

Independent assessment report of Danone's marketing practices in Panama against the Danone Policy on the Marketing of Breastmilk Substitutes ('BMS')



Introduction

Bureau Veritas UK Limited ('Bureau Veritas UK') has been engaged by Danone Specialized Nutrition ('Danone') to provide an independent assessment of alignment of its business in Panama, operating through a third-party known as Droguería SARO S.A. (the 'Distributor'), with the Danone Policy for the Marketing of Breast-Milk-Substitutes (the 'BMS Policy'), the corresponding internal Corporate guideline, the BMS Directive, and any applicable local regulation ('reference documents').

In Panama, the Government has implemented aspects of the WHO Code and related requirements through the following instrument(s): Executive Decree 1457 of October 30, 2012 and Decree 513 of May 14, 2013 and Law No. 50 of November 23, 1995 by which breastfeeding is protected and promoted in Panama (collectively the 'Local Code').

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

Scope of Work and Methodology

The assessment activities were conducted during the period 7th – 17th December 2020 with two auditors from Bureau Veritas UK undertaking activities remotely and one auditor from Bureau Veritas Panama undertaking activities in-country ('the assessment team').

During the audit, Bureau Veritas undertook the following activities:

- Interviews using video conferencing applications with 7 Distributor and Danone personnel responsible for BMS sales, marketing, and compliance;
- Review of requested documentation and records relating to BMS marketing practices on a sample basis via file-sharing and screen-sharing applications. Topics covered included:
 - local procedures and alignment with the BMS Policy and other reference documents;
 - compliance monitoring, consumer and medical marketing materials and events, labels, internal and regulatory approvals, distribution of products for professional evaluation and training.
- Review of local e-commerce sites selling Covered Products, and social media webpages managed by the Distributor;
- Visual assessment of 5 healthcare organisations (HCOs) and 54 retail locations selling Covered Products in Panama City. Bureau Veritas independently selected the locations that were visited;
- A Health Care Professional (HCP) survey with 10 respondents, including 4 Paediatrician - Neonatologist, 2 Paediatricians, 2 Gastroenterologist Paediatricians, 1 Nurse and 1 Paediatrician Allergist. Danone was

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not disclosed as the client prior to the survey in order to avoid bias in responses, nor was the Distributor informed of the individuals surveyed.

Any findings identified during the verification 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 Code 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 Code, could be improved to further strengthen the Distributor's practices.

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

Non-conformances:

1. Distribution of Products for Professional Evaluation (PPE)

The Distributor provides Covered Products to HCPs on a frequent basis as PPE. However, this does not meet the criteria in BMS Policy Article 6.3 which states that PPE may only be supplied to HCPs under certain conditions such as new or changed product or labelling changes or for introducing to a new HCP.

2. Covered product placement in retail

A special display in the form of a gondola end containing Covered Products was observed in one retail store. This is considered a promotional device as defined in Article 3.3 of the BMS Policy which states that 'Danone does not use point of sale, advertising, sampling or any other promotional devices to induce sales of Covered Products directly to the consumer at retail level.' We note that the gondola end display did not only contain Danone products and there is no evidence to suggest this display was set up at the request of the Distributor or Danone.

Opportunities for improvement:

1. Provision of Training

Article 11.1 of the BMS Policy states that 'All Danone Employees and Partners responsible for the Marketing of Covered Products 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.' Based on the induction and refresher training materials reviewed during the assessment for those involved in distribution and sales, the materials do cover the relevant clauses of the WHO code, but give only limited reference to the BMS Policy and the Local Code. The 2020 training records reviewed were not complete for employee training, and the Distributor could not demonstrate that training has been received by all of its employees involved in the distribution and sales of Covered Products.

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2. PPE distribution tracking

The Distributor tracks PPE distribution through a book of HCPs signatures against a disclaimer which acts as HCP receipt and acknowledgement. This disclaimer can be improved and should include all the requirements of BMS Policy Article 6.4 around reasons of providing the PPE, and non-linkage of the same to any inducements as well as understanding of the Local Code and WHO code.

3. Whistle-blowing system

The awareness of the Danone Ethics Line should be improved through increased training on the topic and possibly some local awareness campaigns as well.

4. Allegations, Investigations & Sanctions

The Distributor should put in place a formal process for internal tracking and reporting of non-compliances with the BMS policy and also encourage monitoring of the same through their employees.

5. Information and educational materials

The printed detailing aids which are provided to HCPs should have legible size and clearly visible statement around "For Health Worker use only - not for distribution to the general public".

There were a number of areas identified where the compliant practices are well managed and these instances have been summarised in an internal report to Danone.

Limitations

2020 – Amended Delivery Approach

Due to the COVID-19 pandemic outbreak and associated travel restrictions, the delivery approach in 2020 was amended as the Bureau Veritas UK team leading this assessment was unable to travel to Panama.

Bureau Veritas Panama coordinated and conducted visits to retail outlets to visually assess alignment with the Policy. Interviews with the Distributor personnel and review of relevant documentation were conducted remotely via video conferencing and electronic file-sharing. Face-to-face interviews with HCPs could not be conducted due to the health risks associated with visiting Health Care Organisations (HCOs) during the pandemic. Instead, a remote survey of HCPs was conducted via telephone. A detailed methodology of the assessment conducted is provided in the Scope of Work and Methodology section of this statement.

The amended delivery approach in 2020 has a number of limitations, such as:

- Document review and interviews with stakeholders may not provide the same level of detail or information when conducted remotely.

These are in addition to the limitations of conducting this type of engagement where travel to the country of assessment is possible.

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Visual inspections of retail outlets were limited to Panama City. Whilst our methodology is designed to provide an objective independent assessment, it remains that some of the statements made by stakeholders are anecdotal and evidence may not be available to support their claims.

This statement is not intended to provide a definitive opinion as to whether or not the Distributor complies with the BMS Policy. Neither the assessment conducted by Bureau Veritas nor this statement constitutes a guarantee or assurance by Bureau Veritas that infringements against the BMS Policy and Local Code 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 BMS Policy.

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 190 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 verification team members do not have any involvement in any other projects with Danone outside those of an independent assessment 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.

The core team of Bureau Veritas UK has extensive experience of undertaking WHO Code assessment related work. 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

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