

Independent assessment report of Danone’s marketing practices in Paraguay against the Danone Policy for the Marketing of Breastmilk Substitutes (BMS)



Introduction

Bureau Veritas UK Limited ('Bureau Veritas') has been engaged by Danone Early Life Nutrition ('Danone') to provide an independent assessment of alignment of the Danone Specialized Nutrition business in Paraguay (the 'CBU'), 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 Paraguay, the marketing of Breast Milk Substitutes ('BMS') is regulated principally through the *Ley 1478 – de Sucesdaneos de la Leche Materna* (the 'Local Code').

Products covered by the BMS Policy and the Local Code are BMS intended for infants aged between 0 and 12 months, including those for special medical purposes ('Covered Products').

Scope of Work and Methodology

The assessment activities were conducted between 16-27 October 2023 using one Lead Auditor, one from Bureau Veritas and one local Auditor from Bureau Veritas Paraguay. The Lead Auditor conducted the head office interviews via videoconference calls, and the local Auditor conducted the marketplace audit in-country.

During the audit, Bureau Veritas undertook the following activities:

- Interviewed 10 personnel from the distributor representing the CBU responsible for BMS sales, marketing, and compliance using video conferencing applications;
- Reviewed 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 product for professional evaluation and training;
- Reviewed 7 e-commerce sites selling Covered Products;
- Visually assessed 56 retail locations selling Covered Products in Asunción. Bureau Veritas independently selected the locations that were visited;
- Conducted a Health Care Professional ('HCP') survey with 8 respondents by telephone;
- Visually assessed 7 Healthcare Organisations ('HCOs')

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

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- 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 the Local Code, could be improved to further strengthen the CBU's practices.

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

Non-conformances:

1. Labelling requirements

Article 21(b) of the Local Code states that labels of Covered Products must include the language "Breastfeeding is the best nutrition for the baby, preventing diarrhoea and other illnesses." Bureau Veritas reviewed a sample of labels and identified that they did not include the complete statement as per the local code, instead referencing partially that breastfeeding is the best nutrition for the baby. As such, this has been classed as a non-conformity against article 21(b) of the Local Code. However, Bureau Veritas notes that based on sampling the prerequisite regulatory approvals for the commercialisation of the products and labels were in place.

2. Mandatory Statements on HCP Materials

Section 5.2 of the BMS Policy sets out requirements for information materials and communications with HCPs. In addition, Article 14(c), (d) and (e) of the Local Code set out additional mandatory statements to be included in such materials regarding complementary feeding. Bureau Veritas reviewed a sample of 8 HCP information materials and communications and found that these were missing elements of both Article 14 from the Local Code and Section 5.2 of the BMS Policy. These instances have been grouped into one single non-conformance against both the BMS Policy and the Local Code.

3. Products for Professional Evaluation (PPE)

Sections 6.3 and 6.4 of the BMS Policy establishes the requirements for distribution of PPE. Bureau Veritas reviewed the records for distribution of PPE and based on this the reason for distributing PPE was not clearly aligned with the permitted conditions in Section 6.3 of the BMS Policy. Bureau Veritas also found that the 2 unit maximum per HCP set out in Section 6.4 of the BMS Policy was also not consistently adhered to in selected instances. Finally, the document trail for distribution off PPE should include a receipt that stipulates the purpose for distribution as professional evaluation only and that it is not an incentive to purchase, resell or recommend Covered Products. These deviations against the BMS Policy regarding PPE distribution have been grouped into one single non-conformity.

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4. Promotion of covered products in store and online

Section 3.1 of the BMS Policy states that “Danone does not advertise or promote Covered Products to the general public”. In addition, Section 3.3 of the Danone Policy establishes, “Danone does not use point of sale, advertising...or any other promotional devices to induce sales of Covered Products directly to the consumer at retail level.” Bureau Veritas visited 56 retail location and identified 4 stores with point of sale materials (POSM) promoting discounts applicable to Covered Products. Nutrilon Stage 3 branded shelf liners were also placed under Covered Products. Finally, in Paraguay it is understood that it is common practice for pharmacies to offer set discounts on all products from all brands for loyalty customers without excluding Covered Products, as observed both online and in store. These multiple instances have been grouped into one single non-conformity against Sections 3.1 and 3.3 of the BMS Policy. However, we note that there was no evidence to suggest that these promotions have been placed at the request of Danone or the CBU.

Opportunities for improvement:

1. Low value gifts to HCPs

Article 19(a) of the Local Code states that it is prohibited for health agents to accept gifts of any kind and value from a manufacturer, importer or distributor. The definition for health agents in Article 3(a) is interpreted by Bureau Veritas to include health professions as defined in Article 3(o). Bureau Veritas found that the CBU gifts low value items to HCPs on occasion. We note that these gifts refer exclusively to non-Covered Products and that the prohibition is addressed to health agents. Nonetheless, irrespective of local practice, it is recommended that the CBU distributor consider refraining from offering gifts to HCPs in support of HCPs meeting the requirements under the Local Code.

2. BMS Policy Training

Under section 11.1 of the BMS Policy “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”. The CBU delivers training to its employees on an annual basis. However, Bureau Veritas suggest that the training content be updated to better incorporate of local context and regulation as well as include more interactive and visual content. In particular, the training could include what is the channel for reporting non-compliances and what is expected with respect to monitoring and reporting of BMS Policy breaches.

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3. PPE Tracking

Sections 6.3 and 6.4 of the BMS Policy set out the conditions and requirements for when distribution of PPE of Covered Products is permitted. Bureau Veritas reviewed the records for distribution of PPE and identified an opportunity to strengthen centralised control and visibility of this activity clearly setting out the date, quantity, and reason for distribution of PPE on that occasion.

4. Regulatory Checks and Approvals

The BMS Policy established throughout that its requirements are subject to local laws where these are stricter. Whilst a process has been introduced with the CBU to provide approval for any materials shared by Danone with the CBU, there is no documented checklist or process for reviewing these materials against Local Code requirements. It is suggested that this be put into place.

5. Reduced price sales to HCOs by Tender

Section 4.6 of the BMS Policy specifies the requirements for the supply of BMS to healthcare organisations. The CBU supplies public hospitals with Covered Products as per an established public and competitive tender process. Bureau Veritas understands that the CBU does not fix a minimum price due to fluctuation in costs, instead agreeing on viable discounts on a case by case basis. It is recommended that the CBU retain a document trail to support the proposed reduced price and demonstrating that it is not loss leading and therefore susceptible to the perception of promotion of Covered Products.

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

2020-23 – Amended Assessment Approach

Since the COVID-19 pandemic outbreak in 2020, Bureau Veritas has transitioned to an amended hybrid delivery approach. In this instance, a UK based auditor conducted the CBU interviews remotely and an in-country auditor conducted visits to retail outlets only in order to visually assess alignment with the BMS Policy in Paraguay. HCP surveys were conducted by telephone instead of face-to-face interviews at HCOs. This amended delivery approach has the limitation that 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 all activities are undertaken in the country of assessment.

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Visual inspections of retail outlets were limited to the city of Asunción, Paraguay. 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 the CBU 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 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 BMS Policy.

Statement of independence, impartiality, and competence

Bureau Veritas is an independent professional services company that specializes 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 assessment 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 BMS Compliance 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 BMS compliance.



Bureau Veritas UK Ltd

London

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