

Danone

Independent Green Book / Blue Book Audit Statement

Brazil (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 Brazil, 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 Sao Paulo between 1 and 5 December 2014. Bureau Veritas developed an audit protocol to address the requirements of Danone's Policy and its Internal Management System Manual and any local legislative requirements for the marketing of BMS. Products which are covered by the scope of the Green Book in Brazil 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
 - No healthcare professionals accepted Bureau Veritas' invitation directly for an interview as part of the assessment of DNELN's compliance with the Green Book. Therefore an alternate approach was implemented (see below)

Due to the challenges encountered by Bureau Veritas in organising independently the meetings with healthcare professionals during the initial audit in December 2014, an alternative approach was implemented whereby the auditor was introduced to healthcare professionals by DNELN's medical representatives during their routine visits, and the auditor was left to interview the healthcare professional privately. The sample of ten healthcare professionals to be interviewed utilising the alternative approach was selected by Bureau Veritas. The interviews with healthcare professionals were undertaken by the auditor on the 30 March and 1 April 2015.

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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, Labeling, Healthcare Facilities, Humanitarian Aid, Clinical Studies, 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.

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

- The CBU could not demonstrate that retail customers, distributors and other parties, acting on behalf of Danone, involved in bringing Covered Products to the market had received communication regarding the requirements of the Green Book. This represents a non-conformance with Article 18 of the Green Book which requires Danone to make retail customers, distributors and other parties acting on behalf of Danone in bringing Covered Products to the to the market aware of the importance of abiding by relevant laws and the Green Book, and the importance of complying with their requirements.
- At present, the CBU distributes Product for Professional Evaluation (PPE) to health workers when a new product is launched. In accordance with a local procedure the CBU obtains the signature of the health worker on the health worker's receipt of the PPE. However, the CBU could not demonstrate that they had received an authorised, written request for the PPE from the health worker, which is a requirement of Article 16.4 of the Green Book. Article 16.4 of the Green Book requires the CBU to obtain written request from the health worker, which includes the amount of PPE required and clearly states the health worker's certification that: a) The requested PPE is solely for purposes of evaluating tolerance and acceptability; b) The health worker is aware of the obligations set forth under the relevant laws of the country; c) The PPE is not being provided as an incentive to purchase or resell or recommend a particular brand of Covered Products and d) The PPE provided is not to be resold or taken for personal use by the health worker or its staff.

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

- The CBU had not completed an annual self-assessment of compliance with the Green Book in the last 12 months. This represents a non-conformance with Article 5.2 of the Blue Book.
- The CBU had not completed and sent to the head office in the last 12 months an annual report summarising any Green Book violations identified and actions taken to remediate these violations. This represents a non-conformance with Article 8.2 of the Blue Book.

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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. 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.

All ten health workers interviewed by Bureau Veritas confirmed that they had received a sample of a Covered Product for professional evaluation purposes, and noted that they were only required to provide a signature on a receipt form on receiving the PPE. The health worker's interviewed did not indicate that they had provided an authorised, written request for the PPE to the CBU. This represents a non-conformance with Article 16.4 of the Green Book which requires the CBU to have obtained written request from the health worker.

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. 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.



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