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 Peru (May 2015)
Independent Assurance Statement by Bureau Veritas

Introduction

Bureau Veritas has been commissioned by Nestlé S.A. to provide independent assurance of Nestlé Infant Nutrition’s business in Peru 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 local legislation implementing the WHO Code in Peru. In Peru, the Government has implemented the WHO Code through the ‘Supreme Decree No. 009-2006-SA, Regulation of Infant Feeding’ ("Peru Code"). The Peru Code is stricter than the Nestlé Policy and Instructions and applies to the marketing, and practices related therein, of the following designated products: breastmilk substitutes, infant formulas, complementary foods (when they are marketed as a partial or total replacement for breastmilk), and bottles and teats, for infants from the age of 0 - 24 months.

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 Peru between 27 April and 8 May 2015, using two assurors from Bureau Veritas UK (Bureau Veritas) and a professional Peru translator. The core team has extensive experience of undertaking WHO Code compliance related work.

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

- requested a list of Nestlé Nutrition Peru employees with responsibilities for the marketing and sale of infant nutrition products in Peru and details of local healthcare facilities, healthcare professionals, and business partners in the country;
- requested from Nestlé Nutrition Peru 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 Peru during the audit.

During the assurance Bureau Veritas:

- interviewed 23 employees and conducted a review of Nestlé Infant Nutrition Peru’s documentation and records relating to specific areas of compliance with the Nestlé Policy and Instructions;
- interviewed a total of 29 key external stakeholders (business partners and healthcare professionals). In all meetings with HCPs Nestlé was not disclosed as the client prior to the
interview in order to avoid bias during interviews, neither was Nestlé Infant Nutrition Peru informed of who would be interviewed; and
- visited 14 healthcare facilities and 66 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, the local Code or the local Nestlé Policy and Procedures Manual, these will be categorised as:

**Major Non-conformance:**
- 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 non-conformances 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 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 and local Code, could be improved to bring benefits to Nestlé Nutrition Peru.

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<th>During the audit, one minor non-conformance and a number of Opportunities for Improvement were identified. The following is a summary of key findings from interviews, observations and document reviews undertaken.</th>
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**Material intended for HCPs**
A sample of information and educational materials developed by Nestlé Nutrition Peru and intended for HCPs include the message that 'Breastfeeding is the Best' option for the baby. However; according to Article 7.2 of the Nestlé Policy and Instructions, informational materials intended for HCPs must also include items b) to e) of the information specified in Article 4.2, which are absent in these materials. Nestlé Nutrition Peru provided a letter from the Ministry of Health in Peru to justify their decision to develop such materials with lesser requirements for messaging. According to the Nestlé Policy and Instructions, in case an article of the aforesaid Policy is more restrictive than the national code, operating companies must follow the stricter rule laid down in the Policy unless otherwise required by the government.

Nestlé Nutrition Peru interpreted that the letter from the government superseded the stricter requirements of the Nestlé Policy and Instructions. We believe that the government letter does not supersede the requirements of the Nestlé Policy and Instructions and therefore Nestlé Nutrition
Peru should include the additional items as per Article 4.2 of the Nestlé Policy and Instructions. This finding was classed as a minor non-conformance with the Nestlé Policy and Instructions. Nestlé Nutrition Peru will therefore include the full statements required by the Nestlé Policy and Instructions on these materials.

**Sampling for Professional Evaluation**

It was observed during the audit that samples of infant formula are being given to healthcare professionals (HCPs) on their request, in line with PROC12 which allows for 1-2 tins per healthcare professional for a new product or product formulation as a ‘one time provision’. This is in line with requirements set out in the Nestlé Policy and Instructions, Article 7.4. We believe that the Nestlé Code is not explicitly clear on whether sampling for professional evaluation is allowed.

On our recommendation for Nestlé Nutrition Peru to confer with Nestlé S.A. to gain a collective opinion on its position in relation to the provision of samples for professional evaluation, Nestlé S.A. reviewed this issue and confirmed its understanding that the local activities are being carried out in accordance with the provisions of the local law.

**Sponsorship of HCPs**

Sponsorship of HCPs to support scientific activities with the aim to develop their professional capabilities is allowed under Article 7.5 of the Nestlé Policy and Instructions, and under PROC9 of the Peru Procedure Manual, as long as certain conditions are met. The Peru Code may be interpreted that sponsorship of any kind is not allowed to any healthcare professional who works in a healthcare institution which is receiving supplies of infant formula through government tender procurement.

Nestlé Nutrition Peru’s interpretation is that the Peru Code does not allow healthcare professionals to receive a personal benefit as a direct result of Nestlé’s supply to the healthcare facility with infant formula. On our recommendation for Nestlé Nutrition Peru to confer with Nestlé S.A. to gain a collective opinion on its position in relation to the sponsorship of HCPs under such circumstances, Nestlé S.A. reviewed this issue with Nestlé Nutrition Peru and confirmed its understanding that the local activities are being carried out in accordance with the provisions of the local law.

**Healthcare facilities and HCPs**

Bureau Veritas visited 14 healthcare facilities in Lima and Piura and interviewed 23 healthcare professionals. The following general observations were made concerning Nestlé Nutrition Peru’s interaction with the healthcare system:

- no samples of products covered by the scope of the Nestlé Policy and Instructions were observed on display in the healthcare facility;
- there were no allegations of Nestlé Nutrition Peru having direct contact with mothers;
- no healthcare facility reported to have received donations of medical equipment from Nestlé Nutrition Peru and no equipment were observed in the healthcare facilities;
- no healthcare facility reported any instance of Nestlé Nutrition Peru having or requesting direct contact with mothers;
Distributors
Bureau Veritas was not able to meet with any representatives of Nestlé Nutrition Peru's distribution partner during the audit due to time constraints experienced during the audit.

Retail
In order to assess Nestlé Nutrition Peru's compliance in the marketplace, Bureau Veritas carried out visits to 66 retail outlets in Lima and Piura:
- 47 Pharmacies (chain and independent)
- 10 modern trade
- 9 traditional trade

Two observations concerning retailer mis-placement of a promotional aisle runner and a shelf talker were seen and, whilst not in direct non-compliance with the Nestlé Policy and Instructions, could indirectly promote infant formula at the point of sale. It is recommended that Nestlé Nutrition Peru contact these retailers to remind them on the main aspects related to commercialization of breast-milk substitutes.

Bureau Veritas opinion
From the assurance activities, evidence and observations, it is Bureau Veritas opinion that:
- One minor non-conformance with the Nestlé Policy and Instruction and the Nestlé Nutrition Peru Policy and Procedures Manual were identified during the audit;
- A number of opportunities for improvement were identified across all compliance areas.

Bureau Veritas next recommendations
Detailed findings and recommendations from our assurance activities have been provided to Nestlé S.A. and Nestlé Nutrition Peru as part of an internal Management Report. As a priority, Bureau Veritas suggests that Nestlé Nutrition Peru should implement any recommendations made in the Internal Management Report, and specifically:
- take immediate action to address improvement opportunities that could otherwise lead to potential non-compliance with its own Policy and Procedures and the Peru Code;
- 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 Lima and Piura in Peru.

This limited assurance is not intended to provide a definitive opinion as to whether or not Nestlé Nutrition Peru complies with the Nestlé Policy and Instructions. 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 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 assurors.

Bureau Veritas UK Ltd
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