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# Marketing of breast-milk substitutes in Zambia: evaluation of compliance to the international regulatory code

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## ABSTRACT

**Background** We sought to assess the level of non-compliance with the International Code of Marketing breast-milk substitutes (BMS) and/or Statutory Instrument (SI) Number 48 of 2006 of the Laws of Zambia in two suburbs, Kalingalinga and Chelstone, in Zambia.

**Methods** This was a cross sectional survey. Shop owners (80), health workers (8) and mothers (214) were interviewed. BMS labels and advertisements (62) were observed. The primary outcome was mean non-compliance defined as the number of article violations divided by the total 'obtainable' violations. The score ranges from 0 to 1 with 0 representing no violations in all the articles and one representing violations in all the articles.

**Results** A total of 62 BMS were assessed. The mean non-compliance score by manufacturers in terms of violations in labelling of BMS was 0.33 (SD = 0.28; 95% CI: 0.26, 0.40). These violations were mainly due to labels containing pictures or graphics representing an infant. 80 shops were also assessed with mean non-compliance score in respect of violations in tie-in-sales, special display, and contact with mothers at the shop estimated as 0.14 (SD = 0.14; 95% CI: 0.11, 0.18).

**Conclusions** Non-compliance with the Code and/or the local SI is high after 10 years of domesticating the Code.

**Keyword** public health

## Introduction

World Health Organization (WHO) estimates that more than one million babies could be prevented from dying each year by breastfeeding.[1] Breastfeeding is protective particularly from otitis media, gastroenteritis and respiratory tract infections in children as well as from type two diabetes, breast and ovarian cancers in mothers.[2] The WHO Code of marketing breast-milk substitutes (BMS) was adopted following the reports on the general decline in the prevalence of breastfeeding in many parts of the world.[3] The Code is a global public health policy frame work which restricts the marketing of BMS and encourages proper use through informed choice.[4] Since 1981, many countries have enacted legislation implementing the provisions of the code and relevant World Health Assembly resolutions. In Zambia, the code is enacted as Statutory Instrument (SI) no. 48 of 2006 in the Food and Drug Act.[5] Manufacturers and distributors are obliged to comply with the code articles and/or regulations of the local SI.

Manufacturers who do not comply from elsewhere have been reported to advertise BMS in the electronic and print

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media.[6–8] They also engage in labelling of BMS with statements and visuals to entice mothers.[9,10] In addition, they offer gifts and samples to mothers and health workers.[9–11] Mothers have been offered 'tie-in sales' (i.e. buy two, get one free) and gifts with purchase.[9,11] Gifts to health workers include formula, pens, note pads, obstetric stethoscopes, leaflets, calendars as well as sponsorship for training.[9,11,12] Distributors have been reported to engage in special displays and promoting BMS to mothers.[10,11]

Non-compliance with the Code and/or SI no. 48 could arguably lead to uncontrolled use of BMS, and reductions in the prevalence of breastfeeding that results in mass growth faltering and ultimately increased morbidity and mortality in infants and young children.[13,14] This is so because it discourages good dietary habits in young children.[15] Feeding bottles and water used may be a source of infections.[16,17] Many mothers who give BMS, also face difficulties to afford appropriate and adequate supplies for the period the baby will need the feed.[18]

While the law has been adopted in Zambia for 10 years now, there is lack of evidence on compliance with the international code or indeed the domesticated local SI. We set out to assess the level of non-compliance with the international code and SI no. 48 of 2006 of the Laws of Zambia by manufacturers and distributors. We did this assessment through cross sectional surveys in Kalingalinga and Chelstone suburbs in Lusaka, Zambia.

## Methodology

### Study design

This was a cross sectional survey conducted between August 2016 and November 2016.

### Setting and population

The study was conducted in Lusaka, the capital city of Zambia. Lusaka was convenient as an urban district where more people are likely to use BMS than in rural communities.[8,11] Two study areas within the city of Lusaka were selected: Kalingalinga, a medium density suburb and Chelstone, a low density area with similar incomes as they closely reflect the urban living standards of most Zambians. Targeted study participants were shop owners who sell BMS brands, health care staff and mothers of infants aged below one year.

### Sample size consideration

We assumed that the mean non-compliance score by manufacturers in terms of violations in labeling BMS was 0.50 (SD = 0.30). We therefore required a total of 74 BMS samples to detect a 40% reduction at an 80% power using Satterthwaite's $t$ test assuming unequal variances. This was performed using Stata MP 14 (StataCorp, College Station, TX, USA).

### Sampling

Shop owners were selected systematically, by picking every fifth shop in consecutive order. Within each shop we randomly selected BMS for assessment of violations in labeling. These shops were also assessed for violations in terms of; low price sales, special displays and contact with mothers. Four health care workers out of 140 (3%) from Kalingalinga and four out of 154 (3%) from Chelstone were conveniently recruited. Only health care workers available on the day of the interview were considered. A total of 214 mothers of infants (<1year) were conveniently recruited and interviewed as they came for children's under five clinic (Table 2). The recruited mothers represent 3% (107/3285) from Kalingalinga, and 2% (107/4549) from Chelstone.

### Data collection

Six people from each site were trained to collect data using Standard International Baby Food Action Network Monitoring (IBFAN-SIM) forms within a total of 10 days. SIM forms are designed to capture data on violations of articles of the Code and/or local SI[4,8] (Table 1). Articles of interest were around advertising, labeling, and sales strategy. Samples of labels that violate the code are captured in Fig. 1.

Background of enumerators (data collectors) included Nutritionist,[2] Environmental Health Technologists (EHT),[3] Nurses and Community Health Worker (CHW).[1] Except for the CHW, the other enumerators had tertiary education. Pretest of the questionnaire was conducted in the pilot townships prior to start of the study. This was done in Mtendere and Chipata townships, which have similar contexts with the study areas. The tools were revised following the pretest.

### Data analysis

The primary outcome was mean non-compliance score defined as the number of article violations divided by the total 'obtainable' violations assessed by each source of data (Table 1). For example, Article number 4 in Table 1 has four obtainable violations. Therefore, if a manufacturer violated one then non-compliance score in respect of breast milk substitute would be 0.25 (i.e. 1/4). The score ranges from 0 to 1 with 0 representing no violations in all the articles and one representing violations in all the articles. Non-compliance by manufacturers was assessed through mothers,

**Table 1** Provisions of the International Code and/or SI no. 48 of 2006 of the Laws of Zambia on marketing breast-milk substitutes included in this study

| *No.* | *Articles* | *Category* | *Source of data* |
|---|---|---|---|
| 1 | No advertising of breast-milk substitutes to families | Manufacturers | Mothers |
| 2 | No gifts to mothers and health workers | Manufacturers | Mothers/health workers |
| 3 | No free samples to mothers and health workers | Manufacturers | Mothers/health workers |
| 4 | No labels violating the Code in the following ways: | | |
| | Containing words or pictures idealizing artificial feeding | Manufacturers | BMS |
| | Containing pictures or graphics representing an infant | Manufacturers | BMS |
| | Indicate use of feeding bottle | Manufacturers | BMS |
| | Not explaining the benefits of breastfeeding and costs and hazards associated with artificial feeding | Manufacturers | BMS |
| 5 | No contact between marketing personnel and mothers at the shop | Manufacturers | Shops |
| 6 | No price reduction (tie-in-sales) | Distributors | Shops |
| 7 | No special displays | Distributors | Shops |
| 8 | Shop owners advertising to mothers | Distributors | Shops |


**Fig. 1** Examples of labeling that violates the Code.

health care workers and breast-milk substitutes whereas non-compliance by distributors was assessed through observations at the shops (Table 1). To examine individual article violations we presented bar graph with error bars for each source of data. Analysis was performed using Stata MP 14 (StataCorp, College Station, TX, USA).

### Ethics statement

The Excellence of Research Ethics and Science converge Institutional Research Board reviewed and approved the study (ref. No. 2015-June-028). Permission was also obtained from the Lusaka District Health Office to conduct the research and pretest in the study sites. Written informed consent was obtained from all participants.

## Results

### Respondents

Shops in Kalingalinga included 38 retail outlets, one wholesale and one pharmacy (Table 2). In Chelstone shops included 39 retail outlets and one wholesale. A total number of 31 BMS labels were included in observations in each site (Table 2). These were three milk cereals, 13 brands of formula and 15 other BMS labels (teats, teethers and feeding bottles). Eight health workers were included in the study across professions such as nurses and clinical officers. In Kalingalinga an EHT was also recruited while in Chelstone a Nutritionist was recruited. A total of 214 mothers of infants (<1year) were recruited from each site. The general characteristics of study population between Kalingalinga and Chelstone were not significantly different $P > 0.05$ as summarized in Table 2.

### Non-compliance by manufacturers and distributors

The mean non-compliance score by manufacturers in terms of advertising, free gifts and free samples to mothers and health workers was 0.08 (95% CI: 0.06, 0.10) (Table 3). Regarding violations by manufacturers in labelling, the mean non-compliance score was 0.33 (95% CI: 0.26, 0.40). Violations by manufacturers were mainly due to labels containing pictures or graphics representing an infant (Fig. 2). For distributors, the mean non-compliance score in respect of violations in price reduction, special display and contact with mothers at the shop was 0.14 (95% CI: 0.11, 0.18) (Table 3).

## Discussion

### Main findings of this study

We found that non-compliance with the Code and/or SI no 48 of 2006 of the Laws of Zambia by manufacturers and distributors was prevalent. This is despite the efforts to control unethical marketing strategies through the implementation of the Infant and Young Child Feeding (IYCF) programme and enforcement of the Law.

Of note, manufacturers' labels with visuals violating the Code and/or SI no. 48 included graphs representing infant

**Table 2** Characteristics of study population

| *Characteristics* | *Kalingalinga** | | *Chelstone** | |
|---|---|---|---|---|
| | n | % | n | % |
| Manufacturers' BMS | 31 | 100.00 | 31 | 100.00 |
| Milk cereals | 3 | 9.68 | 3 | 9.68 |
| Formula | 13 | 41.94 | 13 | 41.94 |
| Other[a] | 15 | 48.39 | 15 | 48.39 |
| Distributors | 40 | 100.00 | 40 | 100.00 |
| Retail outlets | 38 | 95.00 | 39 | 98.00 |
| Pharmacies | 1 | 2.50 | 0 | 0.00 |
| Whole sales | 1 | 2.50 | 1 | 2.50 |
| Health workers | 4 | 100.00 | 4 | 100.00 |
| General nurse/midwife | 2 | 50.00 | 2 | 50.00 |
| Clinical officer | 1 | 25.00 | 1 | 25.00 |
| EHT/nutritionist | 1 | 25.00 | 1 | 25.00 |
| Mothers of children below 1 year | 107 | 100.00 | 107 | 100.00 |
| Introduced children on BMS < 6 months | 31 | 28.97 | 35 | 32.71 |
| Milk cereal | 6 | 5.61 | 12 | 11.21 |
| Formula | 17 | 15.89 | 16 | 14.95 |
| Other[b] | 9 | 8.41 | 12 | 11.21 |
| Introduced children on BMS > 6 months | 76 | 71.03 | 72 | 67.29 |

*Pearson's $\chi^2$ $P > 0.05$.

[a]Teats, teethers and feeding bottles.

[b]Maize porridge, nshima, supa maheu, fresh/sour milk.

**Table 3** Mean non-compliance scores, articles of violation by suburb

| *Articles of violation* | | *Kalingalinga* | *Chelstone* | *Total* |
|---|---|---|---|---|
| Advertising, gifts and free samples to mothers | Number of mothers/health workers | 111 | 111 | 222 |
| | Mean score | 0.06 | 0.1 | 0.08 |
| | SD | 0.13 | 0.15 | 0.14 |
| | 95% CI | [0.04, 0.09] | [0.07, 0.13] | [0.06, 0.10] |
| Labelling (feeding bottle, photo of infant, | Number of manufacturers breast milk samples | 31 | 31 | 62 |
| idealizing feeding, missing breastfeeding explanation) | Mean score | 0.35 | 0.31 | 0.33 |
| | SD | 0.28 | 0.29 | 0.28 |
| | 95% CI | [0.25, 0.45] | [0.20, 0.41] | [0.26, 0.40] |
| Promotions (price reduction, special displays, | Number of distributors | 40 | 40 | 80 |
| contact with mothers at shop) | Mean score | 0.14 | 0.15 | 0.14 |
| | SD | 0.18 | 0.16 | 0.17 |
| | 95% CI | [0.08, 0.19] | [0.10, 0.20] | [0.11, 0.18] |

wellbeing and text idealizing use of the product. These inadvertently attract mothers to buy the BMS, and can be construed as encouraging artificial feeding; especially among mothers not so well educated. Distributors were also found to employ special displays of unsuitable products close to reputable brands of BMS. These include other types of milk and cereal products. This gives an impression that the products could also be used for infant feeding. It also reduces opportunities for receiving relevant information that may support mothers' feeding and child care practices.[19] Generally, setting BMS apart was common and particularly so at outlets that were closer to health facilities; this practice

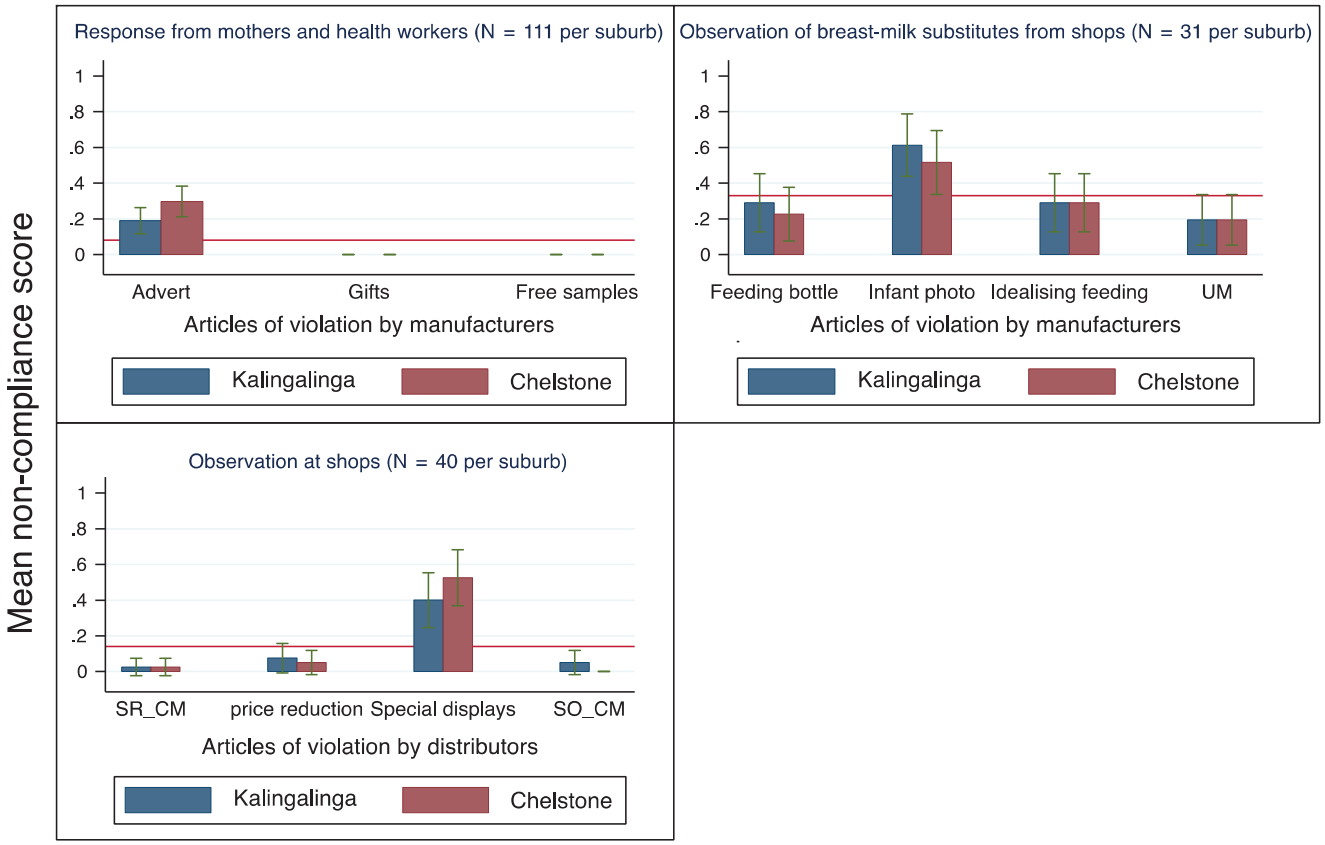


**Fig. 2** Mean non-compliance by article violations.

abrogates the stipulations of the Code as it can be seen as enticing mothers to buy.

## What is already known

Similar findings elsewhere have shown that manufacturers and distributors who do not comply engage in labelling BMS with visuals and text that violate the Code as well as special displays.[11] Contrary to our findings, in the Philippines and China advertising on TV and radio were significant.[7,11] Additionally, health workers who were aware of the Law in Pakistan have been reported to be more likely to receive gifts and free samples.[12] In this study advertising was not significant and we hardly found any practices that undermine breastfeeding at health facility level similar to findings in Ghana.[20] While many manufacturers will generally point to the value of breastfeeding, albeit in small print and less catchy, we found it hard to explain why the breastfeeding messages were reportedly missing on the labels in Lao and Turkey.[11,21] Perhaps there may be a lack of local law enactment of or complete failure to enforce the international code.

## What this study adds

To the best of our understanding, this is the first evaluation on compliance to laws governing ethical advertising for BMS in Zambia. We also could not find much on this subject from countries of similar settings as Zambia, therefore our report may be broadly applicable within the Sub-Saharan Africa region.

Foremost, we here report that the international code and indeed SI no. 48 of the laws of Zambia is presently not well adhered to by both manufacturers and distributors of BMS. While there are justifiable situations when these supplements can be beneficial, the broad message of exclusive breastfeeding for newborns which is national policy, is negatively impacted by these non-compliant commercial practices. It is

known that bottle feeding mixed with breastfeeding, affects the mother's ability to provide constant breast-milk supply. Insufficient breast-milk is often cited as the reason for sudden early weaning and sucking problems.[22] In addition, bottle feeding is known to increases the risk of dying from diarrhoea and respiratory tract infections in children;[23] possibly due to contamination and over dilution of the infant formula feed.[24] A safer alternative is use of a cup which is easier to clean and reduces the risk of infections associated with artificial feeding; but this is difficult in practice as feeding bottles offer a closer resemblance to the breast with the possibility of sucking.[25]

### Limitations

Our study sampled only two urban settlements of Lusaka. While this is not representative of the entire country, we believe our findings are nationally relevant as the manufacturers and distributors are similar across the country. Promotion strategies for foods also tend to vary depending on the targeting communities, and so our reports may be more applicable to the low-middle income urban settings of Zambia. Nonetheless, we believe that these are the settings which bear the bulk of the population in Zambia and across Africa, and therefore similar settings to these represent the bulk of the urban African population among whom best feeding practices would have a large public health impact.

Further comprehensive studies are required to review the levels of compliance in the more rural and high-income urban settings. Further formative research is required to streamline conditions under which BMS may be appropriate and to find better ways of promotion that do not infringe upon currently recommended feeding practices; particularly exclusive breastfeeding for the first 6 months of life.

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