



Interactions with Healthcare Professionals and Healthcare Entities

CORPORATE COMPLIANCE SOP



CORPORATE POLICY

RB HEALTH COMPLIANCE GLOBAL POLICY

Interactions with Healthcare Professionals and Healthcare Entities

1. Purpose and Scope

Purpose

Reckitt Benckiser's Health Business Unit and its subsidiaries ("RB") are committed to the ethical promotion and distribution of RB Health products ("RB products"), including but not limited to, over-the-counter medicines and devices, sexual health products, personal hygiene and skin care products, foot care products, vitamins, dietary supplements and nutritional products for infants, children, and adults. RB acknowledges that it is often necessary to collaborate with healthcare professionals ("HCPs"), government officials ("GOs") acting as healthcare professionals and healthcare entities ("HCEs") to assist in business development efforts, share clinical experiences and educate HCPs, patients and other stakeholders about product-related information. RB is committed to promoting its products and sharing knowledge in a fair and balanced way, concentrating on science and education.

RB recognizes that interactions with HCPs, HCEs and GOs that involve any transfer of value (e.g. payment for service, sponsorships, grants, or any other benefit) represent a risk of being perceived as an inducement or bribe to direct business to RB. This Policy ("Policy") describes the global compliance standards and processes that must be followed in order to ensure that:

- (i) RB never offers or provides inducements to HCPs, HCEs or GOs to win business or to use, prescribe, purchase, influence, or recommend RB products or reward past purchases, and
- (ii) RB's interactions with HCPs, HCEs and GOs comply with all applicable legal and regulatory requirements and are ethical in both appearance and in fact.

Scope

This Policy is applicable to all RB employees, contractors and sub-contractors (including any agents and other third parties interacting with HCPs, GOs and HCEs on behalf of RB). This Policy sets forth RB's minimum compliance standards for interacting with HCPs, GOs and HCEs. Where local law, regulations, standards or other RB procedural documents apply and require more stringent controls, then such more stringent controls must be followed. These more stringent local requirements and controls are set forth in the Appendices to this Policy and the applicable SOPs that support this Policy.

It is the responsibility of each local market to ensure that such more stringent local requirements and controls are properly and accurately reflected in the Appendices to the Global SOPs and strictly adhered to. If a proposed interaction with an HCP, GO or HCE is not contemplated by or described in this Policy and related SOPs and Appendices, then such interaction is not permitted. See section 5.A Advice & Questions should there be a question about a contemplated activity.

In some countries, HCPs who are employed full- or part-time by public hospitals, universities, institutions, or organizations are considered GOs. Public hospitals, universities, institutions and organizations are considered government entities ("GEs"). This Policy applies to all HCPs and HCEs, regardless of whether they are also considered government officials or government entities. However, additional rules apply to all individuals who are GOs or GEs, please review RB's "Anti-Bribery Policy" for further guidance. For additional guidance regarding specific interactions, please consult a member of the Ethics & Compliance team.



2. Policy Statement

Interactions with HCPs and HCEs

Interactions with HCPs and HCEs must be professional exchanges intended to communicate information regarding RB's products and services or share education through non-promotional interactions. Listed below are permissible interactions RB may have with HCPs and HCEs. Within each SOP there is guidance on acceptable interactions and an Appendix which captures more stringent local regulations and requirements which must be followed in each applicable market. The following must always be read in conjunction with the related Global SOP and Appendices.

1. Fee-For-Service Arrangements

RB may engage qualified HCPs and HCE personnel (e.g. nurses) as speakers or consultants to provide bona fide and appropriate services to RB such as: speaking to HCP audiences on behalf of RB, consulting on product development or product claims, participating in an RB-sponsored advisory board, clinical trials, publications, or market research. See Global SOP [“Fee For Service Arrangements”](#).

2. Sponsorship, RB meetings and Visits to RB Facilities

In certain appropriate and limited situations, RB may:

- a) Provide sponsorship to HCPs to attend events organized, developed and hosted by third party organizations such as medical conferences and medical education events;
- b) Provide financial support to third party organizations for medical education events attended by HCPs that are organized, developed and hosted by those third-party organizations;
- c) Hold educational and product training meetings and events regarding RB products for HCPs and HCE personnel in third party facilities or at RB facilities (organized directly or indirectly by RB).

See Global SOP [“Sponsorships, RB Meetings, and Visits to RB Facilities”](#).

3. Meals, Gifts, & Hospitality

RB may from time to time in connection with consulting arrangements, product training and certain education activities provide modest meals and/or hospitality to HCPs. Where permitted by local law, applicable industry standards, institutional restrictions, and RB policies and processes, [as set out in the SOP] appropriate items may be provided to HCPs [and HCE personnel] that are practice related items, patient delivered items, promotional items or cultural/social courtesy gifts. These must be modest in value, not excessive in quantity and given infrequently. Appropriate values are further detailed in the Global SOP [“Meals, Gifts, & Hospitality to HCPs and HCEs”](#).

4. Grants & Charitable Contributions to HCEs

In limited situations, RB may provide grants to reputable institutions, organizations, or associations for the advancement of science or patient and public education in relation to health and nutrition. RB may provide charitable contributions to reputable institutions, organizations or associations to support established charities and foundations. See Global SOP [“Grants & Charitable Contributions to HCEs”](#)

5. Samples and Products for Professional Evaluation (PPE)

Samples and associated accessories/devices intended for trial use may be provided to HCPs and HCEs so that they can better assess the effectiveness of RB products and acceptance from their patients. PPE is a small quantity of IFCN Covered Products which enables HCPs and HCEs in “Higher-Risk” countries to gain experience on the efficacy of RB Products while evaluating tolerance and acceptability from their patients (as defined in the BMS Marketing Policy). See Global SOP [“Samples and Products for Professional Evaluation \(PPE\) to HCPs and HCEs”](#) and [“Breast Milk Substitution \(BMS\) Marketing Policy”](#).



6. HCE Purchase / Use Agreements

Bids, tenders and contracts are processes and means by which a hospital, hospital system, or payer negotiates the price and term of purchase/use of RB products. These interactions are highly regulated in each country as transfer of value exists that could be perceived as an inducement or bribe. See Global SOP “HCE Purchase and Use Agreements SOP”.

7. Scientific Interactions with HCPs

Scientific engagements with HCPs are regularly held by RB for the development of scientific understanding and innovation in our products. Some of these activities are Clinical Studies, Advisory Boards, Steering Committees, Scientific Consultancy and internal education and training. See Global SOP “Scientific Interactions with HCPs”.

8. Interactions with Pharmacists

Interactions with Pharmacists (with or without license) that are in position to administer, influence or recommend the purchase or use of RB products at a pharmacy, drugstore, supermarket or any other location. These interactions are sometimes regulated in the countries and special care should be taken to ensure these are not perceived as an inducement or bribe. See Global SOP “Interactions with Pharmacists”.

3. Requirements for Additional Activities

A. Promotional Materials

Where allowed, promotional materials may be disseminated to HCPs and HCEs to promote the understanding of RB products’ claims thus contributing to customer care.

- a. All promotional content must be accurate, scientifically sound, factual, balanced (i.e. address not only positive, but also side effects and evidence, as well as any product warnings) and objective, reflect the current state of scientific knowledge and be consistent with the label information and licensed indications as approved by local regulatory authorities.
- b. No product shall be promoted to HCPs or HCEs (or consumers) prior to the grant of the product’s license or registration. This does not prohibit educating HCPs about products and ingredients that are being considered in the future for approval.
- c. Promotion of products outside of the licensed/approved indication(s) (off-label use) is prohibited. HCPs shall be advised on how to report adverse events occurring in relation to RB products. Where an RB employee or representative receives an adverse event report from an HCP or HCE they shall follow the process outlined in RB’s Code of Conduct and related health and safety policies.

Utilization of Branded and Unbranded Materials

For all interactions with HCPs and HCEs, branded and unbranded materials are required to be reviewed and approved through the applicable approval process (e.g. Brandworks, Labelling Excellence Approval Process (LEX), Promomats, ZINC or other system/process, depending on the availability in the country/region). The applicable approval process confirms that the information contained in materials is fair and balanced, accurate and – where and when available – based on clinical data, appropriate for the audience, and consistent with international and local regulations on advertising to consumers and HCPs.

Approval process for promotional materials to be delivered to HCPs or HCEs must include an approval by:

- (1) Regulatory and/or Legal (2) Marketing (Promo) (3) Medical and/or Nutrition Science.



Scientific materials to be delivered to HCPs for use on Clinical trials, advisory boards or other non-promotional scientific activities will follow the review and approval process established by the Medical function mentioned in Global SOP “Scientific Interactions with HCPs”.

All approved documents must be retained and archived by the local market, region or global function with evidence of such approval.

B. Detailing

Where permitted, RB employees (e.g. sales representatives) may interact one-on-one or with a group of HCPs to discuss product, product-related service details and scientific information on a product’s uses and benefits. RB personnel are prohibited from compensating a HCP for time or participation in a detailing session. Materials used for detailing may only be those that have been reviewed and approved through the applicable approval process (section 3A above).

C. Advertisement on HCP or HCE Owned Materials or Domains

Payments for the advertising of RB products in HCP or HCE owned domains where the HCP or HCE receives all or a portion of such payment(s) (directly or indirectly from RB) is permitted only where payment is at fair market value (“FMV”). The calculation of the FMV must be documented and should not be based on the return on investment.

- a. Advertising in HCP or HCE domains includes advertising on the premises of an HCE or HCP’s facility or office, on its website and in other materials. All advertising must be fully removable from the premises when the advertising agreement ends. For example, construction of permanent advertising signage or displays or other renovations to the HCP or HCE space that increases the functional use of the premises is prohibited (e.g. RB may not paint, wallpaper, or otherwise remodel the HCP/HCE premises for purposes of complementing the advertising). All such arrangements must be approved by the Regional Ethics and Compliance Director prior to the placement of any paid advertising in HCP or HCE domains through the agency.
- b. Advertising at congresses, at other CME type events or within a Medical Association or Society Journal are also permitted provided its payment is at fair market value and subject to any other limitation or requirements of this Policy or related SOPs.
- c. In High Risk Countries as defined in the BMS Marketing Policy, advertising (displays, placards or posters) of IFCN covered products in HCEs facilities is not allowed.

4. Appendix

Market Restrictions Grids

Review the market restrictions grid available for your country (by accessing the web-link located in the Rubi>Corporate Policies>Interactions with HCP/HCEs) to determine if there are further requirements that must be followed in your market.

In case of doubts with the applicable regulation for your country/region, please contact a member of the Ethics & Compliance team or from the Legal function.

5. Contact Information

A. Advice and Questions

If you ever have doubt about the right course of action, or if you have questions about this Policy or compliance, please consult a member of RB’s Ethics and Compliance group. Exceptions to this Policy or the related SOPs and Appendices are expected to be exceedingly rare. Requests for exception to this Policy



or related SOP must be approved in advance by the country GM (or his/her designee) and the RB Chief Ethics and Compliance Officer (CCO) (or his/her designee).

Any revisions to this Policy and the SOPs must be approved by the CCO and any revisions to the Appendices to reflect changes in local laws, regulation or standards that are more stringent than this Policy and the SOPs must be approved by the CCO or designee and the GM of the market(s) impacted by the change. Changes to the Appendices that would result in a local requirement that is less stringent or restrictive than this Policy and related SOPs listed under section 2 above are not permitted.

B. Raising Concerns and Reporting Obligations

As set forth in the RB Code of Conduct, if you become aware of a situation that may involve a potential or actual violation of this Policy or other wrongdoing that affects our business, you are expected to speak up and report the issue as soon as possible in accordance with the requirements of RB's "Speak Up Policy Concerning Potential Breaches of Code of Conduct".

6. Discipline for Non-Compliance

Violations of an RB policy or process may also constitute violations of law and may result in civil or criminal penalties for which RB personnel will be held responsible. In some cases, RB may have a legal or other obligation, or may otherwise determine that it should report violations to the appropriate enforcement authorities. Leaders in RB are expected to demonstrate the appropriate "tone at the top" and provide the necessary guidance and support to their team members, including resource allocation when necessary, allowing them to comply with the provisions of this policy. RB may take disciplinary action against its employees and contractors, up to and including termination or cancellation of contract, as applicable, for failure to comply with this Policy.

7. Applicability of this policy

This policy supersedes all previous version of any Policy and SOPs (global or local) regarding interactions with HCPs and HCEs, either from RB legacy or Mead Johnson Nutrition. This include any guidelines established for Interactions with HCPs and HCEs in the PACT policies (e.g. "Marketing support and resources brand promotion, consumer samples, coupons"). This policy should be interpreted together with other related RB policies such as Responsible Advocacy, BMS Marketing Policy, Anti-Bribery and Corruption and others as needed. Additional restrictions may apply in relation to IFCN Covered Products, which are noted in the respective SOPs of this Policy and the BMS Marketing Policy

**Appendix. Global Definitions**

Term	Definition
Advisory Boards and Counsels	A group meeting of 3 or more paid consultants, at least one of whom is an HCP, retained by RB to provide RB specific business advice, or knowledge-enhancing scientific information for RB products or RB areas of interest. Examples: Global Allergy Advisory Board, Global Respiratory Infection Partnership (GRIP) for Strepisils, Chicago Neonatal Intensive Care Unit (NICU) to discuss Enfamil Liquid Human Milk Fortifier and nutrition for the neonate;
Bids & Tenders	A process in which public or private hospital, hospital system, or payer negotiates the price and term of product use, purchase, rotation, availability, etc. Examples could include: Women, Infants and Children (WIC), Requests for Proposals (RFPs), hospital contracting, Group Purchasing Organization (GPO) contracting, or Government Tenders or reimbursement application. National private and government tenders on yearly basis, etc.
Breast Milk Substitutes (BMS) Marketing Policy	The BMS Marketing Policy is the guideline established by RB with regards to any food, being marketed, or otherwise presented as a partial or total replacement for breast-milk, for Infants up to 12 months, whether or not suitable for that purpose. RB's BMS Marketing Policy outlines the mandatory marketing practices on Covered Products in Higher-Risk Countries.
Consultant	An HCP, HCE, medical or scientific advisor, or other third party retained by RB to provide consultancy services to the RB.
Consultant Engagement	Paid services by RB in which HCPs retained by RB to provide bona fide RB specific business advice or knowledge; enhancing scientific information for RB products or RB areas of interest. Examples could include: HCP advice and/or development of a Medical Education program (e.g. Allerni, nurse board to develop Nurse Medical Education Program), Contract Consultant, Advisory Board (e.g. NICU advisory board to discuss/evaluate RB NICU portfolio), Expert Panel (Gaviscon Ad Board to discuss Alginate + PPIs co-prescription science).
Continuing Medical Education (CME)	Continuing medical education refers to a specific form of continuing education that helps those in the medical field maintain competence and learn about new and developing areas of their field. These activities may take place as live events, written publications, online programs, audio, video, or other electronic media.
Contract	A written agreement that defines obligations and is enforceable by law.
Covered products	RB IFCN products including, infant formula, follow on formulas, delivery products and complementary foods and beverages for infants under six months of age in Higher-Risk Countries.
Detailing (Group and 1 on 1)	A meeting between RB employees and an individual HCP or a group of HCPs that is used to provide product, product related service details, and scientific information on a product's potential uses and benefits.
Entertainment	Any activity resulting in amusement or enjoyment, unrelated to the scientific or business purpose of such interaction. Examples include sporting activities, sightseeing, bars, nightclubs, concerts, or gambling.
Ethics & Compliance	RB Group Ethics & Compliance Department based in RB Global Headquarters.
FMV	Fair Market Value
Fee for Service	A charge or payment, based on Fair Market Value, to an individual HCP for a bona fide service to RB.
Formal visits of RB Facilities	Invitations by RB personnel to HCPs to visit a particular RB facility (such as the Pediatric Nutrition Institute) to demonstrate and explain RB's products, exchange knowledge-enhancing scientific and nutritional information, or to obtain appropriate business advice. Examples could include: visit to PNI; visit to RB office; and visit to a RB manufacturing facility.



Gifts	Anything of value, including but not limited to goods, services, food items, gimmicks, business courtesies, or other non-financial benefits provided as a mark of appreciation or business relationship not in exchange for commercial benefit. Examples: USB drives containing scientific literature; Medically-related text books; Pens; Note pads.
Grants	Support provided to a reputable institution, organization, or association only for the advancement of science or patient and public education in relation to a relevant and appropriate purpose and only where there is no expresses or implied benefit to RB in return, other than general goodwill, which cannot contain a commercial benefit. Examples could include: restricted or unrestricted Grant to an independent University education program.
Government Officials (“GOs”)	Government Officials (GO) include: any officer, full or part-time employee, or person acting in an official capacity for a local or national government; a government department, agency, or instrumentality; a commercial enterprise owned or controlled by a government; or a public international organization. HCPs working in public HCEs are also considered GOs, for additional guidance, please see RB’s “Anti-Bribery Policy”.
Healthcare Entity (“HCE”)	An organization that is comprised of HCPs or academic institutions, specialty societies, or patient care organizations that provide healthcare services or conduct healthcare research or training. HCEs include hospitals, pharmacies, and any other entities which purchase or dispense prescription pharmaceutical products. HCEs also include any entity which reimburses or pays for prescription pharmaceuticals such as sovereign or government health funds, insurance companies, and other payers.
Healthcare Professional (“HCP”)	Any professional who provides health care services or who is otherwise in a position to administer, influence, dispense or recommend the purchase or use of RB products. This includes but is not limited to: physicians, nurses, dieticians, physician assistants, midwives, medical residents, licensed pharmacists or pharmacy technician, and members of the formulary committees. HCPs can work in a variety of settings, including: private offices; hospitals; clinics; universities; pharmacies; and other scientific institutions.
High Risk Country	Countries included in the Listing of Higher Risk Countries that can be found at Annex 1 of the BMS Marketing Policy.
Market Research	An organized effort to gather and interpret information to inform business strategy and practices.
Meals / Hospitality	Interactions or meetings that include meals or beverages, lodging, or transportation provided to HCPs, with a genuine informational, scientific, business, or educational discussion or presentation. Examples could include: Snacks at medical conventions; Lodging provided during a consulting engagement; Transportation provided during a consulting agreement; Offsite (out of HCP office) meeting at a restaurant to educate a small group; etc.
Local Ethics & Compliance Function	RB Ethics & Compliance Department employees supporting each RB Health Area, Region or Country.
Lodging and Transportation	Accommodation, travel, and other incidental expenses paid or reimbursed by RB.
Pharmacist (licensed or technician)	Pharmacy personnel (qualified with degree), Pharmacy Technicians (holds a recognized vocational course) and Assistant Pharmacy Staff (completes a on-the-job training) in the position to recommend the use or purchase of RB products.
Products for Professional Evaluation (“PPE”)	A single container with a small quantity of “Covered Products” (maximum of 500 grams or the smallest container available –excluding sachets-) offered by RB in particular market provided at no cost to a HCP for the purpose of professional evaluation.
Product Provision	A supply of company products and associated accessories intended for trial use.
Product Purchase or Use Agreements	Agreements to secure and provide RB products in the medical customer's place of patient interaction (hospital, HCP office, etc.)



Promotion	Interactions to communicate information on pediatric nutrition science or RB products to HCPs or HCEs.
Promotional Activities	Activities undertaken, organized, or sponsored by or on behalf of RB that is intended to promote the prescription, recommendation, supply, administration, sale, or consumption of RB products.
RB Meetings and Events	Events and meetings attended by HCPs where RB business and/or scientific information are discussed. Examples could include: RB Cow's Milk Allergy Symposium; RB Allergy Day Medical Education Event; KOL speakers bureau lectures; RB hosted Nurse conference; PNI Meetings and Symposia; Gaviscon + PPIs co-prescription symposium; etc.
Samples	RB product and associated accessories provided to HCPs or HCEs, intended for trial use, to provide patients and HCPs an opportunity to become more familiar with RB products.
Speaker	An HCP engaged by RB to speak on behalf or about RB, its product portfolio or therapeutic fields related to RB products.
Speaker Engagement	RB engages HCPs to speak at events to share relevant scientific/educational information and educate others on RB's products and/or topics pertaining to the healthcare and wellbeing. Examples could include: RB paid speakers at a scientific lecture; speaker at an open or closed Scientific Symposia; Radio; TV; internet or video testimonials; HCP web-based speaking engagement; etc.
Sponsorship	Financial support provided to an HCP or HCE related to a meeting or event.
Sponsorship to Attend Third Party Events	Financial support provided to fund the attendance by HCPs at congresses and conferences managed by third parties. Examples could include: HCPs registration fee to attend a congress (ESPGHAN, AAP, PAS etc.); support to attend a medical congress or medical education event; sponsorship to attend a national or regional medical conference; UEGW; APDW; FIP, etc.
Sponsorship of Third Party Meetings and Events	Sponsored meetings / events that provide product, disease state, or other product-related information to HCPs for promotional or non-promotional reasons. Examples could include: Accredited Continuing Education programs (e.g. Annenburg); Non-accredited Continuing Education programs (e.g. ESPGHAN symposium); Congresses (UEGW, APDW, Sexual Health Conference, ESPGHAN, AAP, PAS etc.); Local and/or regional HCP professional association (Gastro conferences of Thailand, Pakistan, etc.); Continuing Medical Education; and Nonexclusive External Sponsorship of 3rd Party Events, FIP, etc.
Third Parties	Vendors, agents, travel agents, suppliers, distributors, joint venture partnerships, or research partners, including third parties hired by one of the above on behalf of RB (often referred to as sub-contractors).
Utilization of Branded Materials	Product branded materials utilized with HCPs to promote and/or educate RB products for customer use for purposes of understanding of product claims related to usage, prescription, consumption, or sales of an RB product. Examples of materials that may be branded: medical sales detailer (iPad, printed etc.); public relations materials (press release etc.); literature distributed or displayed at a medical conference; promotional activities during a CME event; medical education slides; digital content; and slide deck for KOL speakers bureau. Additional guidelines for IFCN products are included in the BMS Marketing Policy.
Utilization of Unbranded Materials	Non-product branded materials utilized with HCPs to inform about the use, target population, safety, efficacy related to an RB product. Examples of materials that may be unbranded: medical sales materials; public relations materials; abstracts; reprints; manuscripts; congress presentations and posters; digital content; brochures; CME invitations; and slide deck for KOL speakers bureau.