

Independent assessment report of Reckitt Benckiser Plc's marketing practices in Dominican Republic 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 the Dominican Republic, operating as Mead Johnson Dominicana S.A. ('Reckitt DR'), 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 the Dominican Republic (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 25th September – 5th October 2023 with one auditor from Bureau Veritas UK undertaking activities remotely and one auditor from Bureau Veritas Dominican Republic undertaking activities in-country (the assessment team).

During the audit, Bureau Veritas undertook the following activities:

- Interviews using video conferencing applications with 22 Reckitt DR personnel responsible for BMS sales, marketing, or compliance;
- Review of 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 local e-commerce sites selling Covered Products, and social media webpages managed by Reckitt DR;
- Visual assessment of 51 retail locations selling Covered Products in Santo Domingo, including pharmacies, supermarkets and baby centres;
- Visual assessment of public waiting areas of 10 healthcare facilities;
- A Health Care Professionals (HCP) survey by telephone with 10 respondents; and
- Two anonymous calls to the customer careline.

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



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 DR's practices.

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

Non-conformances:

1. Distribution of Samples

Reckitt DR has engaged in distribution of Covered Products to HCPs which goes beyond permitted Product for Professional Evaluation (PPE) purposes specified in BMS Policy Article 7.4. The HCPs pass these Covered Products on to mothers of infants, which is considered indirect sampling to consumers and not permitted according to BMS Policy Article 5.2. The Local Code does not define PPE, but does define samples which BMS Manufacturers are not permitted to distribute for Covered Products according to Articles 11 and 15.

In addition, the Covered Products distributed are not labelled correctly as required by BMS Policy Article 7.4.

2. Utility Items for HCPs

Free gift utility items provided by Reckitt DR to HCPs were printed with the company name and logo which is not permitted according to Local Code Article 11(c).

3. Supply of Covered Product to Healthcare Entities (HCEs)

Reckitt DR supply Covered Products to HCEs as part of their procurement, invoicing and payment processes, but the requests from the HCEs are not always given in writing as required by BMS Policy Article 6.6.

4. Promotion to the General Public

A total of 51 third-party retail outlets selling Covered Products were visited as part of the audit. During these visits, two instances of promotional activities were identified, which is not permitted according to BMS Policy Article 5.1 and Local Code Article 11. There was no evidence to suggest that these promotions were placed at the request of Reckitt DR.

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



Opportunities for improvement:

1. Information Materials for HCPs

A selection of HCP detailing aids were reviewed as part of the audit. Although all of items reviewed had the required statements from Policy Articles 7.2 and 4.2, the text 'for HCP Only' was not clearly visible, as it was often contained in a footer and/ or on end pages of the document.

We would recommend that the disclaimer text to indicate that the material is just for HCPs should be clearly marked on the front page of any detailing materials to ensure the intended user is clear to anyone reading the documentation.

2. Training

Training records for selected individuals were reviewed as part of the audit. While no gaps in records were identified, there is an opportunity to formalise the approach for compiling training records so that a complete overview is available for all employees and with a system that can flag when refresher training is due or overdue.

3. Internal Audit

Prior internal audit reports were reviewed as part of the audit and were found to be conducted on a regional basis and there was not a focus on individual country legislative requirements (Local Code). For future internal audits that are carried out on a regional basis, we would recommend that country specific regulations are taken into account.

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 DR.

Limitations and exclusions

2020-23 – Amended Assessment Approach

Since the COVID-19 pandemic outbreak in 2020, we have transitioned to an amended hybrid delivery approach where the Bureau Veritas UK team leading the audit does not travel to the country of assessment, but a Bureau Veritas in-country auditor conducts visits to retail outlets to visually assess alignment with the Policy in Dominican Republic and also carries out a telephone survey of HCPs instead of face-to-face interviews due to continued restrictions in place at most Health Care Organisations. This amended delivery approach has the limitation that 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 does take place.

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



Additionally, visual inspections of retail outlets were limited to the city of Santo Domingo. 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 DR 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, 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, 3rd September 2024