

# 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 2015

## 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 and promote 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 Policy and Management System Manual, we aim to clarify the minimum standards of behaviour expected from all employees.

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 the WHO Code and local/national regulations at all times.

## MONITORING OUR PRACTICES AT DANONE

In 2013, Danone published its Policy for the Marketing of Foods for Infants and Young Children (the 'Green Book') and the Management System Manual for the Marketing of Foods for Infants and Young Children - (the 'Blue Book'). The audits that have been undertaken in the year 2015, and as described further in this report, were to verify compliance with the Danone Policies in effect during this period. <sup>1</sup>

The Management System Manual, focusses on the following four key areas:

1. Assessment and Verification
2. Managing Allegations of Non-compliance
3. Reporting (internal and external) of Non-compliance
4. Responsibilities of Danone Employees.

## THE PROCEDURES MANUAL - ASSESSMENT AND VERIFICATION

To ensure that both our Policy and Management System Manual are effectively and correctly implemented, assessments and verifications are conducted, which aim to:

- Ensure Danone fulfils its commitments to market Breast-Milk Substitutes ("BMS") responsibly at all times;
- Monitor compliance with the Danone Policy for the Marketing of Foods for Infants and Young Children, and local laws and regulations;
- Identify deficiencies in the internal control processes and systems;
- Recommend corrective actions for deficiencies identified.

Verifications, audits and/or reviews can be undertaken by both internal and external resources. Danone has engaged suitably qualified third party experts, to undertake external audits.

In 2015, we had committed to an annual audit plan - in which a minimum five (5) Country Business Units ("CBU's") were audited. As was the case for the 2014 reporting year, these audits were undertaken by Bureau Veritas UK Limited<sup>2</sup>, an independent, external audit and verification firm.

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<sup>1</sup> Attached is the [Policy for the Marketing of Foods for Infants and Young Children](#) and the [Management System Manual for the Marketing of Foods for Infants and Young Children](#), which were in place for the year 2015.

<sup>2</sup> 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>).

Bureau Veritas conducted an analysis of the changes to the Policy and also the Procedures Manual for implementing the Policy. They concluded that had the audits been based on the updated Policy and Procedures Manual, the findings would not have been materially different.

**BUREAU VERITAS, AND AUDIT WORK CONDUCTED 1 JANUARY TO 31 DECEMBER 2015**

Bureau Veritas undertook audits in 2015 in the following locations: India, Kingdom of Saudi Arabia (KSA), Kazakhstan, United Arab Emirates (UAE) and Spain. 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 Workers. The reporting to management by Bureau Veritas is on areas of concerns and other recommendations.

If during the course of the audit, Bureau Veritas notes that that processes or controls are not in place, or that there are systematic deviations from the Policy, then this would be reported as an Area of Concern.

- A. For each audit undertaken, we have noted below: An executive summary of the areas of concern – analysed as to whether originating from CBU review, retail outlets or Interviews with Health Care Workers, and
- B. A summary of the follow up actions undertaken, and
- C. Areas of good practice identified from the audit (if applicable).

**KAZAKHSTAN**

- A. **The audit of the Kazakhstan Business Unit, identified the following area of concern:**  
Implementation of Systems for complying with the Policy: There was no evidence in place for monitoring the Customer Relationship Management (CRM) employees' compliance with the Policy.
- B. **Follow up and Actions Taken:** Whilst the general scripts provided to the CRM employee, have gone through an extensive internal Communication Validation Management (CVM) procedure, we recognise the need to periodically ensure that the scripts are understood. We will on a regular basis, ask the CRM employee to reiterate his/her understanding and comprehension of the communication, and on an ad-hoc basis place calls to the CRM line to verify what is being stated. Any communications that are not clear or concise can then be followed up on, as required.

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

**KINGDOM OF SAUDI ARABIA (KSA)**

- A. **In relation to Interviews with Health Care Workers, the following areas of concern were noted:**
  1. *Education Events:* Out of nine Health Care Workers interviewed, one indicated that written approval is not consistently sought prior to providing or conducting non-product related educational events for mothers;
  2. *Product for Professional Evaluation (PPE):* Out of nine Health Care Workers interviewed, one indicated that a verbal request (instead of a written request) for PPE is sufficient to obtain Covered Products.
- B. **Follow up and Actions Taken:** The principles of our Policy regarding written approval before providing education and support (in Health Care Facilities) and before providing PPE has been reiterated to all employees that liaise/interact with Health Care Workers. Training materials to employees have included special attention on these 2 observations.
- C. **In terms of areas of good practice:** Of the nine health care professionals interviewed, all reported that Danone has one of the strictest approaches to compliance with the regulations for the marketing of BMS.

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

**SPAIN**

There were no areas of concern arising from the audit of the Spanish Business Unit.

**In terms of areas of good practice:** Formal documented processes and controls are mostly in place, and effectively implemented for compliance with the BMS Policy. The Health Care Professionals interviewed reported that Danone maintains high ethical standards.

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

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## INDIA

### A. The audit of the Indian Business Unit, identified the following areas of concerns:

1. *Informational & Educational Materials:* Some of the materials examined recognised the superiority of breastfeeding statement but did not include the full statement on the use of infant formula.
2. *Communications to Distributors:* Not all distributors had been made aware of the importance of abiding by relevant laws and Danone Policies on BMS.

### B. Follow Up and Actions Taken::

1. *Informational & Educational Materials:* A complete review has been conducted on all information & educational materials, to ensure the correct and full statements as required by the Policy, have been included. Additionally, the CVM process for the review and approval of all informational and educational materials has now been implemented locally.
2. *Communications to Distributors:* Management recognised this is as an area to be addressed, and commenced a nation-wide distribution to major distributors, to reiterate the aims and principles of a) the WHO Code, b) the Danone Policy for the Marketing of BMS, c) responsible marketing practices and d) local laws and legislation surrounding BMS. In addition, as part of a continual improvement programme, in 2016, Distributor Principles have been drafted that reiterate the key principles from the Danone Policy for the Marketing of BMS as applicable for distributors.

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

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## UNITED ARAB EMIRATES (UAE)

There were no areas of concern arising from the audit of the UAE Business Unit.

**In terms of areas of good practice:** All health care professionals interviewed stated that Danone has one of the strictest approaches to compliance with the regulations for the marketing of BMS.

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

## SUMMARY

Bureau Veritas have provided detailed audit findings to the CBUs and to the Early Life Nutrition (ELN) Divisional Headquarters of Danone.

Each CBU has reviewed the detailed audit findings, and documented actions required to address the findings.

In conclusion, for Danone, the undertaking of external verifications with an independent and recognised third party is crucial to our continuous improvement as an organisation. We appreciate the objectivity provided by Bureau Veritas, as their thorough audit processes have highlighted areas where we can progress further our compliance with our Policy.