



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 Uganda (August 2016)



Move Forward with Confidence



Independent Assurance Statement by Bureau Veritas

Introduction

Bureau Veritas has been commissioned by Nestlé S.A. to provide independent assurance of Nestlé Nutrition's business in Uganda on compliance with the Nestlé Policy and Instructions for the Implementation of the WHO International Code of Marketing of Breast milk Substitutes (herein referred to as 'Nestlé Policy and Instructions'). In Uganda, the Government does not have a separate local regulation for the implementation of the WHO code, rather has a guideline which mentions the manufacturers should implement the requirements of the WHO code.

Nestlé does not have a local entity or their own office in Uganda and therefore WHO Code related compliance is co-ordinated from the Nestlé office in Kenya and all sales of bona-fide Nestlé infant and follow-on formula products (IF) in Uganda are through their sole, authorised distributor - Translink.

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 Uganda between 8th and 19th August 2016, using two assurers from Bureau Veritas UK (Bureau Veritas) and a local auditor from Bureau Veritas Kenya who acted as translator as well. The core team has extensive experience of undertaking WHO Code compliance related work.

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

- requested a list of Nestlé Nutrition Kenya employees with responsibilities for the marketing and sale of infant nutrition products in Uganda and details of local healthcare facilities, healthcare professionals, and business partners in the country;
- requested from Nestlé Nutrition Kenya a list of local external stakeholders with an interest in infant nutrition, the protection of breastfeeding, or with responsibility for national compliance monitoring programmes, including healthcare professionals (HCPs), NGOs, medical associations and the Ministry of Health; and
- independently determined a schedule of external stakeholder interviews and visual assessments to take place in Uganda during the audit.

During the assurance Bureau Veritas:

- interviewed 14 Nestlé employees and 7 employees of the distributor in Uganda. We conducted a review of Nestlé Nutrition's and the distributor's documentation and records relating to specific areas of compliance with the Nestlé Policy and Instructions.
- interviewed a total of 35 key external stakeholders (NGOs, government representatives and healthcare professionals). In all meetings with stakeholders Nestlé was not disclosed as the client prior to the interview in order to avoid bias during interviews, neither was Nestlé Infant Nutrition Kenya informed of who would be interviewed; and

- visited 20 healthcare facilities and 98 retail locations to visually assess compliance with the Nestlé Policy and Instructions. Bureau Veritas independently selected which locations were to be visited.

Where non-compliance is identified with the Nestlé Policy and Instructions, or the local Nestlé Policy and Procedures Manuals, these are categorized as:

Major Non-conformance:

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

Minor Non-conformance:

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

Additionally, improvement opportunities are categorised as '**Opportunity for Improvement**' and represent a process/activity/document that, while currently conforming with the Nestlé Policy and Instructions, could further strengthen Nestlé Nutrition's practices.

During the audit one major non-conformance, four minor non-conformances and five opportunities for improvements were identified. The following is a summary of key findings from interviews, observations and document reviews undertaken.

Opportunities for improvement

Document control and staff training

A number of opportunities for improvement were identified in key documentation, specifically in the wording of the contract with the distributor and in the "important reminder" to trade. Whilst neither of the current documents directly violates the Nestlé Policy and Instructions, they could be reviewed for further improvements.

Consumer services Scripts

Nestlé provides its consumer services staff (which for Ugandan consumers is based in Kenya), with a document of frequently asked questions. These should be customized to ensure that answers are appropriate to the Ugandan market, which was not the case in some instances. For e.g. there were references to a local code in the FAQs section, however this does not exist in Uganda.

Nestlé should look at developing a standard script to attend to consumer calls as is the case in other markets. This would help to ensure standardization and prevent any potential deviations from the Nestlé

Policy and Instructions that may occur during consumer contact.

Products close to Expiry on Shelves

Two instances of IF products being near to expiry (less than 1 month) were observed in the marketplace.

Nestlé/Translink should look at replacing these products and should have products with more than 1 month of shelf life remaining in the stores. This should be reinforced to the sales personnel and merchandizers.

Internal Approvals of Labels

It was confirmed by Nestlé Kenya that the Ugandan labels, as well as the internal approval process of labels, are shared with other countries in the region.. Whilst the current labels comply with the Nestlé Policy and Instructions, the actual internal approvals for the IF labels, specifically for the Ugandan market, could not be shown to Bureau Veritas. Nestlé Kenya should look at strengthening the documentation control and retaining all signed approvals provided within Nestlé for the labels used in the Ugandan market.

Parallel import Infant Formula products at low price in retail stores

During its review in the Uganda market, Bureau Veritas came across various instances of infant formula products being supplied through parallel import channels rather than the bona-fide distributor channel. These products had different pricing and labels. There was one instance observed where a retailer – who is a customer of Translink - was offering Nestlé IF products at a considerably lower price. We understand that the products on display at a considerably lower price could be parallel imported products and are not under the influence of Nestlé/Translink. However, as this retailer is a customer of Translink, this could be a risk to Nestlé where the products may be perceived to be on discount/promotion.

Nestlé should continue to work with the authorities and retailers to stop this practice. .

Minor Non-conformances

Language and pictures used in the medical detailing material

As per Article 7.2 of the Nestlé Policy and Instructions, IF related information intended for health professionals should avoid promotional language and content, whether textual or pictorial, aiming at idealising formula over breast-feeding. During the review of materials intended for HCPs, a few instances of statements comparing certain characteristics of IF with those of breast milk without the relevant clinical studies references were found. In addition, an image of an infant (i.e. not intended to enhance the educational value of the information nor to add to the scientific information) was used. Bureau Veritas verified that these materials are intended for HCPs use only, and do not reach the general public. Hence, this is classified as a minor non-conformance with the Nestlé Policy and Instructions article 7.2

Absence of a contract with the distributor prior to 2016

Nestlé has one distributor - Translink for the sale and distribution of all of its products in Uganda. It was noted that there was no contract in place with Translink before January 2016, which makes it

difficult to ensure its obligation to abide by the Nestlé Policy and Instructions and WHO code. However, it was noted that regular trainings on the WHO code and the Nestlé Policy and Instructions were provided to the distributor's personnel; and a contract has been signed by both parties in August 2016.

Hence, this is classified as a minor non-conformance.

Traceability of medical detailing materials

Article 7.2 of Nestlé Policy and Instructions for the material intended for Health workers states that medical detailing materials "should conspicuously mention that they are destined for health workers only and bear a date and a print-code for traceability purposes". Whilst the medical detailing materials used by the medical delegates are only available in electronic format and are not printed and left behind to the HCPs, they did not fulfill all of the above requirements.

IF products' pictures and information on the distributor's (Translink's) website

As per Article 5.1 of the Nestlé Policy and Instructions, infant and follow-up formula must not be advertised or promoted directly to mothers or the general public either through public media or by personal contact between company representatives and the public. Bureau Veritas noted that the Nestlé portfolio of IF products available in Uganda is displayed on Translink's public website along with some text. We recognize that the primary aim of this webpage is to inform Business to business (B2B) parties about the products available – since Translink acts as a distributor.

However, the text used to describe the products is not the same as the information available on the labels and could be deemed as a form of advertisement.

Major non conformances

Special displays in the marketplace

The placement of covered IF products in special displays, such as gondola ends, in several stores represents a major non-conformance with Art. 5.3 of the Nestlé Policy and Instructions. It was understood that many of these instances may have been taken up by the retailers to reduce theft/pilferages.

Nestlé Kenya should continue sending the reminder letters and engage further with the pharmacy chains and retail customers on this matter to enhance their level of adherence to Nestlé Policy and Instructions.

Healthcare facilities and HCPs

Bureau Veritas visited 20 healthcare facilities situated between Kampala and Entebbe and interviewed 35 healthcare professionals. The following general observations were made concerning interactions with the healthcare system:

- no samples of products, displays or posters covered by the scope of the Nestlé Policy and Instructions were observed on display in any healthcare facility;
- there were no allegations of Nestlé or its representatives having direct contact with mothers;
- no healthcare facility reported any instance of Nestlé or its representatives in Uganda having or requesting direct contact with mothers.

Bureau Veritas opinion

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

- One major non conformances and four minor non-conformances with the Nestlé Policy and Instructions were identified during the audit;
- Five opportunities for improvement were identified.

Bureau Veritas next 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 any recommendations made in the Internal Management Report, and specifically:

- take immediate action to address all non-conformances identified;
- take immediate action to address improvement opportunities that could otherwise lead to potential non-compliance with its Policy and Instructions;
- update its internal policy and procedures documents to ensure that they accurately reflect the observations and recommendations made in the Management Report.

Limitations

Visual inspections of healthcare facilities and retail outlets and external stakeholder interviews were limited to the cities of Kampala and Entebbe in Uganda.

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 in its operations in Uganda. Neither the limited assurance conducted by Bureau Veritas nor this statement constitutes a guarantee or assurance by Bureau Veritas that other infringements against the Nestlé Policy and Instructions have not taken place.

Statement of independence, impartiality and competence

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 members do 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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