

Danone

Independent Green Book / Blue Book Audit Statement

Egypt (2014)



Introduction

Bureau Veritas has been commissioned by Danone to provide an independent audit of the compliance of its Danone Nutricia Early Life Nutrition (DNELN) operations in Egypt, with Danone's Green Book (version 3, April 2013), Danone's Blue Book (version 3, April 2013), and any local legislative requirements for the marketing of breast milk substitutes (BMS). The Green Book is Danone's Policy for the Marketing of Foods for Infants and Young Children. The Blue Book is Danone's Management System Manual for the Marketing of Foods for Infants and Young Children.

Scope of Work and Methodology

The audit was conducted in Cairo between 30 November and 4 December 2014. Bureau Veritas developed an audit protocol to address the requirements of Danone's Policy, and its Internal Management System and any local legislative requirements for the marketing of BMS. Products which are covered by the scope of the Green Book in Egypt include infant formula and follow-on formula designed to satisfy the nutritional requirements of healthy normal infants from birth up to the age of 12 months (known as 'Covered Products').

Bureau Veritas undertook the following activities to assess DNELN's compliance with its Policy and relevant local legislation:

- Country Business Unit (CBU) Audit:
 - interviewed key DNELN's local management at the CBU head office with roles and responsibilities for the sale and marketing of BMS and reviewed supporting documentation and records
 - conducted five 'mystery shopper' calls to the CBU's consumer hotline (the Careline) to test the understanding and implementation of the Green Book
- Marketplace audit: Bureau Veritas independently determined, scheduled and visited:
 - ten retail outlets to visually assess how DNELN products are sold to assess compliance with the Green Book
 - ten health workers to conduct interviews to assess DNELN's compliance with the Green Book.

Danone
Independent Green Book / Blue Book Audit Statement
Egypt (2014)



CBU Audit Summary

The CBU demonstrated compliance with, and the implementation of a management system for the following articles of the Green Book – General Public and Mothers, Information and Education, Health Workers, Humanitarian Aid, Products for Professional Evaluation, Clinical Studies, Retail Trade and Distributors, Events for Health Workers and Educational Grants. An internal validation process, implemented by the CBU ensures that materials such as labels, informational and educational materials and medical marketing materials are reviewed and approved for compliance with the Green Book in terms of content, use of logos and breastfeeding support messages, prior to distribution. All employees receive training on the requirements of the Green Book, and bonus and incentive calculations for employees are not based on individual or collective sales targets for Covered Products.

Four non-conformities with the Green Book were identified during the CBU audit:

- The CBU has not implemented a formal documented process in place for managing and tracking progress of the implementation of corrective action, which represents a non-conformance with Article 7.6 of the Green Book which requires the CBU to have clear processes for recording and tracking corrective actions for all reports of non-compliance.
- Sales and Marketing employees receive regular refresher training and have signed declarations of compliance with the Green Book, however there is no formal documented process in place for monitoring on a continual basis staff's compliance with the Green Book. This represents a non-conformance with Article 7.4 of the Green Book which requires the CBU to have an on-going, systematic, internal monitoring of compliance.
- The breastfeeding statement on all Covered Products labels is clear, conspicuous, and easily readable, however the local Ministry of Health Regulation (Article 64) requires that breastfeeding statement should be preceded with the sentence "Important Notice" in bold font size 14. The "Important Notice" sentence on the labels of the Covered Product was observed to be in regular font size 9. This represents a non-conformance with Article 8 of the Green Book which requires CBUs to follow national measures, in addition to the Green book, where the national measures are more demanding than the Green Book. It should be noted that the labels in question were approved by local authorities during the product registration process.
- Evidence was observed during the audit indicating that the CBU has provided supplies of Covered Products to two healthcare facilities for free of charge on the request of the healthcare facilities. As per Article 13.4 of the Green Book, supplies of Covered Products to Health Care Facilities should only be provided at full or below full price.

Danone
Independent Green Book / Blue Book Audit Statement
Egypt (2014)



Four non-conformities with the Blue Book were identified during the CBU audit:

- The internal process for notifying Danone management of substantiated allegations of violations of the Green Book does not fully align with the process set out in the company's Blue Book. This represents a non-conformance with Article 7 of the Blue Book.
- The CBU has not undertaken an annual internal self-assessment to determine compliance with the Green Book in the last 12 months. This represents a non-conformance with Article 5.2 of the Blue Book. The last assessment was undertaken 2012.
- The Danone Charter poster is not currently displayed in the offices. This represents a non-conformance with Article 3.3.2 of the Blue Book.
- The employment letter for newly appointed Medical Representatives contains the statement that the CBU is committed to compliance with the WHO Code of Marketing of Breast-milk Substitutes, however it does not reference the Green Book. This represents a non-conformance with Article 3.1.2 of the Blue Book.

Marketplace Audit Summary

No non-conformities with the requirements of the Green Book were identified during visual inspections of the retail outlets visited by Bureau Veritas during the audit. In all retail outlets visited, DNELN'S Covered Products were observed to be displayed and sold in compliance with the Green Book, and no use of promotional devices such as special displays, discounting, sampling, free gifts or point of sale promotional materials were observed.

The health workers interviewed confirmed that medical representatives of DNELN have not solicited contact with the general public to promote its Covered Products or provided feeding demonstrations to mothers of infants. They also confirmed that representatives of DNELN had not provided gifts or samples to the general public which promote the use of Covered Products. Bureau Veritas did not observe any non-compliant DNELN materials, or witness any non-compliant activities being conducted by DNELN in the healthcare facilities visited during the audit.

Detailed findings and recommendations from the audit have been provided to DNELN as part of an Internal Management Report.

Disclaimer

DNELN was not disclosed as the client to external stakeholders in order to avoid bias during the audit, nor was DNELN informed in advance of who would be interviewed. Some of the statements made by external stakeholders are anecdotal and evidence may not be available to support their claims. Whilst the audit protocol is designed to provide an objective independent assessment, it remains that in some cases the verification of such statements is dependent solely on the credibility of the party presenting the evidence.

Danone

Independent Green Book / Blue Book Audit Statement Egypt (2014)



Where Bureau Veritas did not find objective evidence to support statements made by external stakeholders this is clearly expressed in this statement. Neither the audit conducted by Bureau Veritas nor this statement constitutes a guarantee by Bureau Veritas that violations against the Green Book or relevant local legislation have not taken place.

Statement of independence, impartiality and competence

Bureau Veritas is an independent professional services company that specialises in quality, health, safety, social and environmental management advice and compliance with more than 180 years of history in providing independent assurance services. Bureau Veritas has implemented a Code of Ethics across its businesses which ensure that all its staff maintains high standards in their day to day business activities. We are particularly vigilant in the prevention of conflicts of interest. In our opinion this audit does not raise any conflicts of interest.



Statement issued by Bureau Veritas UK

May 2015