

# 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.<sup>1</sup> 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).<sup>2</sup>

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

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<sup>1</sup> [http://www.who.int/nutrition/topics/WHO\\_brief\\_fufandcode\\_post\\_17July.pdf](http://www.who.int/nutrition/topics/WHO_brief_fufandcode_post_17July.pdf).

<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup> 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

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<sup>3</sup> <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.

<sup>4</sup> 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.<sup>5</sup> 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

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<sup>5</sup> 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
<b>Total</b>	<b>44</b>	<b>45</b>	<b>5</b>	<b>0</b>	<b>13</b>	<b>31</b>

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.<sup>6</sup>

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.

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<sup>6</sup> <http://www.bpni.org/IMS-ACT/BTL-7-24022016-low-res.pdf> and <http://www.bpni.org/IMS-ACT/BTL-6.pdf>