

Introduction

Bureau Veritas UK Limited ('Bureau Veritas UK') has been engaged by Reckitt Benckiser Plc. ('RB') to provide an independent assessment of alignment of its business in Brazil, operating as Mead Johnson do Brasil Comércio e Importação de Produtos de Nutrição Ltda. in Brazil ("RB Brazil"), with the RB Policy and Procedures on the Marketing of Breast-milk Substitutes (BMS) – April 2018 (the "Policy") and the applicable local regulations implementing the WHO Code in Brazil (the "Local Code").

Products covered by the Policy and Local Code are BMS intended for infants aged between 0-12 months ('Covered Products').

Scope of Work and Methodology

The assessment activities were conducted over a five days during the period 21st September and 12th October 2020 with one auditor from Bureau Veritas UK undertaking activities remotely and one auditor from Bureau Veritas Brazil undertaking activities in-country (the assessment team).

During the audit, Bureau Veritas undertook the following activities:

- Interviews using video conferencing applications with RB Brazil 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:
 - o local procedures and alignment with the 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 Brazil, local e-commerce sites selling Covered Products, and social media webpages managed by the RB Brazil;
- Visual assessment of 43 retail locations selling Covered Products in Sao Paulo, including pharmacies, supermarkets, hypermarkets and baby centres;
- Visual assessment of 5 healthcare facilities;
- A telephone Health Care Professional ('HCP') survey with 4 respondents, including a GP and three Paediatricians; and
- Two anonymous call to RB Brazil's 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 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 ('OFI'):

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

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

Non-conformances:

1. Statements on informational material for HCPs:

Bureau Veritas reviewed detailing materials being used by RB Brazil for providing product information to HCPs. As per Article 7.2 of the Policy the below requirements apply to all materials – whether informational, educational or audio-visual: [...] Marketing, informational and/or educational materials are clearly labelled as 'For HCP Only - not for distribution to the general public' and should also include all information noted in Article 4.2 of this BMS Marketing Policy.

All materials that RB present to HCPs are understood to be in electronic format only. The electronic informational materials intended for HCPs that were presented during the audit were not clearly labelled 'For HCP only - not for distribution to the general public'.

2. Promotional devices for Covered Products:

RB Policy and Procedures Article 5.3 states that 'RB does not use point-of-sale advertising, sampling or any other promotional devices to induce sales of Covered Products directly to the consumer, at retail level'. This is also a requirement of the Local Code.

RB Brazil have permanent Stock Keeping Units (SKUs) for the sale of 1600g Covered Products which consists of two 800g containers sold together in one pack. The product was seen in the market and the internal approvals for the product were reviewed. The presentation of two 800 g containers being sold together in tertiary packaging could act as an inducement of sales to the consumer where the double container packaging is perceived as a combination sale and therefore has the effect of a promotional device which is not permitted as per Article 5.3 of the Policy and the Local Code.

3. Covered Products Placement in retail stores

During retail visits, Bureau Veritas identified two instances where Covered Products have been placed in a prominent position in store window and adjacent to the cashier. RB Policy and Procedures Article 5.3 states that 'RB does not use point-of-sale advertising, sampling or any other promotional devices to induce sales of Covered Products directly to the consumer, at retail level'. This is also a requirement of the Local Code.

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4. Promotion to the general public

In five retail outlets a price reduction promotion was offered for Covered Products, RB Policy and Procedures Article 5.3 states that 'RB does not use point-of-sale advertising, sampling or any other promotional devices to induce sales of Covered Products directly to the consumer, at retail level'. This is also a requirement of the Local Code.

5. Product promotion via online platform

On three ecommerce sites a price reduction promotion was offered for single or multiple item purchases of Covered Products. RB Policy and Procedures Article 5.3 states that 'RB does not use point-of-sale advertising, sampling or any other promotional devices to induce sales of Covered Products directly to the consumer, at retail level'. This is also a requirement of the Local Code.

Opportunities for improvement:

1. Compliance monitoring process:

The RB Procedures, Article 4 as contained in the Policy states that "allegations from both inside and outside the Company will be investigated and remediated (if necessary) promptly, with a target response that is reasonable and expeditious". The process applied was observed during the audit, but there was not a formal process for tracking the closeout of allegations of violations raised by external stakeholders or communication of closeout to the stakeholder. RB Brazil should consider developing a more formalised process to track closeout of issues and communication of action back to the stakeholder who reported the issue.

2. Distribution of Product for Professional Evaluation (PPE):

The RB Procedures, Article 7.4 as contained in the Policy states that "[...] Distribution of PPE of Covered Products is only provided in response to an authorised, written request from the HCP [...]". For PPE authorisation RB appeared to be following the procedure, but it was not possible for RB Brazil to evidence via the RB electronic records system that the HCPs have requested or received the PPE. It should be noted that this was not an issue where hard copy forms are used and scanned where full evidence was available. RB Brazil should work with the electronic records system developer to ensure that complete records are maintained for future PPE requests, and to see if records can be recovered for prior PPE issue.

3. Communication to Third Parties:

There have been recent contract amendment letters sent to wholesaler distributors to include reference to the BMS Policy. In addition to this measure, RB Brazil should consider communications and training to a wider group to raise awareness of the BMS Policy, WHO Code and Local Code.

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

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Limitations and exclusions

2020 – Amended Assessment Approach

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

Bureau Veritas Brazil coordinated and conducted visits to retail outlets to visually assess alignment with the Policy. Interviews with the Brazil personnel and review of relevant documentation were conducted remotely via video conferencing and electronic file-sharing. Face-to-face interviews with Health Care Professionals (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 has a number of limitations, such as:

- It is not possible to conduct visual assessments of Health Care Facilities without visiting and inspecting the practitioner areas of those facilities; and
- Document review and 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 is possible.

The following select elements of RB's Policy and Procedures were excluded from our review at the request of RB: Article 8.1 on Bonuses and sales incentives; Section 2 on Training and Communications for own employees and distributors involved in marketing and sales of BMS.

Additionally, visual inspections of retail outlets were limited to the city of Sao Paulo.

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. For this reason, the telephone HCP survey conducted was not used to raise findings in this report.

This statement is not intended to provide a definitive opinion as to whether or not the Brazil 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 against 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.

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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 RB 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 RB 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, 11th January 2021

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