

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

Introduction

Bureau Veritas UK Limited ('Bureau Veritas UK') has been engaged by Danone Early Life Nutrition ('Danone') to provide an independent assessment of alignment of its business in Ecuador, operating as Ecuaquimica Ecuatoriana de Productos Quimicos S.A. (the 'Country Business Unit' or '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 Ecuador, the Government has implemented the WHO Code and related requirements mainly through the following laws and regulations:

- Law of the Promotion, Support and Protection of Breast-Feeding: Law No. 101, Registro Oficial 814 de 1 de Noviembre de 1995
- Law No. 1479 Registro Oficial 321 de Jueves 18 de Noviembre de 1999
- Regulations Authorization and Advertising Processed Food Promotion: Ministerial Agreement 40, Official Registry 388 of February 18, 2011

that regulate the marketing of Breast Milk Substitutes (collectively the 'Local Code').

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

Scope of Work and Methodology

The assessment activities were conducted remotely in October 2024 using one Lead Auditor from Bureau Veritas UK and two auditors from Bureau Veritas Ecuador. The Bureau Veritas UK Lead Auditor conducted the head office interviews via videoconference calls, and the Bureau Veritas Ecuador Auditors and conducted the marketplace audit both in country.

During the audit, Bureau Veritas undertook the following activities:

- Interviewed 14 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 15 e-commerce sites selling Covered Products, and social media webpages managed by the CBU;
- Visually assessed 50 retail locations selling Covered Products in Quito. Bureau Veritas independently selected the locations that were visited;

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- Conducted a Health Care Professional (HCP) survey with 10 respondents and visited 10 health care facilities in Quito; and
- Placed four anonymous inquiries to the customer careline.

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 the Local Code, could be improved to further strengthen the CBUs practices.

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

Non-conformances:

1. Promotion of Covered Products

During the audit it was observed that multiple e-commerce platforms and retail stores were offering discounted prices for Covered Products. These instances are considered promotion of Covered Products contrary to Article 3.3 of the BMS Policy and have been collectively grouped into one non-conformance. There was no evidence to suggest that these promotions were placed at the request of Danone or the CBU.

2. Product for Professional Evaluation (PPE)

The system used by the CBU to document PPE distributed during 2024 does not record sufficient information to demonstrate that the requirement of sections 6.3 and 6.4 of the BMS Policy have been met. Specifically, the system does not record the reason for PPE distribution or the full written receipt from the HCP. In addition, from review of a selection of records of PPE distribution from 2024, it was evident that more than two units of (the same) Covered Products have been supplied to individual HCPs; this does not meet with the requirements of BMS Policy section 6.4 which states a maximum of two units of Covered Product per HCP.

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3. Material for the General Public

A selection of information materials to the general public, distributed in retail outlets and via HCPs were reviewed as part of the audit. For several materials intended to be provided to mothers of new infants, the complete requirements of Section 2.2 of the Danone Policy regarding the importance of breastfeeding have not included on the materials. In addition, Section 2.3 of the Danone Policy requires that information for mothers should only be provided with the written approval of the appropriate authority/ institution and that information is distributed via the Health Care Organisation (rather than by the HCP), and there is no evidence of this approval being requested for the information material reviewed. The Local Code (Law No. 101: Article 9) also specifies that the name or logo of the manufacturer is not permitted in materials that originate in public hospitals. This requirement has not been met as the material was branded with a name/ logo associated with the CBU.

Opportunities for improvement

1. Training

During review of training records, it was noted that there was no centralised log of completion of all training and no test of understanding or declarations confirming attendance of the training sessions. We would recommend formalising the approach for training records so that a complete overview is available for all employees and with a system that can flag when refresher training is due. The system for recording attendance, completion and understanding of training by employees would also benefit from improvement.

2. Promotion of Covered Products

The process for review of compliance in ecommerce could be extended beyond the current remit with direct contracted suppliers and formalised to ensure that any promotions for Covered Products are identified and removal is requested promptly from third-party retailers.

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.

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Limitations

2020-22 – Amended Assessment Approach

Since the COVID-19 pandemic outbreak in 2020, we have transitioned to an amended hybrid delivery approach where the Bureau Veritas UK team leading the audit does not travel to the country of assessment, but a Bureau Veritas in-country auditor conducts visits to retail outlets to visually assess alignment with the Policy in Ecuador and also carries out a telephone survey of HCPs instead of face-to-face interviews. 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 travel to the country of assessment does take place.

Visual inspections of retail outlets were limited to the city of Quito. 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.

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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 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.



Bureau Veritas UK Ltd

London

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