

Abbott – Corporate Ethics and Compliance Document

ID: GLB-INFNT-FRMULA-MKT

Document Type: Policy

Title: ABBOTT POLICY ON THE MARKETING OF INFANT FORMULA

Effective By Date: May 1, 2017

Approved Date: April 18, 2017

ABBOTT POLICY ON THE MARKETING OF INFANT FORMULA

PURPOSE

We are committed to ethically marketing our products and ensuring that our practices comply with laws and regulations of the countries where we do business. The purpose of this policy is to provide Abbott employees, distributors, and agents with appropriate guidance and instruction in the marketing of infant and follow-on formula.

This policy is global in scope, and is supplemented at a country level by specific country procedures and guidance to reflect national legislation. Abbott believes that individual governments are best placed to decide how to support nutrition needs of their citizens and we therefore follow and abide by the national laws and regulations which govern promotion of our products.

ABBOTT BELIEFS AND COMMITMENTS

Abbott believes that proper nutrition is the foundation for living the best life possible. We aim to make every stage of life a healthy one – and we share this goal with many others around the world. That’s why our nutrition business is dedicated to developing science-based nutrition products for people of all ages.

Summary of Our Commitments

- Breast-feeding provides the best nutrition for infants. Abbott Nutrition supports the World Health Organization’s goal of increasing breast-feeding rates.
- We support, educate and encourage mothers to breast-feed for as long as possible, including, where possible, exclusive breast-feeding during the first six months of life and continued breast-feeding up to and beyond two years of age.
- We support and recognize the importance of introducing appropriate complementary foods from the age of six months onwards. Follow-on formula and complementary foods can play an important role in meeting the nutritional requirements of older infants or for

supplementing breast-milk for breast-feeding mothers who choose to do so. Infant formula, follow-on formula and complementary foods should not be marketed in a way that competes with breast-feeding or interferes with the protection and promotion of breast-feeding.

- We believe parents have the right to make decisions on the most appropriate way to feed their babies, and that we have an important role in ensuring they have the most accurate information about their baby's nutrition and options available.
- We are committed to communicating ethically and responsibly about our products. All statements about our products, in all materials and communications, are balanced and factual. In communicating about our products, we provide information that is supported with scientific evidence and the product labeling requirements in the countries where we operate. Review processes are in place to make sure all of our claims are accurate, supported by sound science and compliant with local regulations.
- We take nutrition seriously. We pursue science in order to help provide the best possible health outcomes for infants and young children who use our products. Abbott has conducted hundreds of clinical studies to demonstrate the safety of use and good health outcomes of our products for babies and young children.

Summary of Our Policy

- Abbott is committed to ethically marketing our products and ensuring that our practices comply with the laws and regulations of the countries where we do business. We want to be able to communicate the science around our products factually, accurately and be trusted as a source of information, so we take our commitment to marketing in this area very seriously.
- This policy and local policies and procedures should be followed to ensure compliance with local laws and regulations regarding marketing of infant formula and follow-on formula.
- We acknowledge the importance of the World Health Organization's 1981 International Code of Marketing of Breast-Milk Substitutes (the "WHO Code") and subsequent World Health Assembly (WHA) resolutions. We respect the aim and principles of the WHO Code to contribute to the provision of safe and adequate nutrition for infants, by
 - a) the protection and promotion of breast-feeding; and
 - b) ensuring the proper use of Breast-milk Substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution.
- We acknowledge that, independently of any other measures taken by governments to implement the WHO Code, we are responsible for monitoring our marketing practices

according to the principles and aims of the Code, and for taking steps to ensure that our conduct at every level in this regard conforms to this Infant Formula Marketing Policy and local law in the countries where we operate.

SCOPE

This Policy applies worldwide to all Abbott employees, to agents and distributors of Abbott that market Abbott infant and follow-on formulas.

Abbott employees engaged in the marketing and sale of infant formula are required to comply with this policy and with relevant national laws and regulations, as well as any relevant industry group codes adopted by Abbott. To the extent that there is a difference between the standards set forth in this Policy and the national law or regulation, the national laws and regulations are followed.

The scope of this Policy includes all countries where Abbott does business. Some of the countries which Abbott operates are designated as “higher-risk” based on infant morbidity and mortality data. (Link to the Global Nutrition Report 2016, specifically page 119-126, where it lists the higher risk countries and malnutrition data. <http://www.globalnutritionreport.org/the-report/>)

Products in the scope of this policy include:

- Infant formula, as defined in the Definitions section below, when intended for use for infant feeding from birth to six (6) months of age
- Any other product represented to be suitable for use as a partial or total replacement of breast-milk for infant feeding, including complementary foods, from birth to six (6) months of age.

For higher-risk countries this Policy also includes:

- Follow-on formula, as defined in the Definitions section below, when intended for use for infant feeding from birth to twelve (12) months of age.
- Bottles and teats when intended for use for infant feeding from birth to twelve (12) months of age.

This Policy excludes the following:

- Products that are specially designed for infants with special medical needs such as inborn errors of metabolism, severe gastrointestinal impairment, treatment of malnutrition and prematurity. Patient access to these products should not be prevented.
- Oral rehydration therapy products.
- Products intended for use by pregnant and lactating women

DEFINITIONS

Note: Definitions in this section represent Abbott global definitions. Local definitions might be different. Where this is the case, the local definition will apply.

Infant - means a person not more than 12 months of age.

Infant formula – means a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of healthy infants during the first 6 months of life up to the introduction of appropriate complementary feeding.

Follow-on formula - means a liquid or powdered product intended for particular nutritional use by infants from 6 months to 12 months of age when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such Infants.

Complementary food – means any food suitable as a complement to breast-milk or to infant formula or follow-on formula when either becomes insufficient to satisfy the nutritional requirements of the Infant.

Infant formula and follow-on formula products described above will be collectively referred to as '*Infant Formulas*' from this point forward, unless otherwise specified.

INFORMATION AND EDUCATION

Educational materials are designed to provide education and support. All educational materials relating to *Infant Formulas* that are to be distributed to HCPs, caregivers and/or organizations outside of Abbott must be approved in accordance with divisional/affiliate procedures and, must contain all required disclosures/disclaimers.

Information provided to HCPs should be scientific and factual, and should not imply or create a belief that bottle-feeding is equivalent or superior to breast-feeding. Pictures and text that idealize the use of breast- milk substitutes over breast-feeding are not allowed.

In higher-risk countries, *Infant formulas* or their specific brand names may not be used in any informational or educational materials about the feeding of infants intended for distribution to consumers, except in those cases where the materials are: (i) intended to provide instructions for the use of the *Infant Formula* and are disseminated through a HCP upon his or her request, or (ii) as part of a government organized health or nutrition program, or (iii) are materials clearly related to products that are not covered *Infant formulas*.

THE GENERAL PUBLIC AND MOTHERS

Sales and marketing personnel in higher-risk countries should not seek direct or indirect contact with pregnant women or with mothers of infants regarding promotion of *Infant Formulas*. This restriction is not intended to prevent appropriately qualified personnel from responding to complaints or requests for information on correct use of *Infant Formulas* or from providing informational or educational materials as outlined above.

In addition, Abbott shall not engage in advertising or other forms of promotion of *Infant Formulas* in the scope of this policy to the general public in higher-risk countries where prohibited by local law or regulation. This includes marketing practices such as television, radio, print; point of sale advertisement or special displays; gifts, promotional no-charge product, brand gimmicks, coupons; special sales or tie-in sales.

Where advertising and promotion is allowed, all advertising and promotion of *Infant Formulas* must be balanced, fair and accurate, supported by sound science and approved in accordance with global, divisional/affiliate promotional procedures. Marketing materials, informational and educational materials for infant and follow-on formula should not be presented in such a way as to discourage mothers or caregivers from breast-feeding or feeding breast-milk to their infants.

HEALTH CARE SYSTEMS

Supplies of *Infant Formulas* may only be provided in accordance with divisional/affiliate policy and procedure. Supplies must be reasonable in quantity and are intended for use by infants and young children during their stay in the institution.

Healthcare systems should not be viewed as a promotional venue and should not be paid to promote or advertise *Infant Formulas*. Abbott understands that healthcare systems and healthcare professionals are in the best position to advise mothers regarding feeding choices. Company personnel may provide educational and instructional materials to healthcare systems and HCPs but should not act as the primary point of contact or advice for mothers. Company personnel should not enter into any relationship with a healthcare system where the company personnel are compensated for promotion or distribution of *Infant Formulas*.

Providing *Infant Formulas* to parents, hospitals, clinics, HCPs, NGOs, or government organizations must be done in accordance with this policy and divisional/affiliate procedures and national laws and/or regulations related to providing no-charge product, product donations (“Charitable Contributions”), or standards with regard to provision of no-charge products. Where product distribution is permitted, it should not be used or distributed with the intent to discourage a mother or caregiver from feeding breast-milk to an infant.

In higher-risk countries, no-charge *Infant Formulas* may not be provided directly to parents or caregivers by Abbott. In addition, such products may only be distributed in response to a formal request made by a healthcare professional, which includes the following elements:

- A request for product for purposes of evaluating tolerance and acceptability;
- The amount of the product requested
- That the HCP is aware of relevant obligations, including the fact that the no-charge product is not to be resold or taken for personal use by the HCP or his or her staff

- That the product is not provided as an incentive to purchase or resell or recommend a particular product.

CHARITABLE CONTRIBUTIONS

All Charitable Contributions to organizations must be in compliance with this Policy, relevant national laws and regulations, and Abbott process AQ1201.A - Quality Management of Product Donation Process.

All humanitarian *Infant Formula* Charitable Contributions to organizations must have prior written approval by Global Citizenship and Policy.

For any request of specialty formula donations outside of the United States, a prior written approval from Global Citizenship and Policy must be obtained.

Organizational requests for *Infant Formula* Charitable Contributions must be made to Abbott in writing and must contain the following information and acknowledgement:

- Name of the Organization that will receive the products.
- Description of the infant circumstances that require infant and follow-on formula.
 - Infants who do not have access to a safe and adequate supply of breast-milk.
 - Infants who are already being fed formula prior to the request for donation.
- Number of infants targeted and quantity needed per infant, and conditions under which it will be fed (i.e., clean water source available for powder formula requests).
- The Organization's process to ensure that *Infant Formulas* are distributed to infants who require it and that supplies can be continued for as long as the infants concerned need them.
- Acknowledgements by the Organization must include:
 - They are aware of and abide by, as applicable, the WHO Code, national laws and regulations regarding infant feeding and any industry code requirements that Abbott has agreed to.
 - The feeding of *Infant Formulas* will be demonstrated only by health workers, or other community workers, if necessary, and only to the mothers or family members who need to use it.
 - They will not seek reimbursement for the products provided as Charitable Contributions.
 - Products provided as Charitable Contributions are not for resale.

The Global Citizenship and Policy Department should be provided and should maintain all documentation and approvals related to these humanitarian Charitable Contributions of *Infant Formulas*.

HEALTHCARE PROFESSIONALS

Healthcare professionals and institutions play an important role in guiding infant feeding practices and providing patient advice. This advice should be independent of influence from

manufacturers and other parties with a commercial interest in the process of bringing a product to the consumer. We are committed to advancing the science of nutrition and working with healthcare professionals in a way that promotes the innovation and advancement of safe, nutritious, and scientifically advanced formulas to meet the needs of infants and young children.

Information provided to HCPs should be scientific and factual in nature, and should not imply or create a belief that bottle-feeding is equivalent or superior to breast-feeding. *Infant Formulas* no-charge product may be provided to healthcare professionals for purposes of professional evaluation in accordance with applicable divisional/affiliate product no-charge procedures. Quantities should be limited to a reasonable amount. *Infant Formulas* may also be provided for clinical or market research in accordance with applicable Abbott policies.

All interactions with HCPs must be appropriate and conducted in accordance with this policy and all divisional/affiliate procedures that guide the provision of Meals, Brand Reminders, Cultural Courtesies, Educational and Third Party Meeting Support, Charitable Contributions. No item, gift or benefit shall be offered or given as an inducement for the purchase, sale, or recommendation of Abbott products.

Scientific and market research regarding *Infant Formulas* must not be carried on for the sole purpose of promotion or marketing of those products. These activities must be conducted with a primarily scientific or educational purpose. None of the above shall prevent data generated from scientific and market research and other surveys from being used for promotion and marketing of *Infant Formulas* in accordance with applicable national law and regulations.

Educational materials should be designed to provide education and support. All educational materials relating to *Infant Formulas* that are to be distributed to HCPs, caregivers and/or organizations outside of Abbott must be approved in accordance with global, divisional/affiliate procedures and must contain all required disclosures/disclaimers.

All educational grants (including any Fellowships or Sponsorships) to support HCP, patient, or public education in relation to *Infant Formulas* must be provided in accordance with divisional/affiliate policies and procedures. Educational grants cannot be tied to past, present, or future purchases of *Infant Formulas* or any other Abbott products.

The purpose and focus of all symposia, congresses and other scientific or professional meetings (“Events”) for healthcare professionals should be to inform them about *Infant Formulas*, complementary foods and/or to provide balanced and accurate scientific and educational information. All events must follow Abbott policies and procedures, including the following requirements:

Venue and Meals:

All events must be held in a venue conducive to scientific or educational objectives and the purpose of the event or meeting. All Meals must be reasonable in cost and be incidental to the main purpose of the meeting and must meet appropriate divisional/affiliate policies and procedures, including applicable financial limits.

Entertainment:

No standalone entertainment may be provided by Abbott at these events. Social activities which are secondary to an event may be supported in accordance with applicable divisional/affiliate policies and procedures.

Payment for Professional Services for Presenters at Events:

Abbott may enter into bona fide Professional Service Arrangements with HCPs in accordance with applicable divisional/affiliate policies and procedures. Payment for such services must be reasonable and consistent with fair market value.

PERSONS EMPLOYED BY MANUFACTURERS AND DISTRIBUTORS

Sales and marketing representatives must abide by the highest ethical standards at all times and must be appropriately trained to follow relevant divisional/affiliate procedures governing their interactions with HCPs and consumers, including appropriate contact with pregnant women and mothers where permitted.

Abbott believes that healthcare professionals are in the best position to advise mothers regarding feeding choices. Company personnel may provide educational and instructional materials to healthcare systems and HCPs but should not act as the primary point of contact or advice for mothers in healthcare systems. Company personnel should not enter into any relationship with a healthcare system where the company personnel is compensated for promotion or distribution of *Infant Formulas*.

Compensation, including any commission, to any sales and marketing representatives who promote *Infant Formulas* cannot be based / fixed specifically on sales of *Infant Formula* products.

Abbott divisional/affiliate leadership is responsible for communicating the requirements set forth in this Policy to direct distributors, retailers, promoters, and other third parties engaged by Abbott to promote, sell, or support the sale of infant and follow-on formula products, as applicable.

LABELLING

Labels for *Infant Formulas* must adhere to all applicable local regulations and requirements, should be clear and conspicuous, provide necessary information about appropriate use of the product, not discourage breast-feeding, be in relevant local languages, be easily read and include all of the following points:

- The phrase “Important Notice” or equivalent
- A statement of the superiority of breast-feeding
- A statement on the proper method of use of the product, and, where applicable, that the product should be used only on the advice of a healthcare professional
- Instructions for appropriate preparation, use and storage of the products and information about the risks of inappropriate preparation.
- Statement of the ingredients used, the composition/analysis of the product in accordance with national regulation, batch number and date before which product is consumed in accordance with national regulation, taking into account the climatic and storage conditions of the country concerned.

Labels for *Infant Formulas* should not include pictures or text or be presented in such a way as to discourage caregivers from breast-feeding.

All labels must be approved according to divisional/affiliate labeling procedures and must contain required elements and likewise refrain from using prohibited statements or images. Labels

should be designed to provide all necessary information on safe and appropriate use of the product in accordance with applicable national laws and regulations.

QUALITY

Abbott is dedicated to improving healthcare by providing high quality, safe, effective products and ensuring compliance. This is achieved through a commitment to quality and the continuing effectiveness of the quality management system to meet customer, stakeholder (e.g., interested party) and regulatory requirements. Abbott maintains compliance with all laws, rules and regulations in every country in which we operate including globally recognized standards such as applicable standards recommended by the Codex Alimentarius Commission and also the Codex Code of Hygienic Practice for powdered formula for infants and young children.