

Independent assessment report of Danone’s marketing practices in UAE against the Danone Policy on 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 UAE, operating as Nutricia Middle East DMCC (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 UAE, the Government has implemented aspects of the WHO Code and related requirements through the following instrument(s): UAE Cabinet Resolution No. (21) of 2018 Regulating the Marketing of Infant and Young Child Feeding Products and Ministerial Resolution no. (257) of 2020 concerning the implementation of some provisions of Cabinet Resolution No. (21) of 2018 regulating the marketing of products related to infant and young child (collectively the ‘Local Code’).

Products covered by the BMS Policy and the Local Code are BMS intended for infants aged between 0-24 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 UAE undertaking activities in-country (‘the assessment team’).

During the audit, Bureau Veritas undertook the following activities:

- Interviews using video conferencing applications with 18 CBU personnel responsible for BMS sales, marketing, and compliance;
- 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.
- Review of local e-commerce sites selling Covered Products, and social media webpages managed by the CBU;
- Visual assessment of 11 healthcare organisations and 52 retail locations selling Covered Products in Abu Dhabi. Bureau Veritas independently selected the locations that were visited;
- A Health Care Professional (HCP) survey with 8 respondents, including 3 Paediatricians, 3 Nurses, 1

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Neonatologist and 1 Dietician. Danone was not disclosed as the client prior to the survey in order to avoid bias in responses, nor was the CBU informed of the individuals surveyed; and

- Two anonymous calls to the 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 of the law without consulting a UAE based legal counsel
- 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.

Area of Risk:

- A finding which is not a failure to meet a written requirement of the BMS Policy but may be interpreted by stakeholders as going against the intention of the BMS Policy or the 'spirit of the WHO Code'.

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

Non-conformances:

1. Promotion of Products for the 12-24 month age range to the General Public

The CBU conducts active marketing of Stage 3 brand Covered Products for the 12-36 month age range through the Danone social media accounts, via ecommerce and in retail stores, including display materials, promotions and discounts. Promotion of Covered Products for the 12-24 month age range which overlaps with the Danone Stage 3 products is prohibited by Local Code Articles 3 and 13 (2018 Regulation).

2. Information and Educational Materials

Article 4 of the Local Code (2018 Regulation) states that Information and Educational Materials on the Infant and Young Child Feeding cannot be published without the prior approval of the Competent Health Authority, but no approvals have been requested or received for any of the Health Care Practitioner (HCP) detailing materials reviewed during the audit. Article 5 of the Local Code (2018 Regulation) states that all forms of information and educational materials regarding the Covered Products shall not contain the brand name, trademark or logo of the Provider. On all HCP detailing materials reviewed, the brand and logo were present. It should be noted that Danone state that there is currently not a Competent Authority established for review of such Information and Educational Materials in UAE.

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3. HCP Events

The CBU sponsors some scientific seminars and events, where they provide support to the organisers directly. Organisers of some past events have included the UAE Ministry of Health. Part of this sponsorship is used to pay the registration fees for select HCPs to attend. Article 13(7) of the Local Code states that the Health worker may not Accept aids for the purpose of arranging or attending conferences, seminars or workshops.

4. Promotion of covered products to the General Public

During the marketplace assessment, Bureau Veritas identified one instance of a price reduction for a Covered Product via an online retailer. We note that there is no evidence to suggest this discount was done at the request of the CBU. Article 3.3 of the BMS Policy 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.'

Opportunities for improvement:

1. Internal Reporting

The process for internal tracking and reporting of BMS non-compliance could be strengthened and formalised as currently any issues identified directly by the Regulatory Affairs team are not captured in the monitoring and reporting process and the quarterly update to Corporate process, though it did appear that there is effective closeout applied based on the records reviewed during the audit.

2. Labelling

Labels can be improved to match exactly with the wording requirements of the Local Code Article 8 (2018 Regulation) which requires the following statement about breast milk: 'It protects against Diarrhea and other diseases.'

3. Training

Records of distributor training attendance could be improved as currently only event details are recorded, not individuals in attendance.

4. Information and Educational Materials

HCP informational material contains a statement that breastfeeding is best for infants but doesn't contain all of the information listed in BMS Policy Article 5.2 (and 2.2). Also, the statement "For Health Worker use only - not for distribution to the general public" is often on the last page only and could be more clearly signposted by adding to the front page of all HCP materials.

5. HCP Gifts

Although there was no evidence that gifts were given to HCPs in 2020, the CBU should update their manual to align to the Local Code (2018 Regulation) which states that gifts are not allowed to be given to HCPs.

Area of Risk:

1. Information and Educational Materials

One of the sampled medical marketing campaigns reviewed during the assessment included language that the audience could interpret as a direct comparison between Covered Products and breast-milk. Danone should consider reviewing the language used in this and future campaigns so that it does not allow for such interpretation.

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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 UAE.

Bureau Veritas UAE coordinated and conducted visits to retail outlets to visually assess alignment with the Policy. Interviews with the CBU 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.

Visual inspections of retail outlets were limited to the city of Abu Dhabi. 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 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 specialises in quality, environmental, health, safety and social accountability with over 190 years history in providing independent assurance services.

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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.



Bureau Veritas UK Ltd

London, 22nd March 2021