



Nestlé S.A.

**Independent Assurance of Compliance with the Nestlé
Policy and Instructions for Implementation of the WHO
International Code of Marketing of Breastmilk Substitutes
in Kenya (May 2014)**



Move Forward with Confidence



Independent Assurance Statement by Bureau Veritas

Introduction

Bureau Veritas has been commissioned by Nestlé S.A. to provide independent verification of Nestlé Infant Nutrition and Wyeth Infant Nutrition businesses in Kenya (herein referred jointly as “Nestlé Nutrition Kenya”) on compliance with the Nestlé Policy and Instructions for Implementation of the WHO International Code of Marketing of Breast-milk Substitutes (herein referred to as “Nestlé Policy and Instructions”) and The Breast Milk Substitute (Regulation and Control) Act 2012 (herein referred to as “Kenya Code”). This follows similar work previously conducted by Bureau Veritas for Nestlé S.A. in other global operations.

Scope of Work and Methodology

The assurance was conducted in Kenya between 23 April and 6 May 2014 by two assessors from Bureau Veritas UK, supported by one assessor from Bureau Veritas Kenya. The team has extensive experience of undertaking WHO Code compliance related work.

Preceding the assurance activities in Kenya, Bureau Veritas conducted the following activities:

- completed a gap analysis of the Nestlé Policy and Instructions and Kenya Code to consider where the scope of Kenya Code differed from the Nestlé Policy and Instructions;
- requested a list of Nestlé Nutrition Kenya employees with responsibilities for the marketing and sale of infant nutrition products in Kenya and details of local healthcare facilities, healthcare professionals, and business partners in the country;
- identified other external stakeholders and local NGOs concerned with the protection, promotion and support of breastfeeding in Kenya; and
- independently determined a schedule of external stakeholder interviews and visual assessments to take place in Kenya during the audit.

During the assurance Bureau Veritas:

- selected 17 Nestlé Nutrition Kenya employees for interview and review of their associated records, as part of its evaluation of Nestlé Nutrition Kenya’s internal processes for managing compliance with the Nestlé Policy and Instructions and the Kenya Code;
- undertook interviews with 28 key external stakeholders including Government, business partners and healthcare professionals. In all meetings with Government and health care professionals, Nestlé was not disclosed as the client prior to the interview in order to avoid bias during interviews, neither was Nestlé Nutrition Kenya informed of who would be interviewed;
- selected and visited 16 healthcare facilities and 23 retail locations to visually assess compliance with the Nestlé Policy and Instructions and the Kenya Code, with particular reference to articles relating to the promotion of designated products and interactions with the general public and the healthcare system.



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Where non-compliance has been identified with the Nestlé Policy and Instructions, the Kenya Code or the local Nestlé Policy and Procedures Manual, these have been categorized as:

Major Nonconformity:

- A frequent or purposeful failure to follow specified requirement written within the Nestlé Policy and Instructions, the local Code or local Nestlé Policy and Procedures Manuals
- A failure to achieve legal or statutory requirements
- Multiple minor nonconformities within the same requirement of the Nestlé Policy and Instructions, the local Code or the local Nestlé Policy and Procedures Manuals
- A purposeful failure of the company to correct nonconformities

Minor Nonconformity:

- Any failure to satisfy a written requirement that is not considered to be a major nonconformity, such as an isolated issue.

Opportunity for Improvement:

- A process/activity/document that, while currently conforming, could be improved to bring benefits to Nestlé Nutrition Kenya.

The following is a summary of key findings from interviews, observations and document reviews undertaken with a range of key stakeholders.

Nestlé Nutrition Kenya

One non-conformity with the Nestlé Policy and Instructions was identified during the audit.

All product presentations developed by Nestlé Nutrition Kenya for use during group healthcare professional meetings, begin with an important notice about the WHO recommendation for exclusive breastfeeding for the first 6 months and for continued breastfeeding as long as possible. This is followed by a slide about Nestlé's commitment to the WHO Code and the benefits of breastfeeding. Whilst the presentations contain information about the benefits of breastfeeding, they do not fully meet the requirements of Article 7.2 of the Nestle Policy and Instructions which requires that any information provided by manufacturers to healthcare professionals on products which are within scope, is to include information specified in Article 4.2 of the Nestlé Policy and Instructions. Specifically the current presentation materials do not contain the information mandated by sub-articles (b), (c), (d) and (e) of Article 4.2. This represents a major non-conformance with the Nestlé Policy and Instructions, due to the systemic nature of the finding.



During the audit, Bureau Veritas raised another two non-conformities concerning the application of the local WHO Code Management System procedures; however, these do not constitute a non-conformance with the Nestlé Policy and Instructions:

- A review of the product label development and approval process highlighted a number of deficiencies in terms of maintaining adequate documentation in support of the approval process. These observations represent a major non-conformance with the procedure for labelling (PROC14), due to the systemic nature of the findings.

- The absence of completed code violation monitoring forms at the head office highlighting the presence of a UK infant formula product with a non-compliant label in the market place imported in parallel by third-parties into Kenya, represents a minor non-compliance with Nestlé's internal procedure for dealing with code violations in the trade (PROC12).

Business Partners of Nestlé Nutrition Kenya

Bureau Veritas interviewed one distribution partner of Wyeth Infant Nutrition Kenya. The representatives of the distributor demonstrated sound knowledge of the Nestlé Policy and Instructions and the Kenya Code and an understanding of the requirements according to their business activities. The distribution partner is considered to be operating in line with the requirements of the Nestlé Policy and Instructions and the Kenya Code and no incidences of non-compliance were identified.

Bureau Veritas was not able to meet with any representatives of Nestlé Infant Nutrition Kenya's distribution partner during the audit due to time constraints experienced during the audit.

Government

Bureau Veritas met with two representatives of one governmental organisation. One representative was of the opinion that Nestlé Nutrition Kenya is doing its best to comply with the Kenya Code. The interactions between the government organisation & Nestlé Nutrition Kenya have always been centred on the principle that breastmilk is best for infants and that in special cases breastmilk substitutes are necessary.

No marketing material violations have been witnessed by the representatives who the audit team interviewed. Nestlé Nutrition Kenya has provided support to the Government organisation to create a nutrition guidance document and host a scientific meeting for Nutritionists to discuss scientific data. It was communicated that Nestlé representatives were not present at the meeting and there was no promotion of Nestlé products in either case. The provision of support was free of any condition to promote, use or prescribe Nestlé's products.

Multilateral organisations/NGOs

Bureau Veritas was not able to meet with any representatives or multilateral organisations or NGOs during the audit.



Healthcare facilities and professionals

Bureau Veritas visited 16 healthcare facilities in Kisumu, Kakamega and Vihiga and interviewed 23 healthcare professionals. The following general observations were made concerning Nestlé Nutrition Kenya's interaction with the healthcare system:

- All healthcare professionals interviewed noted that representatives of Nestlé Nutrition Kenya promote the benefits of breastfeeding, and do not promote infant formulas over breastmilk
- There were no promotional materials concerning Nestlé Nutrition Kenya products covered by the scope of the Nestlé Policy and Instructions and the Kenya Code on display in the healthcare facilities visited
- No samples of Nestlé Nutrition Kenya products covered by the scope of the Nestlé Policy and Instructions and the Kenya Code were observed on display in the healthcare facility
- There were no allegations of Nestlé Nutrition Kenya having direct contact with mothers.

There were allegations made by 4 out of the 23 interviewed healthcare professionals relating to the provision of infant formula samples:

- One healthcare professional indicated that tins of infant formula were given free of charge during a continual medical education event, the purpose of which was to make the healthcare professional's aware of the packaging, label, brand and content of the product. The healthcare professional indicated that a sample would be provided with each talk provided by Nestlé Nutrition Kenya. The last such visit was 6 months prior to the audit.
- One healthcare professional indicated that samples were provided by Nestlé some time ago; however, no further information could be provided concerning the purpose, date and number of samples.
- One healthcare professional indicated that samples (1-2 tins) were given out for demonstration purposes during a continual medical education event.
- One healthcare professional indicated that Nestlé visited approximately 2-10 years ago but could not be sure and indicated that Nestlé may have offered a one or two samples of infant formula.

Bureau Veritas reviewed evidence at Nestlé Nutrition Kenya head office to determine if the allegations made by healthcare professionals could be substantiated. This included the marketing budget and expenditure for the business, the material transfer forms to verify what materials have been distributed to the Medical team, and the free goods records. No objective evidence was found in support of the healthcare professional's claims.

During the interviews with the healthcare professionals, a drop card related to a Wyeth Infant Nutrition product which is covered by the scope of the Nestlé Policy and Instructions was observed in one healthcare facility without the necessary breastfeeding disclaimer as mandated by Articles 4.2 and 7.2 of the Nestlé Policy and Instructions. However, it was found that this was an old discontinued material used in 2011, prior to the acquisition of the Wyeth Infant Nutrition business by Nestlé.



Retail

Wyeth Infant Nutrition formula products with labels containing imagery of the Wyeth Infant Nutrition lion mascot dressed in infant clothing, portraying development milestones of an infant below 12 months were found thus not in conformance with Article 9.2 of the Nestlé Policy and Instructions which requires that *'Neither the container nor the label should have pictures of infants, nor should they have other pictures or text which may idealise the use of infant formula'*. However, Nestlé Nutrition Kenya communicated that these were old versions of the labels and that Nestlé has voluntarily amended the lion mascot stylised graphic on stage 1 and 2 labels following Wyeth's acquisition. The amendment was made to adjust the illustrations to images of the mascot portraying development milestones of children older than 12 months. Nestlé Nutrition Kenya provided a copy of the transition plan which indicated that the new labels will be available in the market by August 2014.

Bureau Veritas also observed on sale in Kenya, Wyeth Infant Nutrition formula products with labels containing imagery which is not compliant with Nestle Policy and Instructions such as images of a mother and an infant. Such products are imported from a lower-risk country (UK) through informal channels by third parties without Nestlé Nutrition Kenya involvement (parallel import). The key challenge is that the influence on retailers with no direct commercial relation with Nestlé Nutrition Kenya is limited due the obligation of complying with antitrust and commercial legislation. When legally permitted, a direct contact with the retailer or the dispatch of a letter to remind the retailer on the practices for commercialization of breast-milk substitutes will configure the only mechanisms to address these instances of non-compliance. Nestlé Nutrition Kenya has already informed the Kenyan authorities on this issue.

Point of sale materials branded with a complementary food product (a product designated by the Kenya Code) was observed as part of the shelf display of covered products in two retail outlets visited. The materials contained promotional slogans such as *'Provide care and affection with Nestlé CERELAC'* and *'Big nutrition for small tummies. Give it all in no time at all'*. These observations represent a minor non-conformance with Article 6.(1)(b) of the Kenya Code which prohibits the use of sales devices such as special displays to promote sales of designated or complementary foods products.

End of aisle displays of Nestlé Nutrition Kenya products covered by the scope of the Nestlé Policy and Instructions and Kenya Code were observed in four retail outlets. Generally, end of aisle displays are designated for promotional displays in modern trade, and therefore the observed end of aisle display of Nestlé Nutrition Kenya products in four retail outlets constitute a minor non-conformance with Article 6.1 of the Kenya Code (which prohibits the use of sales devices, such as special displays to promote sales of designated products and complementary food). Evidence provided to Bureau Veritas during the audit indicates that this practice is attributable to the retailers and implemented by them to prevent theft of products.

Bureau Veritas opinion

From the assurance activities, evidence and observations, it is Bureau Veritas opinion that:

- Two non-conformities with the Nestlé Policy and Instructions and/or Kenya Code were identified during the audit which is attributable to the activities of Nestlé Nutrition Kenya.
- Both the Wyeth Infant Nutrition product drop card observed without the necessary breastfeeding disclaimer, and the two forms of Wyeth Infant Nutrition labels observed in the marketplace are non-conformities with the Nestlé Policy and Instructions, however both materials were produced by Wyeth before its acquisition by Nestlé and have since been discontinued. Two non-conformities with the Nestlé Policy and Instructions and/or Kenya Code identified during the audit were attributable to the activities of third parties.
- Two non-conformities concerning the application of the Nestlé Nutrition Kenya WHO Code Management System procedures were identified; however these do not constitute non-conformances with the Nestlé Policy and Instructions and the Kenyan Code.

Bureau Veritas recommendations

Detailed findings and recommendations from our assurance activities have been provided to Nestlé S.A. and Nestlé Nutrition Kenya as part of an internal Management Report. As a priority, Bureau Veritas suggests that Nestlé Nutrition Kenya should implement the recommendations made in the Internal Management Report, and specifically:

- Take immediate action to correct the non-conformances attributable to Nestlé Nutrition Kenya identified in the management system review, and conduct an investigation into the root cause of the issues and implement appropriate corrective actions.
- Update its internal policy and procedures documents to ensure that they accurately reflect the observations and recommendations made in our Management Report.

Limitations

Visual inspections of healthcare facilities and retail outlets and external stakeholder interviews were limited to the cities of Nairobi, Kisumu, Kakamega and Vihiga in Kenya.

This limited assurance is not intended to provide a definitive opinion as to whether or not Nestlé Nutrition Kenya complies with the Nestlé Policy and Instructions and the Kenya Code. Consequently, neither the limited assurance conducted by Bureau Veritas nor this statement constitutes a guarantee or assurance by Bureau Veritas that infringements against the Nestlé Policy and Instructions and the Kenya Code have not taken place.

Statement of independence, impartiality and competence



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Bureau Veritas is an independent professional services company that specialises in quality, environmental, health, safety and social accountability with over 180 years history in providing independent assurance services.

Bureau Veritas has implemented a Code of Ethics across its business which ensures that all our staff maintains high standards in their day to day business activities. We are particularly vigilant in the prevention of conflicts of interest.

Bureau Veritas has a number of existing commercial contracts with Nestlé. Our assurance team does not have any involvement in any other projects with Nestlé outside those of an independent assurance scope and we do not consider there to be a conflict between the other services provided by Bureau Veritas and that of our assurance team.

Our team completing the work for Nestlé has extensive knowledge of conducting assurance over environmental, social, health, safety and ethical information and systems, and through its combined experience in this field, an excellent understanding of good practice in corporate responsibility, assurance and the WHO Code. The work has been led and reviewed by lead assurers.



Bureau Veritas UK Ltd

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