

# ***Independent assessment report of Reckitt Benckiser Plc's marketing practices in Colombia against RB's Policy and Procedures on the Marketing of Breast-Milk Substitutes***



## **Introduction**

Bureau Veritas UK Limited ('Bureau Veritas UK') has been engaged by Reckitt Benckiser Plc. ('Reckitt') to provide an independent assessment of alignment of its business in Colombia, operating as Reckitt Benckiser (Colombia) SA ('Reckitt Colombia'), with the RB Policy and Procedures on the Marketing of Breast-milk Substitutes (BMS) – April 2018, updated November 2020 (the 'BMS Policy') and the applicable local regulations implementing the WHO Code in Colombia (the 'Local Code').

Products covered by the Policy and Local Code are BMS intended for infants aged between 0-24 months including both Routine and Speciality formulas ('Covered Products').

## **Scope of Work and Methodology**

The assessment activities were conducted during the period 22<sup>nd</sup> September to 13<sup>th</sup> October 2021 with one auditor from Bureau Veritas UK undertaking activities remotely and one auditor from Bureau Veritas Colombia undertaking activities in-country (the assessment team).

During the audit, Bureau Veritas undertook the following activities:

- Interviews using video conferencing applications with 15 Reckitt Colombia personnel responsible for BMS sales, marketing, or 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, etc.;
- Review of online media in Colombia, local e-commerce sites selling Covered Products, and social media webpages managed by the Reckitt Colombia;
- Visual assessment of 47 retail locations selling Covered Products in Bogotá, including pharmacies, supermarkets, hypermarkets and general stores;
- A Health Care Professionals (HCP) survey; and
- Two anonymous call to the Reckitt Colombia Careline.

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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:**

- A process/activity/document that, while currently conforming to the BMS Policy and local directives, could be improved to further strengthen Reckitt Colombia's practices.

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

### **Non-conformances:**

#### *1. Communication of the BMS Policy to Third Parties*

Bureau Veritas reviewed a sample of contracts with third parties. Two instances were identified where the BMS Policy requirements for communication with third parties were not met:

- The BMS Policy Procedures Section 1 requires that written agreements include clauses that address compliance with the Local Code, WHO Code and the BMS Policy. However, there was no reference to the WHO Code or BMS Policy in the sample of contracts reviewed for third-party medical marketing agencies.
- There was no evidence that training on the BMS Policy, the WHO Code or the Local Code has been provided to the third-party agencies who provide support with in-store merchandising. This is required under Article 11.5 of the BMS Policy.

#### *2. Website Promotion to the General Public*

Bureau Veritas identified that a section of the Reckitt Colombia customer facing website promoted a non-covered product as suitable for the 12-23 month age bracket. As per Article 7 of the Local Code it is not permitted to promote infant formula intended for children under 2 years.

#### *3. Ecommerce Promotion to the General Public*

Price reduction promotions for Covered Products were identified in two e-commerce platforms. Promotion of Covered Products is not permitted under Article 7 of the Local Code or BMS Policy Article 5.1. There was no evidence to suggest that these promotions were placed at the request of Reckitt Colombia.

#### *4. Educational Material for HCPs*

Bureau Veritas reviewed a sample of HCP detailing materials. One of these detailing materials did not contain the information on the benefits of breast-feeding from WHO Code Article 4.2, as required by Article 7.2 of the BMS Policy.

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## *5. Distribution of Product for Professional Evaluation (PPE)*

Reckitt Colombia engages in distribution of Covered Products which go beyond permitted PPE purposes as outlined in the BMS Policy Article 7.4. In addition, the Local Code establishes in Articles 8 and 9 that BMS Manufacturers are not permitted to distribute infant formula samples to HCPs or directly and/ or indirectly to mothers.

Whilst the Local Code does not define PPE, Reckitt Colombia have commissioned a legal opinion that concludes that BMS Manufacturers can distribute products to health professionals for their professional evaluation, but this position has not been clarified with the Regulator.

### **Opportunities for improvement:**

#### *1. PPE Requests from HCPs*

HCP request letters for PPE are required under Article 7.4 of the BMS Policy, but not all of these were stored on the Reckitt system. It is recommended that Reckitt Colombia confirm with the Regulator that PPE distribution is permissible under the Local Code; if permitted then then a full document trail in an accessible location should be retained for all PPE requests.

#### *2. Training*

The onboarding training materials reviewed during the audit did not contain complete and accurate information about the process, frequency and conditions under which PPE can be distributed. The training materials should be updated to fully align with the Reckitt Policy and the Local Code.

#### *3. Sponsorship of HCPs*

Several events were reviewed as part of the audit where Reckitt Colombia sponsored HCPs to attend. Article 7.5 of the BMS Policy requires that 'such contributions should be communicated to the institute to which the HCP is affiliated'. While the communication from Reckitt Colombia with the HCPs did mention that it is the responsibility of the HCP to inform their affiliated institute, it could not be demonstrated that this was taking place. Reckitt Colombia could strengthen their processes by making this responsibility clearer to the HCP and collecting affirmation of this from the HCP to ensure that the requirements of BMS Policy Article 7.5 are being met.

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There were a number of areas identified where the compliance practices are well managed, and these instances have been summarised in an internal report to Reckitt.

## **Limitations and exclusions**

### **2020/21 – Amended Assessment Approach**

Due to the COVID-19 pandemic outbreak and associated travel restrictions, the delivery approach in 2020 and 2021 was amended as the Bureau Veritas UK team leading this assessment was unable to travel to Colombia and the Reckitt offices are closed making face-to-face contact with management/employees not feasible.

Bureau Veritas Colombia coordinated and conducted visits to retail outlets to visually assess alignment with the Policy. Interviews with the Colombia 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 below in the Scope of Work and Methodology section of this statement.

The amended delivery approach in 2020 and 2021 has a number of limitations, such as:

- It is not possible to conduct visual assessments of HCFs without visiting and inspecting the practitioner areas of those facilities;
- Document review and interviews with stakeholders may not provide the same level of detail or information when conducted remotely; and
- Only two HCPs agreed to take part in the survey, in part due to the 'remote' format.

These are in addition to the limitations of conducting this type of engagement where travel to the country of assessment is possible.

Additionally, visual inspections of retail outlets were limited to the city of Bogotá. 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. The results of the telephone HCP survey conducted were therefore not used to draw upon findings of this report.

This statement is not intended to provide a definitive opinion as to whether or not Reckitt Colombia 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 of 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,

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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 verification team members do not have any involvement in any other projects with Reckitt 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 Reckitt 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, 3<sup>rd</sup> February 2022**