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 Pakistan (August 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 Pakistan 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 with the requirements of the local legislation implementing the WHO Code (Local Code)\(^1\). 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 Pakistan between 03 August and 11 August 2015, using two assurors from Bureau Veritas Pakistan (Bureau Veritas), supported technically by Bureau Veritas UK core team members.

The scope of the audit focused on activities in the medical sector and of relevant Nestlé Pakistan staff. The Wyeth Infant Nutrition (WIN) business was restructured and the medical detailing of the Wyeth Infant Nutrition product range was incorporated through the existing Nestlé Infant Nutrition Medical team. Nestlé Pakistan continues to sell the Wyeth Infant Nutrition range as part of its bigger Nestlé portfolio.

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

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

During the assurance Bureau Veritas:

- interviewed 10 Nestlé Infant Nutrition Pakistan employees and conducted a review of key documentation and records relating to compliance with the Nestlé Policy and Instructions;
- interviewed key external stakeholders, including 43 healthcare professionals (HCPs) and four individuals from two NGOs. Bureau Veritas arranged an independent schedule of interviews and visits for the assessment period. During interviews, Nestlé was not disclosed as the manufacturer being assessed, in order to avoid bias;

visited 26 healthcare facilities to visually assess compliance with the Nestlé Policy and Instructions. Bureau Veritas independently selected the locations to be visited.

Where non-compliances are identified with the Nestlé Policy and Instructions, the local Nestlé Policy and Procedures Manual, or the Local Code, the following categories can be used for classification.

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 Infant Nutrition Pakistan 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 Infant Nutrition 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.

Opportunity for Improvement:
- A process/activity/document that, while currently conforming, could be improved to bring benefits to Nestlé Infant Nutrition Pakistan.

No non-conformances were identified during the audit. However, opportunities for improvement were identified. The following is a summary of key findings from interviews, observations and document review undertaken:

Nestlé Infant Nutrition Pakistan Policy and Procedures Manual
During the head office audit, no non-conformances were raised concerning the application of the local Nestlé Infant Nutrition Pakistan Policy and Procedures Manual.

Government and Non-Governmental organisations
Bureau Veritas was not able to meet with any Government representatives but did meet with representatives of two Non-Governmental Organisations during the audit.

Healthcare professionals
Bureau Veritas visited 26 healthcare facilities in Lahore, Islamabad and Karachi and interviewed 43 healthcare professionals. The following general observations were made:
a) All healthcare professionals interviewed stated that the Nestle Infant Nutrition Pakistan medical delegates provide detailed information during their visits on products related scientific information only. Nestle Infant Nutrition Pakistan requires that the Local Code is communicated to each healthcare professional at least once per year and medical delegates are assigned in their detailing cycle plan to conduct Code communication at least once a year to every healthcare professional they visit.

Some healthcare professionals interviewed were unable to recall any communication by Nestlé Infant Nutrition’s medical delegates related to Local Code, commenting that detailing is related to product and scientific information only. Nestlé Infant Nutrition Pakistan shared relevant documents that showed that once a year communication around the local Code to healthcare professionals is done and it is recommended that Nestlé Infant Nutrition Pakistan ensures that the Local Code remains central to their communication to the healthcare professionals during their visits.

b) Three healthcare professionals commented that all infant formula manufacturers perform registrations for participation of healthcare professionals in conferences and symposiums, the payment of which is being made by the manufacturers, although no specific manufacturer was referenced as making the payments. According to the Local Code (Clause 7.3) ‘No manufacturer shall offer, or make gift or contributions of any kind, or pay to any extent for any reason whatsoever, or give any kind of benefit, to a health worker or his family, or any personnel employed, directly or indirectly, in a health care facility, or any member of the Board or a Provincial Committee, as the case may be, or the employees thereof’.

Review of Nestlé Infant Nutrition Pakistan’s documents was conducted and no evidence was seen that Nestlé Infant Nutrition Pakistan was paying for registration or sponsorship of healthcare professionals.

c) One healthcare professional claimed that gifts and giveaways are provided to healthcare professionals by infant formula manufacturers, which would be in breach of the Local Code and Nestlé Infant Nutrition Pakistan’s procedure that restrict provision of donation or gifts to healthcare professionals and healthcare facilities. Nestle Pakistan was not mentioned by the healthcare professionals and no evidence of any spending on gifts, promotional material or giveaways was identified which could substantiate the claim being made. It is noted that this comment is anecdotal and that Nestlé Infant Nutrition Pakistan must remain vigilant and ensure that the Local Code requirements are always fulfilled and remain central to communication with healthcare professionals.

**Bureau Veritas opinion**

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

- No non-conformances with the Nestlé Policy and Instructions, the Local Code and the local Nestlé Infant Nutrition Pakistan Policy and Procedures Manual were identified during the audit.

- Opportunities for Improvement were raised to reinforce current practice to ensure continued compliance with Nestlé Policy and Instructions and the Local Code.
Bureau Veritas recommendations

- Detailed findings and recommendations from our assurance activities have been provided to Nestlé S.A. and Nestlé Infant Nutrition Pakistan as part of an internal Management Report. As a priority, Bureau Veritas suggests that Nestlé Infant Nutrition Pakistan should implement the recommendations made in the Internal Management Report and specifically the update of its internal policy and procedures documents to ensure that they accurately reflect the practices on communication of the Local Code to HCPs.

Limitations

Visual inspections of healthcare facilities and external stakeholder interviews were limited to the cities of Lahore, Islamabad and Karachi in Pakistan. This limited assurance is not intended to provide a definitive opinion as to whether or not Nestlé Infant Nutrition Pakistan 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
London, December 2015