



## **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 the Kingdom of Saudi Arabia (November 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 the Kingdom of Saudi Arabia 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 the Kingdom of Saudi Arabia. In the Kingdom of Saudi Arabia, the Government has implemented the WHO Code through "Law of Trading in Breast-Milk Substitutes", Royal Decree No. M/49, (hereafter referred to as "Saudi Code"). The Saudi Code may be interpreted to be stricter on some aspects and Nestlé Policy and Instructions on others.

This assurance 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 the Kingdom of Saudi Arabia between 13 November and 24 November 2016, using two assurors from Bureau Veritas UK (Bureau Veritas) and a local auditor from Bureau Veritas Saudi Arabia who acted as translator as well. The core team of Bureau Veritas has extensive experience of undertaking WHO Code compliance related work.

Preceding the assurance activities in Saudi Arabia, Bureau Veritas conducted the following activities:

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

During the assurance Bureau Veritas:

- interviewed 31 employees and conducted a review of Nestlé Nutrition Saudi Arabia'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 Nutrition Saudi Arabia informed of who would be interviewed; and
- visited 21 healthcare facilities and 47 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 Saudi Code or the local Nestlé Nutrition Policy and Procedures Manuals relating to specific areas of compliance with the Nestlé Policy and Instructions, these will be categorised as:

**Major Non-conformance:**

- A frequent or purposeful failure to follow a specified requirement written within the Nestlé Policy and Instructions, the Saudi Code or local Nestlé Nutrition 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 Saudi Code or the local Nestlé 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.

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

During the assurance visit, two minor non-conformances and five Opportunities for Improvement were identified. The following is a summary of key findings from interviews, observations and document reviews undertaken.

**Opportunities for Improvement:**

*Updating Local procedure on Continuous Medical Education*

Bureau Veritas reviewed a list of all contributions made to healthcare institutions in the last 12 months in support of Continuous Medical Education (CME). As per Nestlé Saudi Arabia's Local Procedure, they have to acquire approvals from the internal Code Compliance Committee depending on the amount of the sponsorship. Bureau Veritas noted that this requirement of approval was changed and the amount limit was increased through an internal communication. Hence, the Local procedure is outdated and needs to be appropriately updated.

*Updating Local Procedure Manual on Labelling requirements*

It was noted that the requirement to have an ingredient list on in-scope Infant Formula products is not present in the Local procedures of Wyeth Nutrition Saudi Arabia on Labelling. All other requirements of the Nestlé Instructions are met in the procedure. Also, the labels of the products currently in the market do contain ingredient lists for all in-scope products. The Wyeth Nutrition Saudi Arabia Local Procedure should be updated to reflect the requirement to have ingredient lists on infant formula product labels in line with Saudi Code Article 10.4 and Nestlé Policy and Instructions.

### *Traceability of Medical detailing material*

Bureau Veritas noted that the reviewed Medical detailing materials do not:

- mention that they are destined for health workers only
- bear a date and a print-code for traceability purposes

Article 7.2 of Nestlé Policy and Instructions for the material intended for Health workers states “All such informational materials should conspicuously mention that they are destined for health workers only and bear a date and a print-code for traceability purposes”

Bureau Veritas also noted that all of these materials are electronic and are not left back or provided to HCPs in hard copies or soft copies in Saudi Arabia. Whilst the medical detailing materials are only destined for electronic display and are not handed or mailed to HCPs they should still meet the requirements of the Nestlé Policy & Instructions to ensure traceability and prevent risk of violation.

As the medical detailing material is not being left back with the HCPs and does not reach the consumers or mothers, this finding is classified as an opportunity for improvement.

### *Supply share related targets*

Bureau Veritas reviewed the job descriptions, objectives setting and personal evaluations done for the personnel involved in sales and marketing of Infant Formula products in Saudi Arabia. During the review it was noted that one of the Nestlé hospital sales executive has a target on supply share for his allotted hospitals for the RTF products compared to the supply share of competition.

Whilst the market share KPIs are allowed for national key account managers, the topic of supply share in hospitals is a new area where more guidance is required for the markets from Nestlé Head office.

This instance has been raised as an opportunity for improvement for Nestlé Corporate to review and issue the guidelines to the market, on the subject of supply share to the hospitals, so that the markets could set the targets and objectives in a way they are not perceived as incentives for sales of covered Infant Formula products.

### *Pricing for hospitals*

It was noted that the price calculations for the products are done as per the Nestlé corporate guidelines for hospitals based on the best wholesale price. However, Article 13 of the Saudi Code mentions: “*To prevent the spread of breast-milk substitutes, health care institutions shall not accept any complementary or reduced-price samples of infant formula and food*”. The Saudi Code doesn’t provide a clear definition of “reduced-price samples” and there may be different interpretations for the same. It is recommended to get more guidance on this aspect to ensure that the practice is aligned with the local code definition of reduced-price.

### **Retail and Health care facilities**

- Bureau Veritas visited 21 healthcare facilities in Jeddah and Riyadh and interviewed 25 healthcare professionals.

- Visited 47 Retail Outlets including modern trade / pharmacies / traditional trade
  - o No promotion materials related to covered infant formula products were seen in the market place
  - o No samples of products covered by the scope of the Nestlé Policy and Instructions were observed on display in the healthcare facility.
  - o There were no allegations of Nestlé Nutrition Saudi Arabia having direct contact with mothers.

**Minor Non-Conformances:**

*Placing of Nestlé Infant Formula – Gondola end*

There was one instance of a special display (gondola end/end of aisle) of Wyeth Infant formulas Illuma 1 and Illuma 2 seen at a retailer. Since, this was an isolated incident seen, it is classified as minor non-conformance. However, there is no evidence that this display was done under the influence of Nestlé Saudi Arabia.

*Placing of Nestlé Infant Formula – Special display*

During the retail visits, Bureau Veritas noted some of the display shelves, which normally would be called “home shelves”, with special illumination. These shelves are seen as an instance of special displays and had covered Infant Formula products (NAN 1 and NAN 2) displayed as well. The placement of Infant Formula products covered products in illuminated home shelves a minor non-conformance with Art. 5.3 of the Nestlé Policy & Instructions.

**Bureau Veritas opinion**

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

- Two 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 Saudi Arabia as part of an internal Management Report. As a priority, Bureau Veritas suggests that Nestlé Nutrition Saudi Arabia 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 own Policy and Procedures and the Saudi 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 Jeddah and Riyadh.



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This limited assurance is not intended to provide a definitive opinion as to whether or not Nestlé Nutrition Saudi Arabia 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 infringement 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.



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**London, August 2017**