. While a small number of women cannot breastfeed, and some infants with rare metabolic diseases cannot be breastfed, the vast majority of babies can be breastfed by their mothers.

C. History and purpose of The International Code on Marketing of Breast-milk Substitutes

The WHO first released The Code in 1981 (see Appendix A). From 1982 through 2016, additional resolutions were adopted by the WHA that expand on and clarify The Code, and for compliance purposes are considered part of The Code (see Appendix B).

The Code was developed as a tool to protect and promote the practice of breastfeeding and to ensure the appropriate marketing of BMS products, bottles and teats. The Code is a recommendation from the WHA calling on Governments to implement its provisions through appropriate national legislation or regulations.

D. Aspects Covered by the International Code

As interpreted for this study in India, the definition of covered BMS products is derived from The Code, subsequent WHA resolutions, and subsequent guidance issued by WHO in May 2016.[19] According to these documents, The Code is considered to be applicable to several types of BMS: infant formula (for infants less than 6 months of age); follow-on formula – sometimes called follow-up formula – (for infants from 6 months of age); growing-up milk (for children from 12 months of age); and complementary foods recommended for infants less than 6 months of age. Since the study design and planning for this study in India began before the new WHA 2016 resolution was published, growing-up milk for this study was defined as for children 12-24 months of age based on WHO guidance published in July 2013.[20] This is also consistent with the definitions in the two previous pilot studies in Vietnam and Indonesia. It is also important to note that if a formula product spanned more than one age range, it was classified as belonging to the younger product

[19] http://www.who.int/mediacentre/news/releases/2016/wha69-28-may-2016/en/

[20] http://www.who.int/nutrition/topics/WHO_brief_fufandcode_post_17July.pdf

type, e.g., a product listed for 0-12 months was classified as an infant formula. The Code also applies to the marketing of bottles, pacifiers and teats but information for these products was not collected in this India pilot study.

The Code sets out its recommendations on marketing of these products in the following articles:

- Article 1. Aim of the Code;
- Article 2. Scope of the Code;
- Article 3. Definitions;
- Article 4. Information and education;
- Article 5. The general public and mothers;
- Article 6. Health care systems;
- Article 7. Health workers;
- Article 8. Persons employed by manufacturers and distributors;
- Article 9. Labelling;
- Article 10. Quality; and
- Article 11. Implementation and monitoring.

This pilot study focused on assessing compliance with those elements of Articles 4-9 covered by the Interagency Group on Breastfeeding Monitoring (IGBM) Protocol, which is described in Chapter 2, Section B, with the specific recommendations that were to be addressed. Articles 1-3 of The Code provide the context for the pilot study but are not monitored per se. Article 10 would require special inspection of manufacturing processes, which is not covered by the IGBM Protocol and therefore not within the scope of this pilot study. Similarly, Article 11 is primarily targeted to governmental responsibilities, is not addressed by the IGBM Protocol, and was not within the scope of this pilot study. Additionally, this approach was adapted to take into considerations the provisions included in the IMS Act. These are described more fully in Chapter 3, Sections A and B.

E. Process of Selecting Westat

Westat was selected through an ATNF-initiated competitive bid process in March 2015 to conduct the pilot studies in two pre-selected countries, Vietnam and Indonesia, based on the IGBM Protocol. As a result of that successful collaboration, Westat was asked to conduct the subsequent pilot study in India.

F. Westat Description

Westat is an employee-owned health and social sciences research organization based in Rockville, Maryland, with more than 2,000 staff members. Westat is one of the leading survey implementation organizations in the United States (U.S.), and the company has extended its expertise to the design and conduct of surveys in developing countries. Westat's professional staff includes senior statisticians with international reputations in survey sample design and statistical analysis; senior scientists in fields such as nutrition, epidemiology, and medicine; international survey experts; and global health evaluators.

Westat has not carried out studies for the infant food industry (manufacturers or business associations), nor does it have any such companies or bodies on its roster of clients. Westat has no conflict of interest in conducting and reporting on this study.

Westat has supported many national surveys for the U.S. Federal Government. Particularly relevant examples are the National Health and Nutrition Examination Survey (NHANES), the leading source of national statistics on health conditions and nutritional status of the U.S. population, which Westat has conducted for the National Center for Health Statistics for the past 20 years; and the U.S. Department of Agriculture (USDA) Food and Nutrition Service Infant and Toddler Feeding Practices Study, which is examining breastfeeding practices in a low income population (the Women, Infants, and Children [WIC] nutrition-assistance program).

Westat has supported health and social science research in developing countries since 1982. Westat has worked in more than 50 countries, including India, and is incorporated in Thailand, which is the base for Westat's Southeast Asia activities. For these global studies, Westat has established strong management controls to ensure the quality and timeliness of work in country. Westat has also

developed substantial experience in identifying qualified local partner organizations that can perform the fieldwork. See the description of Westat's local partner below.

G. In-Country Partner Description

The in-country data collection partner for this pilot study was selected in response to a Request For Proposals (RFP) entitled "India Assessment of Marketing of Breast-milk Substitutes." Centre for Media Studies (CMS) based in New Delhi, India was chosen. CMS is a leading not-for-profit, multi-disciplinary research and facilitative think-tank in India. With established facilities and trained interviewing and data management staff, CMS has 25 years of experience in research, advocacy, and capacity-building projects. CMS has conducted surveys for a range of partners on social development, specifically on topics such as maternal and child health and nutrition, HIV/AIDS, and environment and community development. The organization is also experienced in quantitative and qualitative research methods and in-depth in-person interviews.

CMS's staff includes a core team of professionals, including 55 full time experienced professionals. CMS has a Media Lab which monitors media (TV, press, digital, and radio) and analyzes the portrayal of development issues in India. CMS has an Institutional Review Board (CMS-IRB), registered in the Division of the Assurance and Quality Improvement of the Office for Human Research Protections (OHRP), U.S. to give technical support to research organizations towards maintaining the ethical standards in research on human subjects. CMS is also registered to give Federal Wide Assurance (FWA) for the Protection of Human Subjects for International (Non-U.S.) institutions.

Prior to selecting CMS as an in-country data collection partner, Westat verified that CMS had no commercial links to the BMS companies being assessed and that the staff of the professional media monitoring service, TVADINDX (iBankLIVE) had no personal links to representatives of BMS companies.

H. Support from Municipal Corporation of Greater Mumbai

Prior to conducting the study in India, Westat, ATNF and the CMS contacted the Public Health Department of the Municipal Corporation of Greater Mumbai (MCGM) to gain their support to

conduct this pilot study. The study objectives and the methodology were submitted and the Executive Health Officer was briefed about the study requirements. As the responsible authority, the Public Health Department of the MCGM provided a letter of authorization and all the relevant data for drawing the sample from the wards in the Greater Mumbai. CMS staff had developed strong relationships with the MCGM which facilitated the implementation of the study. Both Westat and CMS secured approval from their respective IRBs to conduct the survey as is required for surveys addressing health issues

I. Project Management

The Westat team is led by a Senior Vice President who heads international research efforts. The management team consisted of two senior managers leading work under the contract: a Project Director and a Project Manager, who have significant experience working and establishing collaborations in Southeast Asia. Other senior members of Westat's team included a Survey Statistician, to consult on survey sample design, weighting and variance estimates; an Information Technology (IT) Manager and Data Manager, to ensure adequate IT support to the project and oversee database programming and data processing. A Research Associate worked closely with the senior managers.

CMS had a Principal Investigator/Project Manager to provide in-country insights and to manage institutional relationships and resources. CMS provided two Senior Researchers who had primary technical responsibility for the work in-country, a Senior Data Manager and a team of data entry staff. CMS also provided an in-country Nutrition Consultant, Dr. Sheila Vir, who has expertise in public health and nutrition and experience working on state and national programs as well as with various national and international agencies.

Responsibilities for survey work were allocated to maximize in-country resources, while using Westat's expertise for management, development, quality control (QC), and data analysis. Westat personnel, in collaboration with ATNF, handled the finalization of survey instruments, selection of the sample, customization of the training, programming the data entry system, cleaning and analyzing data, and preparation of the final report. CMS translated the survey instruments, organized and provided training to data collectors, collected and entered all data, and performed field QC. Because of her special knowledge and expertise in BMS, The Code, and the IMS Act provisions, Dr.

Vir specifically compared the IMS Act provisions with The Code and assisted in questionnaire customization.

ATNF provided project management support to Westat by attending weekly calls for status updates and also by providing guidance at several stages of the India study. During the development phase and data collection process, ATNF attended bi-weekly calls with Westat and the CMS principal investigator and senior researchers.

Research Objectives 2

A. Primary Objective

The primary objective of this pilot study was to monitor compliance with the provisions of The Code, subsequent relevant WHA resolutions, and national measures (IMS Act), where applicable, by all BMS manufacturers selling BMS products (as defined for this pilot study) in Greater Mumbai. This was completed by measuring the type and scale of apparent non-compliance with these provisions through interviews and observations, and attributing them to individual manufacturers. A listing of all companies that were identified as selling BMS products in Mumbai, as well as the products found by the study team, is included as Appendix H. They numbered 44 products made by 8 different manufacturers. All of the 8 companies sell at least one formula product or covered complementary food.

B. Study Tool

The design of the survey was based, with permission from the United Nations Children's Fund (UNICEF),[21] on a Protocol developed by the IGBM, and titled Estimating the Prevalence of Violations of The Code and National Measures. This Protocol was last updated in August 2007, and its ownership rests with UNICEF. Compliance with the provisions of The Code, subsequent relevant WHA resolutions, and national measures was measured using the IGBM Protocol (2007).[22] As noted in the preamble to this protocol, *"The Interagency Group on Breastfeeding Monitoring (IGBM) is a UK-based coalition of international non-government organisations, churches, academic institutions and interested individuals. IGBM members formed the group in 1994 in order to initiate and oversee a monitoring exercise into whether, and to what extent, the International Code of Marketing of Breast-milk Substitutes … was being violated in selected countries. IGBM published its first report, "Cracking the Code", detailing the 1996 research findings, in 1997….Subsequently, a review was carried out to make the IGBM Protocol more suitable for use as part of national*

[21] Permission to base the survey on the IGBM protocol does not imply any endorsement of the resulting report by UNICEF.

[22] IGBM Protocol 2007 Preamble, modified.

level processes. The 2004-2007 IGBM monitoring work followed during which additional changes to the Protocol were made, and sections added, which reflect the lessons learnt during the in-country work."

ATNF selected the IGBM Protocol following recommendations from expert stakeholders they consulted. The IGBM Protocol is a tool which enables monitoring of compliance with The Code and additionally, upon adaptation, with national regulations, in countries which have such regulations. The Protocol and forms were adapted to the India context and took into consideration the provisions in the IMS Act, as described in Chapter 3, Sections A and B.

The IGBM approach to monitoring compliance uses a rigorous scientific research methodology with specified sampling and a null hypothesis. The Protocol is based on sound research techniques. The Protocol is particularly appropriate for establishing a baseline indication of levels of non-compliance with The Code and/or local regulations if the latter exceed the provisions of The Code. Future research findings using this same/similar Protocol can then be compared to the baseline, as a means of assessing the success of implementation of The Code and/or local regulations. The findings can also be used by Governments to augment their monitoring activities, and potentially to strengthen, if necessary, regulations and enforcement.

The IGBM Protocol recommends a sample size estimate of 800 interviews with pregnant women and mothers of young children to test the null hypothesis that there are no instances of non-compliance with specific Articles of The Code related to information that can be reported by the women. This sample size has 80% power to detect at least one reported instance of non-compliance if the true prevalence is 2%. For example, if 2% of pregnant women and mothers of infants in the total population had received a free sample of an infant formula, on average, in 80 surveys out of every 100 surveys of this size we would identify at least one instance of a woman receiving a free sample. This is a hypothesis-testing approach to sample size estimation, but in practice the survey data are used to make prevalence estimates, rather than to test hypotheses.

C. The International Code Articles Addressed in the India Pilot Study

Using the sample design and the data collection forms in the IGBM Protocol, adapted to the India context in consideration of the IMS Act provisions, and needs of this pilot study, we were able to estimate the prevalence of non-compliance for each of the following requirements of The Code and

the IMS Act. (How the study addresses the additional provisions of the IMS Act is set out in Chapter 3.)

Article 4. Information and Education

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:

- The benefits and superiority of breastfeeding;
- Maternal nutrition, and the preparation for and maintenance of breastfeeding;
- The negative effect on breastfeeding of introducing partial bottlefeeding;
- The difficulty of reversing the decision not to breastfeed; and
- 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;
- The health hazards of inappropriate foods or feeding methods; and
- Such materials should not use any pictures or text which may idealize the use of breast-milk substitutes.

4.3 Donation of informational or education equipment or materials by manufactures or distributors should be made only at the request and with the written approval of the appropriate government authority or within guidelines given by the government 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.

Article 5. The General Public and Mothers

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

5.2 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.

5.3 In conformity with paragraphs 1 and 2 of this Article, for products within the scope of this Code, there should be no point-of-sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level, such as:

- Special displays;
- Discount coupons;
- Premiums;
- Special sales;
- Loss-leaders; and
- Tie-in sales.

5.4 Manufacturers and distributors should not distribute to pregnant women or mothers of infants and young children any gifts of articles or utensils which may promote the use of breast-milk substitutes or bottle-feeding.

5.5 Marketing personnel, in their business capacity, should not seek direct or indirect contact of any kind with pregnant women or with mothers of infants and young children.

Article 6. Health Care Systems

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; and
- Specific to Article 4.3.

6.8 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.

Article 7. Health Workers

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 bottlefeeding is equivalent or superior to breastfeeding. It should also include the information specified in Article 4.2.

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.

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.

Article 9. Labelling

9.2 Manufacturers and distributors of infant formula should ensure that each container has a clear, conspicuous, and easily readable and understandable message printed on it, or on a label which

cannot readily become separated from it, in an appropriate language, which includes all the following points:

- The words "Important Notice" or their equivalent;
- Statement of the superiority of breastfeeding;
- A statement that the product should be used only on the advice of a health worker as to the need for its use and the proper method of use;
- Instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation;
- Neither the container nor the label should have pictures of infants, nor should they have other pictures or text which may idealize the use of infant formula. They may, however, have graphics for easy identification of the product as a breast-milk substitute and for illustrating methods of preparation;
- The terms "humanized", "materialized" or similar terms should not be used;
- Inserts giving additional information about the product and its proper use, subject to the above conditions, may be included in the package or retail unit. See "type of material" code; and
- When labels give instructions for modifying a product into infant formula, the above should apply.

9.3 Food products within the scope of this Code, marketed for infant feeding, which do not meet all the requirements of an infant formula, but which can be modified to do so, should carry on the label a warning that the unmodified product should not be the sole source of nourishment of an infant.

9.4 The label of food products within the scope of this Code should also state all the following points:

- The ingredients used;
- The composition/analysis of the product;
- The storage conditions required;
- The batch number; and
- The date before which the product is to be consumed, taking into account the climatic and storage conditions of the country concerned.

WHA Resolution 58.32 1.(3) To ensure that clinicians and other health-care personnel, community health workers and families, parents and other caregivers, particularly of infants at high risk, are provided with enough information and training by health-care providers, in a timely manner on the preparation, use and handling of powdered infant formula in order to minimize health hazards; are informed that powdered infant formula may contain pathogenic microorganisms and must be prepared and used appropriately; and where applicable, that this information is conveyed through an explicit warning on packaging.

Specifications for what was considered possible non-compliance with the specific recommendations, based on the data that were collected on the study's data collection forms, can be found in Appendix E.

Methodology: IGBM Protocol 3

Westat followed the IGBM Protocol very closely to conduct the pilot study, adapted in a few minor ways where necessary, which the IGBM Protocol recommends should be done in line with specific country contexts.

A. Comparison of the International Code to the National Regulations (IMS Act)

Westat obtained "The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 as Amended in 2003 (IMS Act) that is related to breast-milk substitutes. Our BMS Code expert carefully compared the IMS Act with the International Code to identify products and standards that are different from The Code. Analysis by the expert revealed that the IMS Act was similar or exceeded the provisions in most of the requirements of The Code.

The following IMS Act provisions differ from (and in some cases appear to exceed) the relevant Code requirements:

Provision 2 (a) "Advertisement" includes any notice, circular, label, wrapper or any other document or visible representation or announcement made by means of any light, sound, smoke or gas or by means of electronic transmission or by audio or visual transmission.

Provision 2 (f) "Infant food" means any food (by whatever name called) being marketed or otherwise represented as a complement to mother's milk to meet the growing nutritional needs of the infant after the age of six months and up to the age of two years.

Provision 3 No person shall (a) advertise or take part in the publication of any advertisement, for the distribution, sale or supply of infant milk substitutes, feeding bottles or infant foods; (b) give an impression or create a belief in any manner that feeding of infant milk substitutes and infant foods are equivalent to, or better than mother's milk; (c) take part in the promotion of infant milk substitutes, feeding bottles or infant foods.

Provision 5 (b) Subject to the provisions of sub-section (4) of section 8, no person shall donate or distribute any informational or educational equipment or material relating to infant milk substitutes or feeding bottles.

Provision 6 (1) Without prejudice to the provisions of the Prevention of Food Adulteration Act, 1954 and the rules made thereunder, no person shall produce, supply or distribute any infant milk substitute or infant food unless every container thereof or any label affixed thereto indicates in a clear, conspicuous and in an easily readable and understandable manner, the words "IMPORTANT NOTICE:" in capital letters in such language as may be prescribed and indicating thereunder the following particulars in the same language namely: (a) A Statement "MOTHER'S MILK IS BEST FOR YOUR BABY" in capital letters. The types of letters used shall not be less than five millimeters and the text of such statement shall be in the central panel of every container of infant milk substitute or infant food or any label affixed thereto.

Provision 6 (1h) The batch number, date of its manufacture and the date before which it is to be consumed, taking into account the climatic and storage conditions of the country.

Provision 6 (2) No container or label referred to in sub-section (1) relating to infant milk substitute or infant food shall (a) have pictures of an infant or a woman or both; or (b) have pictures or other graphic material or phrases designed to increase the saleability of infant milk substitutes or infant food. The Package and/or any other label of infant milk substitute or infant food shall not exhibit the words, "Full Protein Food", "Energy Food", "Complete Food" or "Health Food" or any other similar expression.

Provision 7 (1) Every educational or other material including advertisements or material relating to promotion of infant milk substitutes, feeding bottles and infant foods whether audio or visual, dealing with pre-natal or post-natal care of the feeding of an infant and intended to reach pregnant women or mothers of infants shall include clear information relating to: (fa) the date of printing and publication of such material and the name of the printer and publisher. (2) No material referred to in sub-section (1) shall be utilized to promote the use or sale of infant milk substitutes or feeding bottles.

Provision 8 (1) No person shall use any health care system for the display of placards or posters relating to, or for the distribution of, materials for the purpose of promoting the use or sale of infant milk substitutes or feeding bottles or infant foods: Provided that the provisions of this sub-section

shall not apply to (a) the donation or distribution of informational or educational or material made in accordance with the proviso to clause (b) of section 5.

Provision 9 (2) No producer, supplier or distributor referred to in sub-section (1), shall offer or give any contribution or pecuniary benefit to a health worker or any association of health workers, including funding of seminar, meeting, conferences, educational course, contest, fellowship, research work or sponsorship.

One significant difference in the IMS Act as compared to The Code is the inclusion within the Act of infant foods after the age of six months and up to the age of two years, as stated above under Provision 2. While these products are not included in the scope of this study in India because they are not BMS (as they were not in Vietnam and Indonesia, in line with the definition used for those studies of breast-milk substitutes), some nutrition experts in country have expressed concern that restricting the marketing of these products has possibly contributed to inadequate feeding of safe, nutritious foods from six months.[23] Others refute this, however.[24]

B. Adaptations of Forms

As the IMS Act provisions included all key requirements of The Code, few substantive changes were needed to the forms. Based on the stronger provisions of the IMS Act described above in Section A, questions were added to Form 3 to obtain information on the date of printing and publication of material as well as the name of the printer and publisher. Questions were added to Form 5 to track the inclusion of the wording "MOTHER'S MILK IS BEST FOR YOUR BABY" in capital letters; the exclusion of pictures or other graphic material and text or phrases designed to increase the saleability of infant milk substitutes or infant food; and the inclusion of the date of manufacture. There were also wording changes to questions on Forms 3 and 5 to reflect specific language in the IMS Act. Appendix F provides a summary of the differences and changes.

With the evolving technological age, one substantive change made was the addition of the internet and social media to Form 1 as platforms for promotion that may be recalled by pregnant women and mothers.

[23] http://www.bmj.com/content/345/bmj.e8131/rr/620553

[24] http://www.bmj.com/content/345/bmj.e8131/rr/620536

The forms were also amended to enable data on all types of BMS noted in Chapter 2 above to be collected and differentiated, for all companies selling products in Mumbai. Some re-formatting was done to ease data collection, which resulted in a slightly different look than those forms that exist in the Protocol. None of the customizations altered the collection of objective measures as designed in the Protocol.

The Consent forms and the survey instruments used for in-field data collection (Forms 1 – 4) were translated to Hindi by staff of CMS. The translations underwent review by bilingual study staff at Westat for changes that were needed to retain the English meaning. The form translations did not alter the collection of objective measures as designed in the Protocol.

The English version of the final forms used for data collection can be found in Appendix G.

C. Data Collected

To capture information in assessing possible non-compliance with these Articles of The Code, it was necessary to:

- Interview mothers and pregnant women;
- Interview health workers;
- Evaluate promotional and educational materials found in those health care facilities visited for interviews;
- Evaluate any marketing and promotions within selected retail stores;
- Evaluate product labels and inserts of available products; and
- Monitor selected media.

The Protocol contains six data collection forms, each designed to objectively capture information from each of the unique sources and relating to specific Articles of The Code.

Form 1. Designed to collect information from pregnant women or mothers to determine whether they:

- Recalled having been advised to use infant formula or any other drink or food for infants under 6 months of age;

- Recalled receiving any sample of a breast-milk substitute during their pregnancy or since the birth of their youngest child;
- Recalled receiving any gift of articles or utensils which may promote the use of breast-milk substitutes or bottle feeding; and
- Recalled having seen advertisements for formula milk (0-24 months of age), drinks/foods for infants under 6 months of age.

Form 2. Designed to collect information from health workers to assess incidents of:

- Health facilities where staff reported receiving samples of breast-milk substitutes;
- Health facilities which had received free or low cost supplies of breast-milk substitutes, in the last six months;
- Health facilities where staff reported having received at least one visit from company personnel in the last six months;
- Health facilities where staff reported having received at least one gift from company personnel in the last six months;
- Health facilities where staff reported having received, from companies in the last six months, materials or equipment; and
- Health professionals who reported having received gifts, financial or material inducements from companies in the last six months.

Form 3. Designed to collect data on information and educational materials in selected health facilities and selected retail outlets to identify incidences of:

- Company-sponsored written information for mothers and pregnant women about infant feeding;
- Company-sponsored visual information about infant feeding or displays; and
- Company-sponsored information about infant feeding for health professionals.

Form 4. Designed to collect information on point-of-sale promotions in selected retail outlets to assess number of those retail outlets where such promotions may be.

Form 5. Designed to collect information on product labels and inserts.

Form 6. Designed to collect information on advertisements to assess the number of advertisements in the public domain.

All information collected from women focused on the period since the beginning of the pregnancy or within the 6 months since the birth of the child. Information from the health workers related to the period of six months prior to the date of the survey. All information collected from shops and other public domain areas relates to the period of the survey, reflecting the products and information as available during the time of the survey.

Clinics and health facilities were not given compensation for allowing the study to be conducted in their facility. For the participation in a study interview, pregnant women or mothers were given a thank you gift as appreciation for their time (worth approximately US$ 7.50) and health workers were also given a thank you gift (worth approximately US$ 7.50), as is usual practice in India.

D. Sampling Health Care Facilities in Mumbai

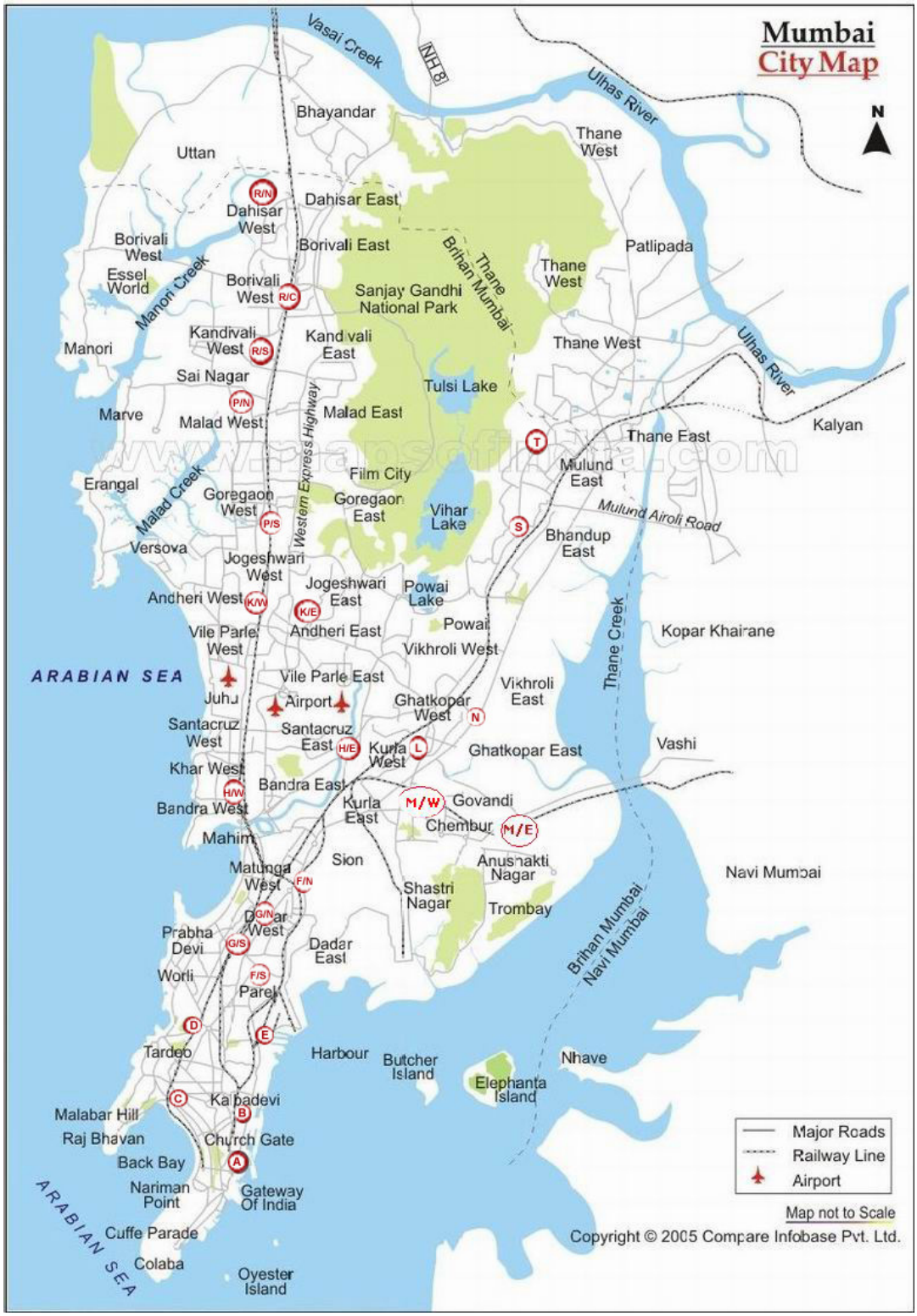
Ten geographical areas (wards), referred to as clusters or primary sampling units (PSUs), were selected for the India assessments of compliance with the International Code of Marketing of Breast-milk Substitutes (BMS) and national regulations.[25] From the PSU frame, 545 public and private health facilities were estimated to be located in the 24 wards within the Mumbai district (15 wards in the suburban district and 9 wards in the city district). The average number of health facilities per ward is about 24, ranging from 4 to 50 health facilities. A total of 15 wards were selected, 5 were designated as reserves. The second stage sampling strategy was to select a total of 75 facilities for the in-person interviews of eligible women.

The goal was to select 40 facilities for the India assessment, stratified by sampled ward. The construction of the frame in the 10 selected wards resulted in 75 eligible health facilities (50 for the main sample and 25 for the reserve sample) (see Appendix A). The 75 facilities were selected with equal probability. To ensure a representative sample of health facilities, the sampling frame was sorted by private/public identifier and facility type (clinic, health post, hospital, maternity home, nursing home) prior to sampling. The distribution of sampled health facilities was comparable to the distribution of facilities in the population.

The final number of facilities included in the study was 40.

[25] Project Sampling Memo: "Sampling of Wards and Facilities for India Assessments," July 1, 2016.

Once the sample of health facilities was provided, CMS began contacting the facilities and clinics to gain approval to visit and conduct interviews. A letter of support from Municipal Corporation of Greater Mumbai was provided in order to gain access to the health care facilities.



Source: Municipal Corporation of Greater Mumbai (http://www.mcgm.gov.in/irj/portal/anonymous?NavigationTarget=navurl://ce7407c74001ac932426502e58da0827)

E. Sampling of Women in Health Care Facilities

Study procedures called for interviews with women to be conducted over a period of two days at each facility, whenever possible. If a sufficient number of interviews could not be completed in the first two days at a particular facility, then the facility was visited for an additional day.

For the facilities, the target was to conduct, on average, 20 interviews with women. Since it was assumed some women might not be available for the interview or might refuse to be interviewed, we attempted to select a sample of 25 women, to obtain an average of 20 completed interviews per facility.

The selection of women was designed to use a systematic random sampling method described in the following paragraphs below. When the number of pregnant women and mothers with children less than 6 months on the patient roster of the identified health care facility allowed, the random sampling method of selecting women was followed. However, when the number of pregnant women and mothers with children less than 6 months in the identified healthcare facility was limited, the selection of women was by convenience. The eligible women were consecutively interviewed over a 2-day period until the target of 20 interviews was met. For any facility that was expected to see more than 25 eligible women over a 2-day period, selection of women was done as follows:

1. If a registration roster of pregnant women and mothers with children less than 6 months at the day of data collection was available, it was numbered consecutively in order of appointment time. If such a roster was not available, then an estimate was obtained of the number of eligible women the facility expected to see over the two-day period.

2. A systematic random sampling method was used to select 25 pregnant women and women with children 0-6 months from the list of women for 2 days of data collection, as follows:

   – The total number of women expected was divided by 25 to get the sampling interval number. For example, if the total number of women in the list was 48, the sampling interval = 48/25 = 1.92. Any fractional sampling interval was rounded up to the next whole number. For example, 1.92 was rounded up to 2. Therefore, every second woman on the list of potential participants was selected. A random number for each facility was selected (to serve as the starting point for systematic sampling.

   – The first woman selected for interviewing was the woman with the code that matched the random digit of that facility; for example, if the random digit was 3,

the third woman on the appointment list (or the third eligible woman who showed up in a facility with no appointment list) was selected. The second woman was the woman that had the code that equaled the code of first woman plus the sampling interval number.

If the end of the list was reached before 25 women were selected, the data collector circled back to the top of the list and continued to apply the sampling interval, skipping over women who have already been selected. In facilities that did not have more than 25 eligible women expected to attend over a 2-day period, all eligible women were approached without any sampling.

No replacements were made if the team failed to obtain 20 interviews. A desired minimum number of women interviewed at each facility was set at 18. After 2 days of data collection, if the number of women who completed interviews was less than 18, additional field-work was arranged to achieve the desired sample size, following the above sampling methodology.

A total of 808 women were interviewed. The range per facility was 19-25 interviews. There were 26 reports of refusals.

F. Sampling of Health Workers in Health Care Facilities

On arrival at the health facility, the team asked for a list of the names and designations of all health workers who have contact with pregnant women and mothers of young infants and who would be present during the days when the team would visit. For this pilot study in Mumbai, the types of health workers included nurses, doctors, midwives and assistants in the maternity ward. The team attempted to interview at least one doctor, one nurse, and one ward/out-patient department staff from the health facility that came in contact with the pregnant women and mothers of young infants.

The IGBM Protocol called for completing only three health worker interviews per facility. The team selected three staff per health facility and interviewed all three.

A total of 120 healthcare professionals were interviewed. None of the health workers refused to participate in the pilot study.

G. Selecting and Visiting Retailers

As part of the model for assessing compliance with The Code, it was necessary to visit a number of retailers to determine whether there were any promotions or materials for products covered by The Code and the IMS Act. The IGBM Protocol did not specify the types or numbers of retail outlets to visit, except to say that this should be done near the health facilities that had been selected for study.

The goal was to sample three retailers in close proximity to each participating health facility. There are many types of retailers in Mumbai that might sell BMS products. Therefore, interviewers were encouraged to include a pharmacy, a supermarket, a medical store, a general store and a large chain store nearby each health facility.

The field teams attempted to select a store from each of these categories around each of the participating health facilities. The plan was to identify, if possible, the store in each category that is closest to the health facility. Since area maps were not available, a healthcare worker at the facility was asked for the location of the closest store of each category or the interviewer identified a nearby retailer by walking around the area near the health facility.

A total of 120 physical retail outlets were visited.

Westat staff also monitored 12 online retail stores for the month of September 2016. These were identified as the most popular and frequently visited websites.

H. Identifying and Evaluating BMS Products

ATNF and Westat staff performed a detailed internet search and review to assemble a preliminary list of all of the known products sold in India that are BMS according to the study definition and therefore subject to the International Code or the India IMS Act regulations. Products included those of major international manufacturers, other manufacturers from outside of India, and in-country manufacturers. This list was provided to CMS staff that further refined the list by confirming which of these products were available in Mumbai and a final product list was prepared. Every product was purchased and photographed for analysis of the labels and inserts.

These products did not need to be purchased at a location near one of the sampled health facilities, since we expected the labels and inserts for products to be the same no matter where in the city they were sold.

For purchasing, the intent was to buy the smallest size available in an effort to contain cost. We expected the labels and inserts to be the same on all sizes.

If the field teams found the product list was incomplete and identified any additional products during their visits to retailers, those products were added to the overall list and a sample was purchased as well. The final list contained 44 products manufactured by 8 companies. (See Appendix H)

I. Media Monitoring

According to the KPMG-FICCI media and Entertainment Industry Report 2016, television is the dominant medium in India, and television advertisements make up more than 37% of media spending in India. Print is second, representing about 33% and digital is third representing about 21% of spending in India, while spending on radio and outdoor advertising make up the remainder. Websites dedicated to pregnant women and mothers are available and these media appear to be potential locations for BMS advertisements. Therefore, we chose to monitor television and newspaper media, which receive the highest advertising spending, as well as pregnancy and motherhood magazines and websites, plus BMS company websites and their social media websites.

The Protocol does not differentiate between websites and social media in terms of internet source; however, due to the growth of social media since the development of the Protocol, Westat decided the three main social media platforms (manufacturing company's Facebook page, YouTube channel and Twitter feed) should be monitored in addition to the top websites geared towards pregnant women and mothers of infants. However, no information is available about the percentage of advertising spent on these media.

CMS entered into an agreement with a local media monitoring organization that tracks television, print newspapers, and mother and baby-related magazines advertising in India. Most of the information from these sources was received in an automated fashion. These media were monitored for one month (July 2016) as was recommended in the Protocol. For the media sources that needed

to be monitored manually (e.g., BMS company local websites and social media sites), CMS monitored BMS company websites, Facebook, and Twitter accounts; parenting and child websites, and online retailer activity for one month (July 2016).

Westat staff also monitored several parenting and child websites for the month of September 2016.

Prior to conducting the media monitoring, Westat developed a Protocol for Media Monitoring in Mumbai, India, trained CMS staff on the Protocol's Form 6, and clarified the information needed from the social media platforms and websites to ensure that everyone understood the BMS products and age ranges that should be included in the study. The following guidelines were followed by CMS for specialty magazines and internet websites:

- **Specialty Online Magazines and Tabloids.** The monitor will purchase the July 2016 issue looking for BMS advertisements, and will take a photo of every UNIQUE advertisement it identifies.
- **Internet.** Once a week over the one-month period the monitor will access 25 most popular websites related to mothers and babies, and scan for BMS advertisements. The monitor will use Microsoft Snipping Tool to capture screen shots of the advertisements.
- **Social Media.** The monitor will identify BMS company specific Facebook pages, YouTube channel(s) and Twitter feeds, and capture the advertisement by taking a picture, video, or screenshot, as appropriate.

In total, CMS monitored 21 TV channels, 3 printed magazines, 12 newspapers and 25 of the most popular websites in relevant categories such as parenting, women's health, pregnancy and nutrition, infant nutrition and child nutrition. CMS also conducted weekly monitoring of the major international BMS manufacturers and their three social media platforms (YouTube, Facebook, and Twitter).

The data for each advertisement were reviewed for completeness and quality.

J. Representativeness and Precision of Results

The design of the IGBM Protocol yields a representative sample of health facilities, pregnant woman and mother of infants less than 6 months, and healthcare workers within those institutions for the sampled areas of Mumbai. Thus, the prevalence estimates for possible Code non-compliance that are reported in Chapter 5 can be considered reasonable approximations of the true prevalence

within these areas for items reported by these sources. Weighting of the data from the women's interviews could change the estimates slightly, and the precision of the estimates would need to take into account the overall design effect related to clustering of facilities and women in the sample selection. The 95% confidence interval for any prevalence estimate based on the women's responses is approximately ± 1.5 to ± 3.0%. Smaller estimates have a smaller confidence interval; larger estimates have a larger confidence interval. For example, for a prevalence estimate of 5.0%, the 95% confidence interval is approximately 3.3-6.7%; for a prevalence estimate of 10.0%, the confidence interval would be about 7.7-12.3%. These guidelines may be applied to any estimates in Chapter 5 that are based on women's interviews.

While the selection of health facilities and health workers is also representative of the sampled area, we do not have precise enough measures of the eligible population to make reliable confidence interval estimates. Therefore, we have not attempted to do so.

The prevalence estimates for promotions in retail outlets cannot be extrapolated to the overall catchment area of the pilot study, since the selection was a convenience sample. For product labels and media advertising, this pilot study conducted a census; therefore, the prevalence estimates do apply to the sampled area of India.

K. Defining Potential Non-Compliance

For each Article of The Code for which the IGBM Protocol collected data, our study team collated definitions from the IGBM Protocol of what would be considered non-compliance with The Code. These definitions are provided in Appendix K, organized by Sub-article of The Code, and showing the exact questions and codes that factored into defining possible non-compliance. As described in Section A above, additional definitions of non-compliance were added as a result of the specific provisions of the IMS Act that exceeded the Articles of The Code. These additional definitions are also included in Appendix K. There were some gray areas related to some recommendations, such as what constitutes a picture idealizing BMS, what type of gift is sufficient to encourage a health worker to promote a BMS product, or the ease of readability of the label and wording that increased saleability of a product. Where we are uncertain, we have noted what data we have and how we have interpreted it.

It should be noted that for the interview data from the women and the health workers, we have emphasized that this is based on recall, and thus, we are not able to verify that the reported event accurately demonstrates non-compliance with The Code. A further discussion of this limitation is presented in Chapter 7, Limitations. For any items that were directly observed by our field team, such as informational materials, promotions, and product labels, we did see the actual items, and therefore we have called these "observations."

For label and inserts non-compliances, Westat performed 100 % QC of Form 5 (label and insert data) for select key variables whose interpretation is subjective, such as "no text or phrases designed to increase saleability," "easy to read" and "in appropriate language." The Westat Project Manager then shared its findings with ATNF for final review. Data was recoded as necessary.

Fieldwork Preparation and Training 4

A. Organization of Field Work

Personnel for data collection in the field included 17 data collectors, 3 field supervisors, and 2 senior researchers. Data collectors were formed into three teams, each accompanied by a field supervisor. These teams were responsible for interviewing pregnant women and mothers and health care workers, and performing data collection at the retail outlets and health facilities. Team supervisors and senior researchers were responsible for contacting health facilities and making appointments for the data collection staff.

CMS had a team of two senior researchers and two assistant researchers who performed the label analysis.

B. Selection and Training of Data Collectors

CMS had a pool of experienced local data collectors in Mumbai, who have partnered with CMS for similar studies. CMS recruited a team of 17 local data collectors from Mumbai for this pilot study. These data collectors were a combination of new graduates and those who had at least one year of experience as an interviewer and/or field data collector. Each of the data collectors were screened and interviewed by the Senior Researchers. The data collectors were alerted 14 days before the training started. CMS recruited more than the required number of data collectors to account for any attrition. Considering local culture, data collectors were gender-matched to set respondents at ease. For example, only female data collectors were responsible for interviewing pregnant women and mothers.

Westat and CMS held training in Mumbai for five days in early July 2016 to provide all selected data collection staff with the knowledge and skills necessary for data collection using the IGBM Protocol. Training was attended by ATNF staff, Westat Senior Managers, CMS Principal Investigator and Seniors Researchers, field supervisors and data collectors. The training followed the approach recommended in the Protocol, and was based on materials provided by the Protocol. It introduced the data collectors to the importance of breastfeeding, oriented them to The Code and local

regulations (IMS Act), and trained them on the use of the IGBM questionnaires and forms. Data collectors were shown a PowerPoint presentation containing an overview of all information. In-depth training on using the data collection forms was provided; the data collectors practiced mock interviews and role plays to simulate use of the forms for interviewing. A field test was conducted with the data collectors to give experience of visiting and performing interviews in the clinics and ensure data collectors understood the proper interviewing techniques. Another field test was conducted for the retail outlet training to determine the stores to visit and to give experience in looking for BMS products and promotions. The team also practiced how to complete Form 4 for retail store promotions.

Westat conducted a separate training for CMS staff responsible for evaluating the labels and inserts of the BMS products purchased for completion of Form 5.

For further detail on the training, please find the training agenda in Appendix J.

C. Introductions to Clinics

In order to conduct the surveys at the health facilities in Mumbai, a letter of authorization was obtained from the Executive Health Officer, from the Public Health Department of the Municipal Corporation of Greater Mumbai (see Appendix D). This letter provided information about the purpose and objectives of the study, who is conducting the study, who will be interviewed and that the information collected will be kept confidential.

The team supervisors, with help and direction from the Senior Researchers, carried out the task of contacting health facilities, explaining study objectives and obtaining permission for the team to conduct interviews with women and health facility staff. All field supervisors as well as the data collectors were able to communicate in Hindi and Marathi. In most instances, contacts were made a day prior to or the morning of the day when the team planned to visit the facility. At first, attempts were made to obtain this permission via a phone call. If necessary, field supervisors met the responsible facility staff, such as the senior doctor, head/chief nurse, manager, office staff; in person to obtain permission. At the same time, supervisors also gathered information about the number and types of wards or departments within a particular facility to locate the respondent population, best day of the week and time to approach potential respondents; as well as estimate the number of potential respondents that visited a facility on a given day. Actual data collection was scheduled

based on this important information to perform data collection in most efficient and least disruptive manner.

D. Data Collection and Entry

Data collectors in the field completed hard copies of the data collection forms, following the procedures outlined in the data collection training and the Protocol. The CMS Data Manager as well as data entry personnel were trained by a Westat Data Research Associate during a 3-day in-person training in Delhi. The purpose of this training was to establish virtual data entry accounts, review data entry screens and functions for entering and saving data appropriately. Actual study data was used to conduct this training. The CMS staff including the Senior Researchers and the Data Research Associate reviewed the completed survey questionnaires for data quality, as outlined in the Protocol, by ensuring all questions were complete, legible, valid, logical, and consistent. The reviewed data collection forms were then entered into Epi Info by the data entry staff using double data entry, initialing and dating the forms after entry completion. The Westat Data Research Associate ran a SAS query to reconcile all first and second pass data and provided any discrepancies to the in-country project coordinator for resolution. This task was repeated until all discrepancies were resolved for all data collection forms. After data entry, all forms were placed for storage in a secure file cabinet.

Special QC procedures were implemented for analysis of product labels. Each BMS company as well as its brands was given a unique identifier. The field interviews were provided with the list of BMS products along with the unique identifier assigned to each product. This topic was included in the interviewer training and they were asked to use brand names as well as the unique identifiers when completing the forms. These unique identifiers were not only pre-populated on the respective data collection forms but were also used to catalogue each product's images in a systematic manner. Adopting this standardized procedure served very effective in performing cross-forms data QC and also assuring that the right images were associated to the companies and brands.

The cleaned raw data from the field was further reviewed for completeness and accuracy by Westat's Data Manager and Senior Project Manager before the analysis tables were produced.

Pilot Study Results 5

The aim of the IGBM protocol is to assess compliance by BMS manufacturers with selected Articles of The Code and national regulations (IMS Act). In practice, this is done by measuring possible non-compliance, i.e., by observing where a particular provision of The Code or the country regulations does not appear to be followed. The results from the analysis of data collected in the India study are presented below, organized by Article of The Code for which data were captured in the IGBM Protocol's data collection forms. For each Article, if there were a substantial number of observations, the accompanying table shows data overall and for the companies most frequently mentioned or observed with possible non-compliance.

Table 1 and Table 2 show the distribution and characteristics of the sample from which the data were collected.

Table 1. Summary of data collection by health facility

District #	Ward #	Facility #	# of women interviewed	# of health workers interviewed	# of retailers visited
1	10	26	20	3	3
1	10	30	20	3	3
1	10	40	20	3	3
1	16	10	20	3	3
1	16	13	20	3	3
1	16	21	20	3	3
1	21	2	25	3	3
1	21	7	22	3	3
1	21	9	21	3	3
2	1	254	21	3	3
2	1	264	20	3	3
2	1	273	20	3	3
2	1	283	20	3	3
2	2	174	20	3	3
2	2	188	20	3	3
2	3	82	20	3	3
2	3	92	20	3	3
2	3	112	20	3	3
2	4	200	20	3	3
2	4	206	20	3	3
2	4	210	20	3	3
2	5	131	20	3	3
2	5	138	20	3	3
2	5	146	20	3	3
2	5	154	20	3	3
2	7	347	19	3	4
2	7	355	20	3	3
2	7	363	20	3	3
2	7	371	20	3	3
2	11	50	20	3	3
2	11	55	20	3	3
2	11	59	20	3	3
2	11	72	20	3	3
2	13	310	20	3	3
2	14	319	20	3	3
2	14	326	20	3	3
2	14	330	20	3	3
2	19	407	20	3	3
2	19	414	20	3	3
2	19	418	20	3	2
Total		**40**	**808**	**120**	**120**
# refused		2	26	0	NA
Total		42	834	120	NA
Participation rate		95.2%	96.8%	100%	NA

Table 2. Characteristics of participants

	Number	Percent
Type of Health Facility		
Hospitals		
Public	3	7.5%
Private	14	35.0%
Maternity Home		
Public	2	5.0%
Private	7	17.5%
Nursing Home		
Private	14	35.0%
Total facilities	40	100%
Women's Status		
Pregnant	413	51.1%
Mother of Infant < 6 months	395	48.9%
Total women interviewed	808	100%
Type of Healthcare Worker		
Doctor	40	33.3%
Nurse	40	33.3%
Midwife	27	22.5%
Assistant in maternity ward	13	10.8%
Total workers interviewed	120	100%
Type of Retail Outlet Visited		
Hospital/Health Facility Pharmacy	13	10.8%
Medical Store	58	48.3%
Medical and General Store	35	29.2%
General Store	11	9.1%
Chain Store or Super Store	3	2.5%
Total retail outlets visited	120	100%

A. Article 4: Information and Education

Data were collected to allow assessment of compliance with Sub-article 4.2, informational and educational materials and Sub-article 4.3, donations of equipment or materials to health facilities and relevant IMS Act provisions.

Sub-article 4.2. Informational and educational materials dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children.

The study team identified 8 items (7 leaflets and 1 booklet) that appeared to be informational or educational materials about infant feeding that were produced by BMS manufacturers. There were

only 5 unique items from 2 BMS manufacturers, with one found in two different facilities and another found in three different facilities. All of the items were found in only 4 of the 40 different health facilities; none were found in any of the 120 different retail outlets. All 5 unique items pertained to infant formula, follow-on formula, or growing-up milk. We found no informational items about complementary food for children less than 6 months of age. The total number by product types is 13, since all of the 5 items referred to multiple product types.

Of the 5 unique items found, Abbott had 3 unique items, and Nestlé had 2 items. None of these materials are allowed to be displayed per the IMS Act provision. The use of this approach to reach women in India appears to be limited. This is similar to our findings in Vietnam and Indonesia, and in fact fewer items were found in India than in those countries.

Sub-article 4.3. Equipment or materials donated to health facilities 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.

Data for this assessment were captured in interviews with healthcare workers. A total of 120 healthcare workers from 40 different facilities were interviewed. None of the 120 workers reported knowing of any non-compliance. Interviewers followed standard neutral interviewing techniques, and it is possible that healthcare workers would not report instances of donations, but we believe the likelihood of any substantial non-compliance is very small.

B. Article 5: The General Public and Mothers

Data were collected to allow assessment of compliance with various sub-articles of Article 5.

Sub-article 5.1. No advertising or other form of promotion to the general public of products within the scope of this Code.[26] Provision 3 (a,b) of the IMS Act. Prohibits all persons from promotions to the public through advertising.

[26] Covered products are those for children 0-24 months of age, except for complementary food, which is for 0-6 months of age.

The 808 women who were interviewed were asked if they had seen any promotions or messages about BMS products since the pregnancy began or since the child was born. This was divided into two sections: electronic media and physical media.

As shown in Table 3, the only source that the women recalled somewhat frequently for seeing advertising of covered BMS products was television (3.6%). The internet (1.0%), social media (0.8%), and shop or pharmacy (0.6%) were mentioned by a small number of the 808 women. No other source had more than one mention. Our independent media monitoring identified no television advertisements over a month of monitoring, so the number of self-reports by women may be an overstatement. They could be remembering ads from some time ago, or ads that they saw for formula products for children of 2 years or older.

The only companies mentioned by name over all the media sources were Nestlé and Danone, with Nestlé being mentioned 21 times and Danone only once. For the majority of mentions, the woman could not recall a company name. Although it was not possible for women to recall specific products by age range most of the time, a few products were identified by the women: Lactogen 1, Nan Pro 1, and Cerelac by Nestlé.

Table 3. Women's recall in interviews related to article 5.1: No advertising or promotion to the general public

N = 808 Company		# Mentions	% Mentions
Danone	Television	0	0.0%
	Internet	0	0.0%
	Social Media	1	0.1%
	Health facility	0	0.0%
	Magazine	0	0.0%
	Shop/pharmacy	0	0.0%
	Billboard	0	0.0%
	Other	0	0.0%
	TOTAL	1	NA
Nestlé	Television	7	0.9%
	Internet	6	0.7%
	Social Media	4	0.5%
	Health facility	0	0.0%
	Magazine	1	0.1%
	Shop/pharmacy	3	0.4%
	Billboard	0	0.0%
	Other	0	0.0%
	TOTAL	21	NA
Don't remember	Television	22	2.7%
	Internet	2	0.2%
	Social Media	2	0.2%
	Health facility	1	0.1%
	Magazine	0	0.0%
	Shop/pharmacy	2	0.2%
	Billboard	0	0.0%
	Other	0	0.0%
	TOTAL	29	NA

Identification of advertising related to BMS products was also done directly by monitoring various media as described in the methodology section (Chapter 3).

Through both methods of active monitoring combined, no non-compliant advertisements were found. This is a very important result, and it is inconsistent with what we found in our studies in Vietnam and Indonesia. A number of India-based experts in this field had informed us in advance that enforcement of the IMS Act's prohibition of such advertising was very strong, and that very few possible instances of this type of non-compliance had been reported through other monitoring mechanisms. The Government appears to have had substantial success in limiting the promotion of BMS products for children less than 2 years of age.

Sub-article 5.2. 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

Of the 808 women who were interviewed, only one woman said that she had received free samples of any BMS product from a manufacturer since the pregnancy began or the baby was born. She could not remember the company name or product name.

Sub-article 5.3. For products within the scope of this Code, there should be no point-of-sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level

Data to assess compliance with this sub-article were collected by visiting retail outlets near each of the health facilities that participated in the study. A total of 120 retail outlets (generally 3 per health facility) were visited. These retailers were selected so as to maximize the possibility that they might sell enough BMS products to offer sales promotions. The types of retail outlets visited are shown in Table 2. No point-of-sale promotions were found in any of the stores. This is also an area where the strong enforcement of the IMS Act appears to have been very successful.

Although we identified no point-of-sale promotions in physical stores, we did detect an important phenomenon that has not been addressed by The Code, any subsequent WHA resolutions, or the India IMS Act. This is the availability of BMS products at promotional prices through online stores. BPNI recently published a report on this problem in India,[27] and we observed the same thing in our study. We accessed 12 online store websites once a week for 4 weeks, including those specified by BPNI, and we observed some point-of-sale promotions for BMS products on two prominent online retailers, www.Discountkart.com and www.Amazon.in (see Table 4 below). However, we could not determine whether these promotions were offered by the BMS companies or by the retailers themselves without manufacturer involvement. We could confirm that some suppliers/distributors are located in India but we were unable to determine whether all are located within or outside of India. We accessed these websites using an Indian IP address so that we would be able to see and order exactly what a person in India would be able to see and do. We noticed this problem of online point-of-sale promotions in Vietnam and Indonesia as well, but our internet monitoring plan did not

[27] BPNI: Breaking the Law and undermining Breastfeeding. Are e-marketing companies making profits at the cost of infant lives? Series 7 (2016).

include a systematic follow-up of these stores. This is a new issue that should be addressed by countries that have regulations prohibiting point-of-sale promotions.

Table 4. Point of sale promotions identified through online stores

Company	Online store/website		Total Promotions	Comments
	www.Amazon.in	www.Discountkart.com		
Danone	1	0	1	
Nestlé	0	7	7	■ Has point of sale promotions for Nestlé's products only ■ Has BMS products advertised at reduced price but upon clicking on every product, the information displayed says "Out of Stock" or "This product is currently out of stock"
Mead Johnson	1	0	1	■ Parallel import product
Abbott	4	0	4	
Total	6	7	13	

Note: No points of sale promotions were found for Heinz, Hain Celestial, Raptakos Bret and Amul.

Other online stores that were monitored, but had no promotions, included: angooor.com, bigbasket.com, hopscotch.in, redlily.com, infibeam.com, bigbazaar.com, firstcry.com, indiamart.com, tradeindia.com, quickr.com

Sub-article 5.4. Manufacturers and distributors should not distribute to pregnant women or mothers of infants and young children any gifts of articles or utensils which may promote the use of breast-milk substitutes or bottle-feeding

Of the 808 women interviewed, 4 (0.5%) reported receiving a gift from someone other than a family member or friend. None of the gifts was from a BMS manufacturer. Three of the four women reported receiving baby powder, cream, lotion, or diapers from manufacturers such as Johnson & Johnson, Mamy Poko, and Himalaya Himalaya. One woman reported receiving a gift from a shop, but she did not specify the gift.

Sub-article 5.5. Marketing personnel, in their business capacity, should not seek direct or indirect contact of any kind with pregnant women or with mothers of infants and young children

Non-compliance with this sub-article was based on a question in the women's interview about whether anyone had spoken with them about BMS products. For purposes of this analysis, both

company representatives and shops/pharmacies, acting as retail distributors of the products, were considered.

Of the 808 women interviewed, none reported having been spoken to by a company representative about BMS products. Three (0.4%) reported having such a conversation with a person at a shop or pharmacy, noting products Lactogen 1 and Nan Pro 1 by Nestlé.

Potentially bigger problems were seen with recommendations by health care workers. Thirty-three (33) women (4.1%) reported being spoken to by a health care worker about using formula, with 23 (2.8%) recommending a particular product. This is covered in more detail under Sub-Article 6.2 below. Unlike in Vietnam and Indonesia, very few women reported having been talked to by a family member or friend.

C. Article 6: Health Care Systems

Data were collected to allow assessment of compliance with the following sub-articles of Article 6.

Sub-article 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.

Possible non-compliance with the provisions this sub-article were identified through two sources: (1) women reporting that a health care worker had spoken to them about using BMS products; and (2) health care workers reporting that a company representative had visited the facility for the purpose of talking to women, obtaining contact information for women, providing materials for women, or distributing samples to women. The results related to possible non-compliance with this sub-article are presented in Tables 5a and 5b.

Overall, 33 (4.1%) of the 808 women reported being spoken to by a health professional about using BMS products, and 23 (69.7%) of those professionals reportedly recommended a specific product. The most frequently mentioned companies were Nestlé (16) and Abbott (4).

Table 5a. Women's recall in interviews of recommendations by health professional covered by sub-article 6.2: No facility of a healthcare system should be used for purposes of promoting products within scope of The Code

Type of representative		# of "Yes" responses	% "Yes" responses
N = 808			
Health Professional			
Total Mentioned by Women		33	4.1%
Recommended Product		23	2.8%
Brands Recommended*	Abbott	4	0.5%
	Nestlé	16	2.0%
	Raptakos Brett	2	0.2%
	Can't Remember	1	0.1%

* One woman mentioned two companies.

Table 5b. Healthcare workers recall in interview of company representative visits that may be covered by sub-article 6.2: No facility of a healthcare system should be used for purposes of promoting products within the scope of The Code

	Number	Percent
Number of Health Facilities	40	100%
Number with at least one health worker responding that company rep visited	14	35%
Number with at least one health worker responding that company rep visited to contact women	0	0%
Number with at least one health worker responding that company rep visited to distribute samples	0	0%
Companies most frequently mentioned (by 120 respondents)		
Abbott	11	9.2%
Nestlé	17	14.2%
Danone	2	1.7%
Mead Johnson	2	1.7%
Raptakos Brett	1	0.8%
Can't Remember	2	1.7%

From the interviews with health care workers, at least one worker at 14 of the 40 facilities (35.0%) reported that a company representative had visited the facility within the past 6 months. However none of them said that the visits were with the intent of talking to women, obtaining contact information for women, or providing materials for women. The most frequently mentioned companies were Nestlé (17) and Abbott (11). None of the representatives reportedly wanted to distribute samples.

Sub-article 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. Provision 8 (1) of the IMS Act. No person shall use any health care system for the display of placards or posters relating to, or for the distribution of, materials for the purpose of promoting the use or sale of infant milk substitutes or feeding bottles or infant foods.

This sub-article was addressed as part of the analysis of Sub-article 4.2, Informational and Educational Materials, where any placards and posters were also identified. As noted previously, 5 items of informational materials from BMS manufacturers were found on public display in 4 of the 40 health facilities, thus not complying with the IMS Act. Interviewers and supervisors were asked to observe any areas of the facility that were open to them, but they did not attempt to see closed areas, such as private offices or locked spaces.

Sub-article 6.8. 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.

We identified no instances of donations covered by this sub-article. Interviewers and supervisors were asked to observe any areas of the facility that were open to them, but they did not attempt to see closed areas, such as private offices or locked spaces.

D. Article 7: Health Workers

Data were collected to allow assessment of compliance with the following sub-articles of Article 7.

Sub-article 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 breast-feeding.

Possible non-compliance with this sub-article was partially addressed by the interviews with the health care workers. Twenty-one (21) workers from 14 of the 40 facilities stated that a company

representative had visited to give product information to health professionals, but the IGBM Protocol interview does not collect specific information on the content of these materials, so we could not fully evaluate this provision.

Sub-article 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. Provision 9.2 of the IMS Act. No contribution or pecuniary benefit to a health worker or any association of health workers, including funding of seminar, meeting, conferences, educational course, contest, fellowship, research work or sponsorship.

From the health care workers' interview responses, we did not detect the provision of any substantial gifts, such as clothing, money, paid attendance at a general conference or meeting, or paid attendance at a company-sponsored event. One (1) of the 120 workers interviewed mentioned a gift – snacks, provided by Nestlé, for a breastfeeding class. As with other items that a worker might consider inappropriate, it is possible that there could be some underreporting because of the interviewers' neutral probing approach.

Sub-article 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, and health workers should not give samples of infant formula to pregnant women, mothers of infants and young children, or members of their families.

None of the 120 healthcare workers who were interviewed mentioned receiving samples from a BMS manufacturer.

E. Article 9: Labelling

As specified in the IGBM Protocol, data were collected to allow assessment of compliance with the following sub-articles of Article 9.

Sub-article 9.2. Manufacturers and distributors of infant formula should ensure that each container has a clear, conspicuous, and easily readable and understandable message printed

on it, or on a label which cannot readily become separated from it, in an appropriate language, which includes all the points. Provision 6(1a) of the IMS Act also requires the statement "IMPORTANT NOTICE:" and "MOTHER'S MILK IS BEST FOR YOUR BABY" in capital letters in the central panel of all containers in letters no less than five millimeters and that several other statements must be included on labels. Provision 6 (2a, b) of the IMS Act also prohibits pictures of an infant or a woman or both, or pictures or other graphic material or phrases designed to increase the saleability of infant milk substitutes or infant food (See Supplemental Table A, Appendix L).

Overall, the labels (and inserts, if available) of 44 infant formulas, follow-on formulas, growing-up milks, or complementary foods intended for infants 0 – 6 months were analyzed. Compliance was very good apart from the seven parallel imports (i.e., intended by the companies to be sold in other markets but imported into India). Because these products were not intended for the Indian market they omitted the important notice about mother's milk being best, and various other wording such as: the product should only be used on health worker's advice; instructions for appropriate preparation and use; and warnings of the hazards of improper preparation and use.

In contrast with Vietnam and Indonesia, the products available for sale in India did not have any pictures that idealize use of formula. There were no pictures of humans but 4 of the 44 products had pictures of animals or other characters.

While no products bore any of the prohibited words or phrases considered to be designed to increase saleability, we noted other wording that is not prohibited but which could be construed to have this intention. Examples are shown in Table 6.

Table 6. Text or phrases that could be construed to be designed to increase "saleability"

Examples of phrases and text determined to be intended to increase saleability
Contains B. lactis. B. lactis is a probiotic culture that helps in increasing the number of bifidobacteria in gut flora of infants.
Delivers the right nutrients to support growth and development. Contains ingredients that support: Immune system, Digestive Health, Brain Development, Strong Bones.
Enfamil Stage 2 Infant Formula is scientifically formulated with precursors of DHA & ARA, Sialic Acid, Choline, Iron and all important vitamins and minerals, and an appropriate protein level to match the nutritional needs of the rapidly growing baby's mental and physical development. Insert has additional text such as "Unlock your child's amazing potential to learn" Smart 10 and goes on with describing the role of each of the Smart 10 key brain building nutrients.
A specialised Infant Milk Substitute containing a blend of Milk Fat and Vegetable Oils rich in ESSENTIAL FATTY ACIDS.

We have analyzed the data by number of products examined for each company so that we could calculate an average number of observations per product (see Table 7).

Sub-article 9.3. Food products within the scope of this Code, marketed for infant feeding, which do not meet all the requirements of an infant formula, but which can be modified to do so, should carry on the label a warning that the unmodified product should not be the sole source of nourishment of an infant.

The IGBM Protocol does contain an item that addresses this point, but the interpretation is not completely clear. Therefore, we are not reporting on this sub-article.

Sub-article 9.4 of The Code. The label of food products within the scope of this Code should also state all of the required information relating to ingredients used, composition analysis, storage conditions required, the batch number and date by which the product is to be consumed. Provision 6 (1h) of the IMS Act also requires the date of manufacture on all labels. (See Supplemental Table B, Appendix L)

This analysis addressed five requirements for labelling contained in The Code, as shown in Supplemental Table B and another item required included by the IMS Act: date of manufacture. Westat performed 100 % QC of Form 5 (label data).

All labels conformed to these requirements apart from one – Amulspray – which omitted storage instructions and one Mead Johnson parallel import that omitted the data of manufacture.

Table 7. Type and number of observations of non-compliance related to labelling, by company

Company	Number of products assessed	Total observations	Average number of observations per Product	Words "Important Notice" or equivalent	Statement that should be used only on advice of health worker	Instructions on appropriate preparation	Warning against hazards of inappropriate use	Age of Introduction	"MOTHERS MILK IS BEST FOR YOUR BABY" in capital letters	No pictures that idealize use of infant formula - human pictures	No pictures that idealize use of infant formula - other pictures	No text or phrases designed to increase saleability	Terms "humanized", "maternalized" or similar should not be used	Ingredients used	Composition/analysis of product	Storage conditions required	Batch number	Date of manufacture	Date before which it is to be consumed	Easily readable	Written in appropriate language
Danone	13	0	0.0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Nestlé	11	4	0.3	2	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0
Mead Johnson	5	8	1.6	2	1	0	0	0	2	0	2	0	0	0	0	0	0	1	0	0	0
Abbott	7	0	0.0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Heinz	2	11	5.5	2	2	2	2	0	2	0	1	0	0	0	0	0	0	0	0	0	0
Hain Celestial	1	5	5.0	1	1	1	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Raptakos Brett	4	0	0.0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Amul	1	3	3.0	0	0	0	0	1	0	0	1	0	0	0	0	1	0	0	0	0	0
Total	44	31	0.7	7	4	3	3	1	7	0	4	0	0	0	0	1	0	1	0	0	0
Percent				15.9%	9.0%	6.8%	6.8%	2.3%	15.9%	0.0%	9.0%	0.0%	0.0%	0.0%	0.0%	2.3%	0.0%	2.3%	0.0%	0.0%	0.0%

Conclusions and Recommendations 6

This report is based on a study carried out for ATNF on a pilot basis. It is one of several in recent years to follow the 2007 IGBM Protocol[28], and the third of three pilot studies for ATNF. While this pilot study did have some limitations (as discussed in Chapter 7), it does provide valuable population-based estimates of compliance with The Code, and it can serve as a model for similar studies in other countries or in other populations, such as non-urban populations. The methodology of the IGBM Protocol can serve as a valuable complement to other approaches to monitoring compliance with The Code, such as the surveillance approach employed by International Baby Food Action Network (IBFAN) globally and BPNI locally.

Conclusions About Compliance with The Code and National Regulations

Strength of Indian Enforcement of the IMS Act. Local experts informed us before initiating this pilot study that the Indian IMS Act was very strong and that it was effectively enforced by the Indian government. Our conclusion from our study findings is that this appears to be true based on our representatively-selected health facilities in Mumbai, but we do not know if this pertains to all of India. Likewise, if a sample based on health facilities does not fully represent all pregnant women and new mothers in Mumbai, then it is possible that practices in under-covered areas would not be detected. Public advertising of covered products appears to be virtually non-existent in Greater Mumbai. Likewise, we were not able to identify any point-of-sale promotions of covered products in any of the "brick and mortar" retail establishments that we visited. While some women mentioned seeing advertisements of BMS products, primarily on television, these were self-reports subject to the uncertain reliability of self-reports, as discussed in Chapter 7. There also appears to be very little printed informational or educational material distributed by manufacturers to clinics or shops, and there appears to be very little contact by company representatives with women or health care workers. Manufacturers' compliance with labelling requirements in The Code was very strong; nearly all of the instances of non-compliance related to parallel imports.

[28] The IGBM Protocol has been used to carry out assessments in Vietnam, Indonesia, Bangladesh, Botswana, Kenya, Poland, South Africa, Thailand, Uganda, and possibly other countries.

We think this is a credit to the relative strength of the IMS Act and to the seriousness with which it is enforced by the Indian government and the health care profession. The government could perhaps look at what more it could do to deter parallel imports.

New Source of Concern: Point-of-Sale Promotions. As noted above, the Indian government appears to have been very successful in eliminating point-of-sale promotions in traditional "brick and mortar" stores. However, we identified sales promotions by online stores as has BPNI. This is a source of sales that may be challenging for regulators to deal with, but an effort should be made to understand it and develop appropriate strategies to limit promotions. This is an area that requires further research and one in which the Indian government might be able to take further action to bring the activities of these online stores into line with the IMS Act.

Company Contact with Women. One source of contact that needs to be monitored more closely are features such as, "sign-ups" and "member registrations" on websites. These require the user to provide a username in order to access information and engage in club-type exchanges with other members. We signed up for several of these to determine if any advertising or promotions were appearing, but we did not identify any. However, it is a method for establishing brand awareness and perhaps encouraging the woman to think about using formula products as a substitute for breast-milk. While we documented very little personal contact of company representatives with pregnant women or mothers, one interesting observation was that a health care worker reported BMS company representatives provided snacks for a breastfeeding class at the health facility. This could be perhaps considered as the provision of a "gift" under the auspices of The Code and the Act.

A summary of observed non-compliance for the 8 producers of covered formula and complementary food products found in India is presented in the Executive Summary Table. Since the number of points of non-compliance varies by Sub-article and their relative importance may differ, this is presented for descriptive purposes only.

Executive summary table: Observations of non-compliance by article and source

Company	Number of formula and complementary food products in study	Total observations	Relevant Code sub-article			
			4.2 Facility/ store observation	5.1 Media monitoring	5.3 Store observation (including online stores)	9.2 and 9.4 Label analysis (total number of non-compliances on all labels)
Danone	13	1	0	0	1	0
Nestlé	11	13	2	0	7	4
Mead Johnson	5	9	0	0	1	8
Abbott	7	3	3	0	4	0
Heinz	2	11	0	0	0	11
Hain Celestial	1	5	0	0	0	5
Raptakos Brett	4	0	0	0	0	0
Amul	1	3	0	0	0	3
Total	44	45	5	0	13	31

Conclusions about The Code and The IGBM Protocol

As noted earlier, this is the third ATNF pilot study on which we have reported, using the same IGBM Protocol for each. Most of our conclusions about The Code itself and the IGBM Protocol are the same as we described in our reports for Vietnam and for Indonesia. Therefore, we will not repeat the detailed conclusions, but refer the reader to the previous reports instead. A listing of the issues that should be addressed is provided below.

Definitions of Non-Compliance. The Code includes a complex set of recommendations, some of which can be challenging to interpret or measure.

The IGBM Protocol is Good but in Need of Updating. The IGBM Protocol was selected by ATNF to assess compliance by BMS manufacturers with the recommendations of The Code because this Protocol is seen as the best existing rigorous research-oriented approach to conduct such an assessment.

With its six sources of data collection, the IGBM Protocol addresses a great number of the sub-articles of Articles 4, 5, 6, 7, and 9 of The Code.

A notable modern change is the need to check for advertisements for covered products appearing on the internet, on Facebook, Twitter, and YouTube. These sources were not a focus of the IGBM Protocol, which was last updated in 2007.

Also, the Protocol does not capture information on some requirements that were issued around the time of its last update or later.

Recommendations

For Companies with Respect to Product Marketing. BMS manufacturers should work to strengthen corporate policies related to practices that are inconsistent with the intent of The Code and the IMS Act. This includes exerting pressure, where possible, on online stores not to discount or promote the covered products, or finding a way to restrict availability of the covered products for sale by the online stores. Also, the use of sign-up portals that allow women to essentially join a "club" on the BMS website is a practice that might be considered direct marketing to the women. The companies that run such sites should be made aware of their responsibilities under the IMS Act.

For WHO and the National and State Governments. Future efforts to promote BMS manufacturers' compliance with The Code should focus in particular on online sales and use of social media to have direct contact with women. These media have changed the face of advertising and promotion, and they also have global reach, since they can be accessed by women from many different countries, not just those in a single country. This is a problem that may be very difficult to control. Specific to India, we believe that the national and state governments of India with the support of the authorized organizations[29] have been highly successful in enforcing the IMS Act in most areas. However, there are a few areas where the government may wish to devote additional efforts. One is the IMS Act's restriction on informational and educational materials. Another area that should receive more attention is the same as we recommended for manufacturers; i.e., control of the sales promotions by online stores. This might be addressed by restricting the authority of these sellers to sell such products to persons in India, or perhaps by prohibiting the parallel importation of the covered products to anyone other than an authorized distributor of the company.

[29] http://wcd.nic.in/fnb/fnbweb.pdf

Strengthen Definitions of Terms. We identified no new recommendations under this topic from the India pilot study, but general recommendations from our previous studies can be found in the above-referenced reports from Vietnam and Indonesia.

7 Limitations of the Pilot Study

As has been noted several times previously, this pilot study followed the IGBM Protocol and data collection forms. The IGBM Protocol does a very good job of addressing nearly all of the sub-articles in The Code that apply to manufacturers. Nonetheless, there are limitations to the study and how the results from it should be interpreted and acted on by users.

A. Recall Bias

The most significant limitation of the study is that much of the information needed to assess compliance comes from interviews with women and with health care workers. In any interview situation, self-reported events or information can be misreported because of incorrect recall, misunderstanding, reluctance to provide complete information, or a perception of what the respondent thinks the desired response should be. When a period of recall is involved, as was the case with both the women and the health care workers, there can also be recall bias that may involve telescoping a remembered event into the recall period, even though it occurred outside of it, or of microscoping an event outside of the recall period when it actually occurred inside of it. We believe that the questions we asked were clear and objectively written, with no suggestion about what answer was desired. The interviewers were also carefully trained not to use leading probes and not to assume an answer if the respondent did not give it completely. Recall bias and incorrect memory are potential cautions when interpreting the data. Where the interviews identify only a very small number of possible incidents of non-compliance, the information should be used very cautiously, since they could be recall errors. On the other hand, when many episodes are reported, one should generally be confident in accepting that a substantial amount of non-compliance did occur even if there are some recall errors. The exact percentage estimate is less important that the obvious magnitude of the problem. In India, most questionnaire items had a relatively low number of positive responses from women, but some did have more than 10 positive responses.

B. Selection of Female Respondents Within Facilities

Our initial sampling plan called for a relatively complex systematic random sampling of women based on an estimate of the expected number of eligible women who would attend the facility over a two-day period. In practice, we were not able to fully implement this plan due to there being fewer women than needed to use this approach to sampling. Therefore, in these cases, the interview teams conducted interviews on a consecutive basis until 20 were completed within the clinic. There is some possibility that this introduced some bias in the representativeness of the sample, if different types of women showed up at different times of day or different days of the week. However, given the small number of positive reports by the women, we believe that this sampling approach is unlikely to have fundamentally altered our results.

C. Selection of Healthcare Workers

A third limitation of the study is that while healthcare workers were randomly selected within each health facility, they might not be the best workers to interview with respect to facility-related issues. We attempted to improve on the variability of respondents by essentially employing a "stratified random" approach so that we could interview one doctor, one nurse, and other type of health care worker. The health care worker interview has one section that is directly related to the worker; the other sections are facility-level questions. For these questions, the most knowledgeable respondents might be the facility manager and the facility financial manager. The study's approach might have resulted in under-reporting of certain items, such as equipment donation and visits by sales representatives.

D. Selection of Retail Outlets

A fourth limitation is related to the selection of retail outlets to observe point-of-sale promotions. This selection was purposive, not representative. The objective was to select stores that were judged most likely to have such promotions so that promotions could be documented if they were occurring. Because of the convenience selection methodology, our results cannot be extrapolated to the universe of stores in Mumbai. Further, each store was visited on only one day, so it is possible that some stores would have had promotions if they had been visited over a period of time.

E. Population of Women Studied

Because the sample was limited to mothers with children only up to 6 months old, the Protocol also does not address the promotion of breastfeeding up to 24 months of age for the children, and consequently may underestimate promotion of BMS products for older children.

F. Other Limitations

Other limitations include the lack of precise definitions for some of the items that needed to be assessed and the lack of sufficient data collection to address a few areas. A number of situations were noted as "gray areas," where it was not clear if something should be considered non-compliance. In such situations we have been cautious about over-interpreting the information.

This pilot study was a one-time cross-sectional survey that provides reasonable prevalence estimates for the point in time that it was conducted. There is currently no ability to monitor changes over time, or to provide continuous surveillance, such as is done by BPNI and the Indian government. Follow-up studies in the same geographic area could make the results from this pilot study a valuable baseline to measure improvements or declines over time in compliance.

The focus of the IGBM Protocol is on BMS manufacturers' compliance with The Code and local regulations. It does not address whether the women chose to use a BMS product at some point, nor does it attempt to estimate what proportion of the women claimed to be exclusively breastfeeding.

Finally, our study findings are based on a representatively-selected sample of health facilities in urban Mumbai. The results should be representative for this city, but they should not be interpreted to apply to all of India, and it is also possible that the results could vary if a different sample of facilities were drawn, as is the case for any sample drawn from a larger population. More importantly, if a sample based on health facilities does not fully represent all pregnant women and new mothers in Mumbai, then it is possible that different results might be found if the study were to use a different frame for sampling, such as a household-based sample. We believe that promotion of BMS products is likely to be highest in an urban area such as Mumbai because of the high density of the population and the ease of reaching women, but we have no evidence from other urban areas or rural areas of India to confirm this belief. In fact, given what appears to be very strong enforcement of the IMS Act, it may be possible that non-compliance could be higher in rural areas because enforcement resources might be more limited. These study results should be interpreted as applying only to urban Mumbai.

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