

Nestlé S.A.

Independent Assurance of Compliance with the Nestlé Policy and Instructions for Implementation of the WHO International Code of Marketing of Breast milk Substitutes in Egypt (November 2015)



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 Infant Nutrition's business in Egypt (herein referred to as "Nestlé Nutrition Egypt") 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 bylaw No. 2075/2010 (herein referred to as "local legislation"), issued in 2010 under the Child Law, which gives effect to the WHO Code in Egypt. The by-law combines marketing restrictions with provisions on food quality, food preparation and food additives which are commonly the subject matter of food legislation. The scope of the by-law has provisions on informational and educational materials too and includes prohibition of communication with pregnant women and mothers and sponsorship of infant feeding programmes.

This follows similar work previously conducted by Bureau Veritas for Nestlé S.A..

Scope of Work and Methodology

The assurance was conducted in Egypt between 1st and 12th November 2015, using two assurors from Bureau Veritas. The core team has extensive experience of undertaking WHO Code compliance related work.

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

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

During the assurance Bureau Veritas:

- interviewed 23 employees and conducted a review of Nestlé Nutrition Egypt's documentation and records relating to specific areas of compliance with the Nestlé Policy and Instructions and local legislation;
- interviewed a total of 36 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 Egypt informed of who would be interviewed; and

 visited 32 healthcare facilities and 51 retail locations to visually assess compliance with the Nestlé Policy and Instructions and local legislation. Bureau Veritas independently selected which locations were to be visited.

Where non-compliance is identified with the Nestlé Policy and Instructions, the local legislation 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 legislation 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 legislation 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 nonconformance, such as an isolated issue.

Additionally, improvement opportunities are categorised as '**Opportunity for Improvement**' and represent a process/activity/document that, while currently conforming and not triggering any eventual non-conformance with the Nestlé Policy and Instructions and local legislation, could be improved to bring benefits to Nestlé Nutrition Egypt.

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

Code Monitoring Form

Nestlé NEAR Procedure 15 (Dealing with Code Violations in Sales Outlets Open to the Public -May 2014) includes a template Code Monitoring Form to be used by staff to report internally any observed violation of the local legislation or of Nestlé's own instructions and procedures. On review of some communications, it was observed that occasionally such information may be reported within an email or through similar but not identical forms.

It is recommended that an internal communication is made to Nestlé Nutrition Egypt medical and sales representatives to refresh their awareness on the applicable form to be used for reporting of observed violations to the local legislation or to Nestlé's own instructions procedures, and to



harmonise the current reporting system. This instance has been raised as an opportunity for improvement.

Contract with distributor

The agreement between Nestlé Nutrition Egypt and one of its distributors made on 1 January 2015 makes explicit reference to the WHO Code (clause 4) and attached to the contract are also the "Important Reminder to the Trade" and Nestlé sales "Do's and Don'ts".

The "Duration and termination" clause (clause 23) states that any material breach of the agreement can result in termination of the contract, and it shall be interpreted as including any breach to the WHO Code.

It is recommended that all contracts with distributors and third parties in general include a clear reference that any breach of the local legislation and of the Nestlé Policy and Instructions could result in termination of the agreement. Such message should be reinforced by listing examples of most frequent Code-related breaches as possible reasons for termination of the contract. This instance has been raised as an opportunity for improvement.

Historical Wyeth-branded material

In one healthcare facility (private clinic), a leaflet holder was observed in the waiting room, branded with the Promil name and logo and including the following statement 'Healthy bodies and minds depend on the right milk'. In addition, the display was used to hold flyers with the picture of an infant. Although the flyers did not relate to any Nestlé or Wyeth Infant Nutrition product, there was an immediate (unintentional) association with the Promil brand in the holder.

It is understood that this historical Wyeth-branded material which does not comply with the Nestlé Policy and Instructions was developed and distributed before the acquisition of the business by Nestlé. Following acquisition by Nestlé S.A., the company has started an extensive program to monitor and recall such historical material, removing material from over 150 healthcare locations and including interventions to correct clinic decorations, pharmacies see through, etc. A timetable for this purpose has been reviewed at Nestlé Nutrition Egypt head office. In the first phase, the company has focused on material which represented a more clear violation of the Nestlé Policy and Instructions; the company is currently finalising such recall, focusing on the remaining items.

It is recommended that Nestlé Nutrition Egypt includes the sample illustrated above in its list of historical material not complying with the Nestlé Policy and Instructions and subject to a recall program. Medical delegates and representatives should also be alerted to the possibility that such material is still in use and encouraged to report this internally to the Code Compliance Manager where not done already. This instance has been raised as an opportunity for improvement.



Baby food display cabinets in pharmacies

In two pharmacies, display cabinets for growing-up milks were also used for infant formula products. Although the cabinet was not provided by Nestlé nor branded with Nestlé logos, it was used by the pharmacy for display of the full range of infant formula available, including Nestlé products. Among other factors, the prominence of infant formula cans in the cabinet among all other baby food products, presence on the cabinet of the picture of an infant and of the statement "For Alert and Active Little Person", and positioning of the cabinet in a more noticeable place than the 'standard' shelves represent in our opinion a special display which could induce sales directly to the consumers at the retail level, in contradiction to the Nestlé Policy and Instructions. This item has been raised as a minor-non-conformance.

It is acknowledged that retail practices and related display of products fall under the responsibility of the retailer.

Informational and educational material for HCPs

In one healthcare facility (private clinic), a set of materials related to Wyeth Infant Nutrition formula products was observed among other informational and educational material intended for HCPs only. On these materials, it is clearly stated that these are for HCP-use only. However, as these samples were left unattended in the waiting room and available to the general public, they could represent a form of improper communication and promotion of infant formula products. This item has been raised as a minor-non-conformance. There was no evidence indicating that this instance was initiated by Nestlé.

Nestlé Nutrition Egypt should continue to monitor healthcare facilities and confer with practitioners for the appropriate use of informational and educational material intended for them only. A risk assessment should be undertaken to determine if these materials are at risk of misuse in healthcare facilities by HCPs.

Code Compliance Committee

Nestlé NEAR procedure PROC2 (Code Compliance Committee) requires such committee to meet every quarter. The committee has not met with the frequency required by the procedure in the last 12 months. Meetings were scheduled quarterly but due to unavailability of some members and changes to governance, they were only held on October 2014 and July 2015.

It is recommended that the quarterly frequency for meeting of the Code Compliance Committee is maintained and complied with, as per the procedural requirement or a revision of the Procedure has to be initiated in a way to reflect Market's practices. This item has been raised as a minor-non-conformance with the local procedure manual.



Internal monitoring information

Nestlé NEAR procedure PROC11 (Monitoring and Reporting) provides for periodic reporting of violations both by Nestlé and competitors. Although no violations have been reported during the last 12 months in relation to Nestlé products, the procedure makes explicit reference to competitors' violations too. Dedicated monthly summary reports have not been observed for the last 12 months, but all violations are reported in the management letter on a monthly basis. Furthermore, the 2014 consolidated annual regional report did not include information on competitors' violations.

It is recommended that Nestlé Nutrition Egypt improves consolidation and auditability of internal monitoring information, as required under its own local procedures. This item has been raised as a minor-non-conformance with the local procedure manual.

Bureau Veritas opinion

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

- Four minor non-conformances with the Nestlé Policy and Instruction and the Nestlé Nutrition Egypt Policy and Procedures Manual were identified during the audit;
- A number of opportunities for improvement were identified across all compliance areas as well as specific recommendations relating to interpretation of the local legislation.

Bureau Veritas next recommendations

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

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

In response to the non-conformances raised by Bureau Veritas, Nestlé Nutrition Egypt has committed to take necessary corrective actions.

Limitations

Visual inspections of healthcare facilities and retail outlets and external stakeholder interviews were limited to the cities of Cairo and Alexandria in Egypt.



This limited assurance is not intended to provide a definitive opinion as to whether or not Nestlé Nutrition Egypt 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 185 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.



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