



Danone Trading ELN B.V.

Independent audit of Danone's marketing practices in Brazil
against the Danone Policy on the Marketing of Breastmilk
Substitutes

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Independent Statement by Bureau Veritas

Introduction

Bureau Veritas has been commissioned by Danone Trading ELN B.V. (Danone) to provide an independent audit of Danone's Breast Milk Substitutes (BMS) businesses in Brazil (the Country Business Unit or CBU) on compliance with the Danone Policy for the Marketing of Breast-Milk-Substitutes (BMS Policy), with reference to the internal HCS Compliance Directive and the BMS Compliance Directive for implementing its BMS Policy (the Directives) and the local regulation implementing the WHO Code in Brazil.

In Brazil, the Government has implemented the WHO Code and related requirements mainly through Law No. 11,265, established in 3rd January 2006 that regulates the food commercialization to infants and young children as well as childcare products in Brazil and by the Decree No. 9579/2018 (collectively, the Local Code).

Products covered by the BMS Policy are BMS intended for infants aged between 0-12 months (Covered Products).

This audit follows similar work previously conducted by Bureau Veritas for Danone in other global operations.

Scope of Work and Methodology

The audit was conducted in Brazil between the 22-26 July 2019, using one verifier from Bureau Veritas UK Ltd (Bureau Veritas) and a local verifier from Bureau Veritas Brazil who also acted as a translator (as applicable). The Bureau Veritas UK team has extensive experience of undertaking WHO Code assessment related work.

During the audit, Bureau Veritas undertook the following activities:

- Visited the CBU head-office in Sao Paulo, interviewed 28 employees and conducted a review of sample documentation and records relating to compliance with the BMS Policy;
- Interviewed 2 representatives from Danone's distributor and reviewed the documentation and records relating to specific areas of compliance with the Danone Policy;
- Interviewed 10 Health Care Professionals (HCPs) including paediatricians and infant nutritionists. In all of these meetings Danone was not disclosed as the client prior to the interview in order to avoid bias during interviews, nor was the CBU informed of who was interviewed.
- Visually assessed compliance with the Policy in 5 healthcare organisations and 49 retail locations including modern trade, pharmacies, and traditional trade. Bureau Veritas independently selected the locations that were visited.
- Conducted one anonymous call to the Danone careline.

Any findings identified during the audit have been categorised as per the following:

Non-conformance:

- Any failure to follow a written requirement specified within the BMS Policy
- A failure to achieve local legal or statutory requirements as per our interpretation

- A purposeful failure of the company to correct non-conformances

Opportunity for improvement (OFI):

- A process/activity/document that, while currently conforming to the BMS Policy and local directives, could be improved to further strengthen the CBU's practices.

The following is a summary of key findings which includes non-conformances, opportunities for improvement and areas of good practices.

Non-conformance:

1. *Point of sale promotion*

During retail visits, Bureau Veritas observed four instances of Covered Products being sold for a discounted price at a chain. This constitutes a point of sale inducement for the sale of Covered Products not permitted under Article 3.3 of the BMS Policy and Article 5 of the local code. We note that there was no evidence to suggest that the discounts were made at the request of the CBU.

2. *Products for Professional Evaluation*

Bureau Veritas reviewed a sample label of a product for professional evaluation (PPE). It contained a barely legible statement 'Venda Proibida'. This does not align with Article 6.5 of the BMS Policy which requires the statement "For Professional Evaluation Only" and "Not for Sale" on all PPE.

3. *Training of Partners*

Article 11.1 of the BMS Policy requires that all Danone Partners receive 'training which includes the aims and principles of the WHO Code and the Danone commitments to responsible Marketing as outlined in this BMS Policy'. While training appears to have been delivered on product specification, there is no evidence of training to cover the WHO Code and BMS policy for distributors. Furthermore, internal distributor training materials reviewed did not refer to the Danone BMS Policy or WHO code. Although formal training has not been delivered, Managers at the distributor have received a link to the 2018 BMS Policy and are required to confirm that this has been received, read and understood.

4. *Contracting of HCPs*

Bureau Veritas reviewed a sample of contracts and noted that they were directly with HCPs and not through their affiliated HCO. No consent was documented. This is not in line with the BMS Policy article 5.6.

5. *Ecommerce Point of Sale Discount*

We identified one instance of a wholesaler promotion for a Covered Product on a Social Media platform from 2018 which had not been removed. This goes against Article 3.3 of the Danone BMS Policy and Article 5 of the local code. Bureau Veritas acknowledges that there is no evidence to suggest that the third party promotion was done at the request of the CBU.

Opportunity for improvement (OFI):

1. *Allegation reporting and follow-up*

The quarterly allegation report sent from the CBU to Danone Head Office does not always contain information about the city as required by BMS Policy Article 18.4. Also, there were several instances where employees interviewed gave examples of policy violations identified in retail or online, which has either been reported to the line manager or dealt with directly through the retailer, but that were not captured in the formal allegation tracking process. As such, it was not tracked whether the violation had been fully addressed with the retailer/platform. For full visibility of all allegations of non-compliance, the CBU should ensure that these are consistently recorded and documented, including actions taken to rectify any violation identified, such as notification to third party.

2. Information material statements

BMS Policy Section 5.2 requires the statement “For Health Worker use only – not for distribution to the general public” on information regarding Covered Products provided to HCPs. This statement could not be located or was so small it was illegible on a Covered Product information flip-booklet supplied to HCP interviewed. The CBU should ensure that mandatory statements on information and education materials are clear and legible.

3. HCP Events

Invitations for small events organised for HCPs by Danone Medical Representatives are made by Whatsapp or by email (which is not necessarily associated with a hospital), this does not align with the requirement of Section 7.2 of the BMS Policy which requires ‘Any invitation is made in writing to the business address of the HCP’. For traceability and transparency, the CBU should maintain records of invitations issued in writing (by letter or business email), including where applicable notification to the relevant HCO.

4. Contracting with Partners

The ‘Scope’ Section of the BMS Policy requires that ‘Danone ensures Partners understand and are made aware of the importance of abiding by this BMS Policy’. While the partners are made aware of the BMS Policy, it could be of benefit to include contractual requirement for BMS Policy compliance when contracts are updated for the recently merged Business Units, or to provide periodic reminders to partners in documented form regarding the current version of the BMS Policy and local code.

Areas of good practice:

1. Danone Brazil staff have an overall good awareness of the requirements of the WHO Code and BMS Policy
2. Requested documentation was readily available and the CBU was well prepared for audit
3. The CBU has a well-established and documented internal review process for the approval of any consumer or HCP marketing activities, materials, and information and labelling
4. During healthcare visits, we saw no evidence of Danone branded materials being given to HCPs for distribution to mothers.

Limitations

Visual inspections of healthcare facilities and retail outlets and external stakeholder interviews were limited to the city of Sao Paulo. Some of the statements made by external stakeholders are anecdotal and evidence may not be available to support their claims. Whilst our audit protocol is designed to provide an objective independent assessment, it remains that in some cases the audit of such statements is dependent solely on the credibility of the party presenting the evidence.

This statement is not intended to provide a definitive opinion as to whether or not the CBU complies with the BMS Policy, nor does this statement constitute a guarantee or assurance by Bureau Veritas that infringements against the BMS Policy and local legislation have not taken place.

It is also not within Bureau Veritas' scope of work to provide an opinion or assessment over the appropriateness of the Policy for the implementation of the WHO Code.

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.

Our audit team members do not have any involvement in any other projects with Danone outside those of an independent audit 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 Danone 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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Bureau Veritas UK Ltd

London, 5th February 2020