

Danone's Report on External Audits Undertaken on Compliance with its Policy for the Marketing of Breast-Milk Substitutes For the twelve months ended 31 December 2018

DANONE AND RESPONSIBLE MARKETING PRACTICES

The World Health Organisation ("WHO") adopted *The International Code of Marketing of Breast-milk Substitutes (the 'WHO-Code')* in 1981, as a minimum requirement to protect appropriate marketing practices for infant and young child feeding. The WHO-Code is a set of recommendations to regulate the marketing of Breast-milk Substitutes ("BMS").

At Danone, we acknowledge the importance of the WHO Code and, via our Danone's Policy for the Marketing of Breast-Milk Substitutes (Policy), we aim to clarify the minimum standards of behaviour expected from our worldwide employees and partners who are involved in products covered under the Policy.

As a company, it is important that we are consistent, clear and transparent. It is also imperative that we continually monitor our marketing practices, ensuring compliance with our Policy and local/national regulations at all times.

MONITORING OUR PRACTICES AT DANONE

The purpose of monitoring our practices is for continuous improvement and to identify whether the Policy is being followed in all Country Business Units (CBU). Verifications, audits and/or reviews can be undertaken by both internal and external resources. To undertake external audits, Danone has engaged suitably qualified third-party experts.

The external audits that have been undertaken in 2018, and as described further in this report, aimed to assess compliance with the Policy in effect during this period. In 2018, we had committed to an annual external audit plan – in which a minimum three (3) CBUs were audited. As it was the case for the 2017 reporting year, these audits were undertaken by Bureau Veritas UK Limited¹, an independent, external audit and verification firm.

Bureau Veritas has provided detailed audit findings to the CBUs and to the Early Life Nutrition (ELN) Divisional Headquarters of Danone. Each relevant CBU has reviewed the detailed audit findings, and documented actions required to address the findings. We appreciate the objectivity provided by Bureau Veritas, as its thorough audit processes have highlighted areas where we can further improve our processes and practices in compliance with our Policy.

¹ Bureau Veritas is an independent professional services company that specialises in quality, health, safety, social and environmental management advice and compliance with more than 180 years of history in providing independent assurance services.

(<http://www.bureauveritas.com>).

AUDIT WORK CONDUCTED 1 JANUARY TO 31 DECEMBER 2018

Bureau Veritas undertook audits in 2018 in the following locations: Ethiopia, Russia and Argentina. These countries have been selected by Danone based on risk management elements which include in-market business developments and rates of children's acute malnutrition and infant mortality. The scope of each of the Bureau Veritas' audits includes interviews and document review with the CBU, visual inspections of retail outlets and interviews with Health Care Professionals (HCP). Bureau Veritas arranged an independent schedule of interviews and visits for the assessment period. Danone was not disclosed as the manufacturer being assessed, in order to avoid bias. Detailed findings and recommendations from the audit have been provided to the relevant CBU as part of an internal management report.

This report represents a summary overview of the 2018 audits, including the corrective actions taken by the CBUs. Any findings identified by Bureau Veritas during the audits have been categorised as per the following:

- A. Non-conformance, and
- B. Opportunity for improvement, and
- C. Areas of good practice.

ETHIOPIA

A. Non-conformance

Bureau Veritas reviewed various employment contracts for the employees and noted that these do not include a statement that the new employee should support the aim and principles of the WHO-Code and a requirement for the employee to comply with the Policy as mentioned in section 7.2 of Danone's Procedures. The CBU has taken corrective action by updating the letter of appointment with the inclusion of complying with the WHO Code.

B. Opportunity for improvement

First of all, the CBU should consider developing a formal internal documentation procedure to demonstrate continual monitoring related to reporting of violations against the Danone Policy and local regulations. Secondly, it is recommended that the wording of work-related targets for medical representatives be reformulated to mention that the is related to coverage of facilities and it is not related to sales. Thirdly, although the local authority has approved the product labels and are not currently enforcing the requirement of having the label at least in Amharic or Amharic and English, Bureau Veritas recommends Danone get further clarification from regulators and take into consideration the introduction of Amharic language on Infant Formula labels to align with their local directives and possible further developments in local regulations. Danone has taken these improvement points into account and will act upon.

C. Areas of good practice

Danone staff has a good awareness of the requirements of the WHO Code and the Danone Policy. During Health care facilities visits, Bureau Veritas saw no evidence of samples of Danone products being provided to Health Care Professionals or Danone

branded materials being given to HCPs for distribution to mothers. Besides, Bureau Veritas saw no evidence of Danone branded special displays/promotional materials or any discounts being offered for Danone Covered Products during the retail visits.

[Link to the Bureau Veritas Summary Audit Statement for the Ethiopia Business Unit.](#)

RUSSIA

A. Non-conformance

Bureau Veritas identified that employees' contracts do not include a statement related to "undertaking induction and regular training on the Danone Policy" and a statement related to "reporting to management any unethical or inappropriate activities in relation to the marketing of BMS". This is noted as a non-conformance to section 7.2 of Danone's Procedures Manual. Danone has all necessary statements from the local normative acts in the employees' contracts.

During its 40 visits to retail outlets, Bureau Veritas identified one instance of discount for Covered Products and one instance of special displays for Covered Products. These instances have been identified as a non-conformance against the requirements of Article 3.1 and 3.3 of the Policy which states that no discount or promotion of Covered Products is allowed. However, the CBU does not have any contractual relationship with these retailers and there was no evidence to suggest that the activities identified were conducted with the CBU's request or consent. In response to these findings, Danone has taken prompt corrective action in collaboration with its business partners to stop the activity initiated by the reseller. Several initiatives have also been rolled out to increase the awareness of business partners related to the marketing of BMS. These include training and development of communication material that reinforce the Policy's requirements regarding the advertising and promotion of BMS.

B. Opportunity for improvement

Bureau Veritas identified 2 online retailers offering discount prices for Covered Products. Bureau Veritas recommended the CBU to monitor and engage with resellers on an ongoing basis to ensure that discount schemes do not include Covered Products, even if the CBU does not have any contractual relationship with these retailers. Danone will keep on re-iterating our commitments and the importance of compliance to our Policy.

C. Areas of good practice

Bureau Veritas identified that Danone staff have a good awareness of the requirements of the WHO Code and the Danone Policy. During HCP interviews it was noted that there is a general perception amongst HCPs that Danone is compliant with the WHO Code and is not promoting Covered Products to mothers. During the retail visits, Bureau Veritas saw no evidence of any Danone direct promotional activity related to the use of point of sale, advertising, sampling or any other promotional devices to induce sales of Covered Products directly to the consumer at retail level. Finally, during a call to the Careline, the response from the operator was fully compliant with the Policy.

[Link to the Bureau Veritas Summary Audit Statement for the Russia Business Unit.](#)

A. Non-conformance

Article 6.4 of the Policy states a maximum of two units of Covered Products may be given to HCPs for Product for Professional Evaluation (PPE) purposes. Due to misinterpretation by the CBU, Bureau Veritas found an instance where the limit stipulated in the Policy was misinterpreted. In addition, one PPE was identified in a healthcare organisation without a sticker 'For Professional Evaluation Only' as required under Article 6.5 of the Policy. Danone has taken corrective action and delivered additional training to the CBU, reinforcing the requirements of the Policy regarding the advertising and promotion of BMS and issued a procedure for the correct labelling of PPE.

During its 44 visits to retail outlets, Bureau Veritas identified one instance of discount for Covered Products and one instance of special displays for Covered Products. These instances have been identified as a non-conformance against the requirements of Article 3.1 and 3.3 of the Policy which states no discount or promotion of Covered Products is allowed. However, the CBU does not have any contractual relationship with these retailers and there was no evidence to suggest that the activities identified were conducted with the CBU's request or consent. Danone is taking corrective action in collaboration with the industry association to stop the activities initiated by the retailers. Several initiatives are also rolled out to increase the awareness amongst retailers of regulations related to the marketing of BMS through the development of communication material reinforcing the requirements of the Policy regarding the advertising and promotion of BMS.

Bureau Veritas reviewed documentation for an educational event for Health Workers organized by the CBU, and noted one instance of insufficient scientific content in the agenda of the event which did not meet the requirements of Article 7.7 of the Policy. Danone has taken prompt corrective action through the delivery of additional training to the CBU reinforcing the requirements of the BMS Policy and the Healthcare Systems Compliance Policy for future scientific events.

B. Opportunity for improvement

Bureau Veritas recommends establishing and following a set procedure for resolving and closing instances or allegations of non-compliance with the Policy with consistently documented corrective actions taken. Also, in order for retailers to be aware of the latest BMS Policy, the CBU should consider issuing periodic and documented reminders to commercial partners regarding compliance with the Policy and local code requirements. Thirdly, Bureau Veritas recommends aligning the wording of the PPE template with the Policy to ensure proper documentation of receipt of PPEs while strengthening the control and oversight of PPE distribution. Danone has taken these improvement points into account and will act upon.

C. Areas of good practice

Bureau Veritas identified that the CBU staff has an overall good awareness of the requirements of the WHO Code and Danone Policy. It was noted that the message of breast-milk being the best is well communicated in the market through the medical-

representatives. During healthcare visits, Bureau Veritas saw no evidence of Danone branded materials being given to HCPs for distribution to mothers. During a sample review of e-commerce sites, Bureau Veritas saw no evidence of promotions or discounts for Covered Products online. Last, Bureau Veritas noted that the CBU has a well-established and documented internal review process for the approval of any consumer or HCP marketing activities, materials, and information.

[Link to the Bureau Veritas Summary Audit Statement for the Argentina Business Unit.](#)