

Danone Early Life Nutrition

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



Move Forward with Confidence

Independent Statement by Bureau Veritas

Introduction

Bureau Veritas has been commissioned by Danone Early Life Nutrition (Danone) to provide an independent verification of Danone's Breast Milk Substitutes (BMS) businesses in Malaysia (the Country Business Unit or CBU) on compliance 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.

In Malaysia, the Government is implementing aspects of the WHO Code and related requirements mainly through the following instruments: Ministry of Health Code of Ethics for the Marketing of Infant Foods and Related Products; and P.U.(A) 437/85 Food Regulations 1985 (incorporating latest amendment - P.U. (A) 200/2017) (collectively, 'the local code').

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

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

Scope of Work and Methodology

The verification was conducted in Malaysia between the 19-23 August 2019, using one verifier from Bureau Veritas UK Ltd (Bureau Veritas) and a local verifier from Bureau Veritas Malaysia who also acted as a translator (as applicable).

During the verification, Bureau Veritas undertook the following activities:

- Visited the CBU head-office in Kuala Lumpur city, interviewed 27 employees and conducted a review of sample documentation and records relating to compliance with the Danone Policy.
- Interviewed 3 employees from the Kuala Lumpur region distributor and reviewed sample documentation on site.
- Interviewed 12 Health Care Professionals (HCPs) including paediatricians, family doctors, hospital administration, chief of staff/nursing, and nurses. 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 BMS Policy in 22 healthcare organisations and 37 retail locations including modern trade and traditional trade. Bureau Veritas independently selected the locations that were visited.
- Conducted an anonymous call 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 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. Placement of Covered Product in retail

During the marketplace assessment, we identified the following: four instances where Covered Products were displayed in a window visible from outside the stores and one instance where point of sale material (POSM) stating 'promo' was incorrectly placed under a stage 2 product in store. Such placement of the Covered Product or POSM constitutes a non-conformance against Article 3.3 of the BMS Policy which does not allow any activities at point of sale which may be perceived as promotional. We note that the shop front displays including Covered Products were multi-branded, that the store promotion was not running on stage 2, and that there was no evidence to suggest any of the mentioned activities were done at the request of the CBU.

2. Medical Detailing Materials

A sample of the detailing materials being used by the CBU to present to HCPs was reviewed. Bureau Veritas found that one sampled digital presentation material used by medical delegates did not include the mandatory statements stipulated in Article 2.2 of the BMS Policy. As per article 5.2 of the BMS Policy, information materials intended for HCPs 'must include the information specified in Art. 2.2 of the Code.' This has been classified as a non-conformance against article 5.2 of the BMS Policy.

Opportunity for improvement (OFI):

1. Compliance Monitoring and Reporting

Bureau Veritas found that the corrective actions for resolving and closing instances or allegations of non-compliance with the BMS Policy are not consistent with regards to third party actions. In addition, quarterly reporting to corporate was found not to include allegations relating to third party violations, nor a clear indication of the city of the alleged non-compliances. Articles 17.1 and 17.2 of the BMS Policy state respectively that 'A process is in place to ensure that accurate and complete data on compliance the BMS Policy is generated and maintained at ELN Divisional level' and 'Each BMS-CM sends her/his quarterly report to the ELN General Counsel'. In addition, article 18.4 of the BMS Policy requires that 'Any alleged non-compliance with the BMS Policy shall be recorded shortly upon receipt in a specific database detailing: city and country...'. Bureau Veritas recommends consistently documenting and reporting all allegations of non-compliance, including where applicable the corrective actions taken, to ensure completeness of records and full visibility at all levels of the business. The CBU should also ensure that responses to third party violations are consistent and aligned.

2. Retention of training records

With the exception of induction training on the BMS Policy, the HR only retains records of periodic training on the

BMS Policy in so far as these are communicated to them. Instead, training documentation relating to BMS compliance is maintained by the General Secretary organisation. Article 15.3 of the BMS Policy states, 'The responsibility for ensuring that training is conducted and that training records are maintained, resides with the Human Resources Department of the CBU'. In order to strengthen alignment with the BMS Policy, it is recommended that communication to HR regarding periodic trainings on BMS compliance be consistent so that Human Resources can track and ensure such trainings are indeed completed by relevant personnel on a regular basis.

3. Notification to commercial partners

As per the Danone Policy Scope, 'Danone ensures Partners understand and are made aware of the importance of abiding by this Policy'. Documented communication with commercial partners did not consistently reference obligations under the most recent Policy and the local code. The CBU should consider issuing periodic and documented reminders to commercial partners regarding compliance with the BMS Policy and ensure that these reference the most up to date Policy and local code requirements. In addition, the CBU should strengthen its efforts to have these communications acknowledged by commercial Partners, including requirements regarding violations reporting.

4. Grants and donations register

The CBU offers grants or contributions for the continuing professional development of HCPs via relevant medical associations and sponsors conferences in collaboration with national medical associations. A documented process is followed for these arrangements as is required by Articles 5.5 and 8.1 of the BMS Policy. Similarly, the CBU has on occasion made donations of Covered Product as is permitted under Article 10.1 of the BMS Policy. In line with internal corporate guidelines, the CBU should look to implement a grants and donations register itemising the details of each financial or in-kind contribution.

Areas of good practice:

- 1. Personnel had an overall good awareness of the requirements of the BMS Policy and the local code.
- During Health Care Facility visits, Bureau Veritas saw no evidence of Danone Covered Product branded materials being left at healthcare organisations for mothers
- 3. During retail visits, Bureau Veritas noted that third party Product Consultants engaged by the CBU are well informed on the local code and being unable to advise on Covered Products intended for under 1 year olds.
- 4. During our sample review of e-commerce sites, we saw no evidence of discount promotions of any Covered Products registered for distribution in Malaysia by the CBU.

Limitations

Visual inspections of healthcare facilities and retail outlets and external stakeholder interviews were limited to the city of Kuala Lumpur and surrounding areas. Some of the statements made by external stakeholders are anecdotal and evidence may not be available to support their claims. Whilst our verification protocol is designed to provide an objective independent assessment, it remains that in some cases the verification 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. Neither the limited verification 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 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 verification team members do not have any involvement in any other projects with Danone outside those of an independent verification 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

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