

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 Peru, operating as RB Health Peru S.R.L. ('Reckitt Peru'), 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 of 1981 in Peru (the 'Local Code').

For the purpose of this report, 'Covered Products' are formula products intended for infants and young children, aged between 0-24 months, as covered by the BMS Policy and the Local Code.

Scope of Work and Methodology

The assessment activities were conducted during the period 10th to 18th October 2022 with one auditor from Bureau Veritas UK undertaking activities remotely and one auditor from Bureau Veritas Peru undertaking activities in-country (the assessment team).

During the audit, Bureau Veritas undertook the following activities:

- Interviewed 32 Reckitt Peru personnel responsible for Covered Product sales, marketing, or compliance using video conferencing applications;
- Reviewed requested documentation and records relating to Covered Product marketing practices on a sample basis via file-sharing and screen-sharing applications. Topics covered included:
 - o 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.;
- Reviewed online media in Peru, local e-commerce sites selling Covered Products, and social media webpages managed by or on behalf of Reckitt Peru;
- Visual assessment of 62 retail locations selling Covered Products in Lima;
- Visual assessment of public areas of 15 healthcare facilities;
- Conducted a telephone survey with four Health Care Professionals (HCPs);
- Placed four anonymous calls to the Reckitt Peru 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 satisfy local legal or statutory requirements as per our interpretation

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 Peru's practices.

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

Non-conformances:

1. Distributor Contracts

Contracts with a sample of distributors used by Reckitt Peru were reviewed as part of the audit. There was no evidence of a contract obligation for the Distributor to certify compliance with the BMS Policy, as required by BMS Policy Procedures Section 4.a.

2. Distribution of Samples/ Product for Professional Evaluation (PPE)

Reckitt Peru has engaged 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 45 and 48 that BMS Manufacturers are not permitted to distribute infant formula samples to HCPs in health facilities.

Reckitt Peru have commissioned two legal opinions that conclude that BMS Manufacturers can distribute samples to health professionals operating independently in their own practice, but this position has not been clarified with the Regulator.

3. Promotion to the General Public

Three instances of price reductions and other promotional activities were identified at e-commerce retailers, which is not permitted according to BMS Policy Article 5.1 and Local Code Article 44. There was no evidence to suggest that these promotions were placed at the request of Reckitt Peru, who do not have a contractual relationship with these e-commerce retailers.



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Opportunities for improvement

1. Sponsorship of HCPs

Several events were reviewed as part of the audit where Reckitt Peru 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 Peru 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. In addition, the Local code Article 49 does not allow sponsorship from BMS manufacturers where sales of BMS are made to the affiliated institute (if applicable), but as the HCPs don't list their affiliated institute and no check has been done on this by Reckitt Peru, it is unclear whether the requirement from the Local Code has been met.

We would recommend that Reckitt Peru require HCPs to disclose any affiliated institute when receiving sponsorship as this would allow Reckitt Peru to cross-reference this with Health Care Facilities where they supply infant formula and ensure they are meeting the requirements of the Local Code and the BMS Policy.

2. Promotion to the General Public

A selection of materials were reviewed as part of the audit, including promotional materials for non-Covered Products. For three of the materials reviewed, the children used appeared to be less than 24 months of age. As such, the promotional materials could give the impression that the product advertised is suitable for infants of less than 24 months, and promotion of such products is not permitted under Local Code Article 32, 41 and 44. For two out of three of these materials, Reckitt Peru could not provide any robust evidence that the children used in these promotional materials were over 24 months at the time of production.

We would recommend that Reckitt Peru has robust evidence to support that any children used in promotional materials for non-Covered Products are older than 24 months and that they are associated with age-appropriate clothing/ items.

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 Peru.

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Limitations and exclusions

2020-22 – Amended Hybrid Delivery 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 Peru 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.

Additionally, visual inspections of retail outlets were limited to Lima. 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.

This statement is not intended to provide a definitive opinion as to whether or not Reckitt Peru 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.

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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, 13th December 2022