



Consumer Safety Policy

Background

RB is committed to delivering innovative solutions for healthier lives and happier homes in a manner that continuously improves the safety profile of our products. Underpinned by our commitment to provide compliant and effective products, consumer safety is fundamental to; the integrity of our global brands and businesses, ethical practice and our responsibility as a producer of high quality products.

At all levels of the company and in all aspects of our businesses, our aim is to actively promote responsibility and concern for the safety of our consumers our employees and the general public.

Policy

It is the Policy of RB to:

1. Develop, market and monitor products that can be manufactured and used safely as directed.
2. Comply with all regulatory requirements for product safety testing, labelling and vigilance wherever a product is developed, manufactured or marketed.
3. Continually assess products, packaging, labelling, ingredients, adverse events and complaints to ensure the health and safety of consumers, customers and employees.
4. Apply consistent consumer safety standards globally.
5. Actively seek scientific, regulatory and consumer information regarding potential consumer safety issues either directly or through responsible trade associations, professional societies, regulatory authorities and consumer groups.
6. Freely disclose consumer safety information on RB products through the release of accurate, up-to-date and relevant information to appropriate governmental, professional and business organisations, and to the public.

Implementation Guidelines and Responsibilities

1. Risk Management Strategy

RB is committed to delivering better consumer solutions and marketing safe quality products. Safety is the probability that harm is unlikely to occur under specific conditions of use, either as directed or under reasonably foreseeable conditions of misuse. Safe disposal after use is also an important consideration. Products can be manufactured and used safely when the health risks associated with their manufacture and use are understood and communicated effectively so that they can be properly managed to acceptable levels by employees and consumers.



Risk management strategies to ensure the safe manufacture and use of RB products comprise:

- a. The use of non-toxic or least toxic raw materials relative to acceptable product performance, where choices can be made.
- b. Clear usage directions, classification, precautionary and First Aid labelling (compliant with regulatory requirements).
- c. Accurate Safety Data Sheets containing pertinent regulatory and safety information.
- d. Accurate product labelling in order to convey safety information to consumers in accordance with all applicable global regulations.
- e. Continual monitoring and appropriate mitigation of risks related to all RB products to ensure a safe consumer or patient experience at all times during the lifecycle of a product

2. Global Application

RB will apply consistent consumer safety standards for Company operations and products across all regions. R&D Category Group Director - Evidence, Consumer Safety & Medical Oversight (ESMO) will ensure that this Policy is applied consistently throughout the Company, and promote the global application of consumer safety practices.

3. Definitions

Hazard is the ability of a substance to harm or produce adverse effects. In the context of our businesses, hazards may be associated with ingredients and manufacturing processes, product packaging, or use and foreseeable misuse (or any misuse) or our products. Hazards may be health hazards, either acute (including irritation, corrosive, systemic effects) or longer-term (including carcinogenicity, sensitization, effects on reproduction and/or development), physical or chemical hazards (flammable materials, reactive materials, compressed gases) or environmental hazards (aquatic, soil and terrestrial or atmospheric). Product labels and Safety Data Sheets, in general, identify the known hazards associated with a particular substance or combination of substances in a formulation.

Adverse Event is any undesirable experience associated with the use of a product or substance in a patient or consumer, but which does not necessarily have a causal link with the product.

Adverse Effect/ Reaction is an undesirable experience which is causally related to the use of a product or substance.

Risk is the probability that an adverse effect will occur under specific conditions of exposure, (e.g. normal use or reasonably foreseeable misuse). Risk is a function of both hazard and exposure, with no exposure resulting in no risk, no matter how hazardous a substance may be.

Safety is the probability that harm is unlikely to occur under specific conditions of use (e.g. normal use or reasonably foreseeable misuse). A safe product is one that presents minimal risk of adverse health effects compatible with the products' chemistry, required efficacy, and use, either as directed or under reasonably foreseeable conditions of misuse.



Risk Assessment is the process by which the risk of harm associated with a specific substance and specific exposure conditions is estimated. Risk assessments, where possible, are comprised of four components:

- Hazard identification
- Dose-response determinations
- Exposure assessments
- Risk characterisation

Risk Mitigation is the process by which unacceptable levels of risk are eliminated or controlled to acceptable levels.

Responsibilities

The R&D Category Group Director, ESMO is accountable for the implementation and upkeep of this Policy.

R&D Category Group Directors are responsible for applying this Policy and implementing together with Global Consumer Safety in all areas of responsibility, involving appropriate Area and Supply colleagues in evaluation and implementation. This will include both the manufacturing and marketing of products and any product acquisitions or development undertaken. They will ensure that a safety assessment has been performed before a product is placed on the market.

Regional Regulatory Directors and Managers will abide by established Company practices to ensure that products are assessed for safety and comply with all regulations. They shall report and assist in the investigation of safety-related findings of risk or harm and take effective corrective and preventive actions.

Consumer Safety personnel are responsible for identifying health hazards, performing safety evaluations and risk assessments, assisting in developing packaging and labelling that meet all regulatory requirements and advising on compliance with consumer safety regulatory requirements and this Policy. They will respond to safety issues which affect company operations or businesses, work to implement risk prevention, management and mitigation measures and participate in scientific, regulatory and consumer debates on safety issues either directly or through relevant and responsible trade associations, professional societies and consumer groups.

All RB products will be continually monitored for adverse events and complaints. Vigilance and drug safety personnel will take specific responsibility for the collection, evaluation, monitoring and reporting of adverse events associated with medicines, cosmetics, vitamins, minerals and supplements and medical devices in accordance with regulatory requirements.

It is the responsibility of all Company employees to understand and act in accordance with the Company's commitment to consumer safety and the provisions of this Policy in their work practices.



Compliance

RB is committed to delivering better solutions to consumers and to marketing safe products. Accordingly, the Company will understand the health and safety risks associated with Company products, will have appropriate product packaging and labelling, will make effective communication of safety information, and will promote the safe and responsible use of our products. The R&D Category Group Director, ESMO and the R&D Category Group Directors shall be responsible for compliance with this Policy. It will be the responsibility of the R&D Category Group Director, ESMO to alert RB management to real or potential consumer safety issues which may endanger the health and safety of consumers and/or employees, or otherwise adversely affect the Company.

Queries regarding this policy should be directed to sustainability@rb.com

Effective February 2016. Executive Committee Policy Owner: Roberto Funari, EVP Category

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