



B Lab Statement on Ferrer's B Corp Certification

B Lab's independent Standards Advisory Council has rendered the following decision and guidance regarding eligibility for B Corp Certification for companies involved in the marketing breastmilk substitutes:

For companies who market breastmilk substitutes and are not individually featured in the Access to Nutrition Index Breastmilk Substitutes Scorecard:

Companies are eligible for B Corp Certification if they (1) have a formal policy endorsing the [WHO's International Code of Marketing of Breast-milk Substitutes](#) and subsequent WHA resolutions ("the WHO Code"), (2) disclose how the company manages compliance to the code, and (3) is transparent about potential areas of non-compliance.

In October 2021, B Lab's independent Standards Advisory Council issued the following update to its guidance on the marketing of breastmilk substitutes:

Non-ATNI listed companies are required to meet the immediate expectations of the [BMS Call to Action](#), and achieve full Code compliance by 2030 in order to maintain their certification. The immediate expectations of the BMS Call to Action are as follows:

Have a Code-aligned BMS marketing policy in place that (1) Covers products designed for use 0-12 months after birth, (2) Is applied globally, and (3) Is upheld in jurisdictions with less stringent or no regulations, and adheres to national law when those laws are more stringent than the policy.

For more information on B Lab's position on the marketing of breastmilk substitutes, please refer to B Lab's statement on the breastmilk substitute industry and B Corp Certification [here](#)*

**Note: public statement currently in process*

As a Certified B Corp earning >1% of its annual revenue from BMS products, Ferrer is required to disclose its marketing practices for BMS products and areas of non-compliance with the Code. If BMS products continue to represent >1% of its annual revenue, Ferrer will be required to meet the immediate expectations of the BMS Call to Action by its next recertification date and achieve full Code compliance by 2030 in order to maintain its B Corp Certification.

Ferrer and Marketing of Breastmilk Substitutes

Ferrer is a vertically integrated pharmaceutical company headquartered in Spain that distributes several Novalac brand breastmilk substitute (BMS) products. Ferrer does not itself manufacture any breastmilk substitutes. Ferrer sells Novalac Premium 1 (0-6 months), Novalac Premium Proactive 1 (0-6 months), Novalac Premium 2 (+6 months), Novalac Premium Proactive 2 (+6 months), Novalac Premium 3 (+1 year old), and Novalac Premium Proactive 3 (+1 year old) as



well as several Novalac formulas that are classified as Food for Special Medical Purposes for infants with digestive disorders and infants with cow's milk allergy (0-36 months).

Ferrer's marketing and distribution of BMS products occurs only in Spain and accounts for approximately 1.3% of the company's total annual revenue. Ferrer adheres to the "Asociación de Fabricantes de Productos de Dietética Infantil" (ANDI) and its [Code of Good Practices](#) for the promotion of children's dietary products (ANDI Code).

Ferrer has created a Policy for the Marketing of Breastmilk Substitutes that is based on the WHO Code and ANDI Code, and commits to the principles of the WHO Code:

"Ferrer acknowledges the importance of the principles of the International Code of Marketing of Breast-Milk Substitutes adopted on 21st May 1981 (the "WHO Code") and the subsequent relevant resolutions of the World Health Assembly ("WHA")."

Company Comments:

Ferrer supports the WHO's global public health recommendation calling for exclusive breastfeeding for the first six months of age and continued breastfeeding up to two years and beyond, combined with the safe introduction of appropriate complementary foods.

In addition to the commitment to the WHO Code, a number of Ferrer's practices align entirely with the WHO Code. Ferrer acknowledges the following areas where that may not be entirely aligned with the WHO Code or where there may be differing interpretations.

Areas of Misalignment or Potential Misalignment with the Code

Definition/ Scope of Products Included in WHO Code and Ferrer's Policy

Ferrer's policy regarding the marketing of breastmilk substitutes applies to a scope of products that differs from the complete scope of the WHO Code.

Article 2 of the WHO Code establishes the scope of applicable products as being "breastmilk substitutes, including infant formula; other milk products, food and beverages, including bottle fed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast milk; feeding bottles and teats." Breastmilk substitutes are defined as "Any food being marketed or otherwise presented as a partial or total replacement for breast milk, whether or not suitable for that purpose." Subsequent WHA resolutions have clarified that follow-up formulas and growing-up milks for children under 36 months are included in the scope of the Code.¹

¹ <https://apps.who.int/iris/bitstream/handle/10665/254911/WHO-NMH-NHD-17.1-eng.pdf>



Ferrer's policy applies to "Covered Products" which includes infant formula, follow-up formula, and Food for Special Medical Purpose (FSMPs), but does not include growing-up milks. Furthermore, some aspects of Ferrer's policy do not apply to the full scope of "Covered Products" (further detailed below).

Portions of Ferrer Policy That Are Not Applied to All Covered Products

Ferrer's policy includes several sections that are specified as only being applicable to products classified as infant formula (i.e., products for infants 0-6 months), whereas in the WHO Code such requirements are applicable to all products in scope, including follow-up formulas and growing-up milks. The sections of Ferrer's Policy applicable only to infant formula are:

- Information and Education (based on WHO Code Article 4)
- General Public and Mothers (based on WHO Code Article 5)
- Healthcare Organisations (based on WHO Code Article 6)
- Healthcare Professionals (based on WHO Code Article 7)
 - Additionally, the section Product for Professional Evaluation (based on WHO Code Article 7.4) is applicable to infant formula and FSMPs.

In alignment with the ANDI Code, Ferrer's policy allows for certain practices that are prohibited by the WHO Code, including, but not limited to:

- Advertising, sampling, and promotion to the general public for stage 2 follow-up formulas (6-12 months) and stage 3 growing-up milks (12-36 months). Ferrer promotes follow-up formula products following the stipulations of the ANDI Code to which it is adhered.
- Advertising, sampling, and promotion to healthcare professionals and healthcare organizations for stage 2 follow-up formulas (6-12 months) and stage 3 growing-up milks (12-36 months).

Company Comments:

Ferrer always encourages breastfeeding, giving all the information in their communication. Ferrer in some situations understands that when breastfeeding is not possible there should be an alternative for their babies and mums should be aware of this back up option. To cover this need, Ferrer carries out its activity always following Spanish legal and sectoral regulations.

Donations and Samples to Healthcare Organizations and Healthcare Professionals

Ferrer's policy allows for the provision of donations, low-price sales, and/or samples to healthcare organizations and healthcare professionals where such practices are prohibited by the WHO Code and subsequent WHA resolutions. WHA 69.9 prohibits donations of free or subsidized supplies of breast-milk substitutes or related products of any kind in any part of the



healthcare system (including health workers and professional associations), except as supplies distributed through officially sanctioned health programmes. Products distributed in such programmes should not display company brands.² This resolution supersedes guidance in the original WHO Code, such as Article 6.6 and Article 7.4.

Ferrer's donations practices are aligned with the original guidance of WHO Code Article 6.6 where "Donations or low-price sales to institutions or organizations of supplies of Infant Formula or other products within the scope of this Code, whether for use in the institutions or for distribution outside them, may be made. Such supplies should only be used or distributed for infants who have to be fed on breast milk substitutes. If these supplies are distributed for use outside the institutions, this should be done only by the institutions or organizations concerned. Such donations or low-price sales should not be used by manufacturers or distributors as a sales inducement." Additionally, Ferrer's policy allows for the provision of Donations of Infant Formula to institutions and organizations in certain conditions as stipulated by ANDI Code Article 8.5. Ferrer delivers Donations of Infant Formula to the requesting government, aid agency, orphanage or other social welfare institutions for distribution amongst infants who, pursuant to medical advice, have to be fed with Infant Formula and for whom breastfeeding is not feasible.

Ferrer does not deliver Donations of Infant Formula directly to parents. The Label or packaging of Infant Formula distributed as Donations must clearly indicate that the product is a "donation – not for sale" for use by the receiving institution or organization, and only for infants who need to be fed with Infant Formula and for whom breastfeeding is not feasible. Furthermore, following ANDI Code and Spanish regulations, Ferrer's policy allows for the provision of donations to healthcare professionals and healthcare organizations for follow-up formulas and growing-up milks.

Ferrer's practices, aligned with the original guidance of WHO Code Article 7.4, also allows for the provision of Infant Formula and FSMP to healthcare professionals specifically for the purpose of professional evaluation or research at an institutional level. Ferrer duly monitors the delivery of Product for Professional Evaluation (PPE) to healthcare professionals and all PPE bears a Label stating that it is "For Professional Evaluation Only" and "Not for Sale". PPE may only be supplied to a HCP for:

- The introduction of a new product or new product packaging/labeling;
- The introduction of a new formulation/recipe of an existing product, or
- The introduction of our range of products to a new or recently qualified HCP.
- To gain experience of the efficacy of the Infant Formula or FSMPs including evaluating, tolerance and suitability.

² https://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_7Add1-en.pdf?ua=1



Direct / Indirect Contact with Pregnant Women and Mothers

Ferrer's personnel involved in the marketing of infant foods "do not solicit direct or indirect contact with pregnant women, or mothers of infants and young children, for the purpose of Marketing or promoting Covered Products. This is not intended to prevent trained staff from responding to questions from consumers about Infant Formula and other foods intended for infants via, for instance, telephone helplines, websites and social media." The WHO Code states that marketing personnel "should not seek direct or indirect contact of any kind with pregnant women or with mothers of infants and young children."

Contributions To and Engagement With Healthcare Providers

Ferrer's policy allows for the company to make "contributions on behalf of an HCP for fellowships, study tours, attendance at professional conferences and symposia and similar informational and educational programmes" as well as to organize education events that "provide either educational or professional training to HCPs or a forum to exchange scientific information related to our products and the HCPs area of professional expertise." WHA 69.9 states that companies should not "give gifts or incentives to health care staff" and should not "sponsor meetings of health professionals and scientific meetings."

Company Comments:

Ferrer firmly believes in the right of the scientific community to be fully informed of medical and scientific advances, and therefore sponsors or organises events for the full and proper exchange of scientific information. Such educational events for the healthcare system run counter to a strict interpretation of the WHO Guidance. It is important to note, however, that WHA "welcomed" the WHO Guidance but acknowledged importantly that its implementation should be "in accordance with national context" and "taking into account existing legislation and policy, as well as international obligations". Ferrer's practice is aligned with the national context and legislation.

Ferrer's Management Practices

Ferrer has the following management practices in place to manage compliance to its own policies and that which have been set out by the WHO Code:

- Ferrer has the following policies and procedures in place: BMS Policy, Promotional Compliance Policy and SOP Marketing Material Review. Regular trainings on Compliance topics are carried out and new employees are trained in the onboarding process.
- Ferrer counts with an automated workflow for the materials approval that requires a multi-step approval that follows a segregation of duties-based approach. Ferrer also has a risk management system where risks and controls are duly monitored through an IT



tool and periodic reporting to the governing bodies is established. Ferrer's Annual Audit Plan includes the revision of Compliance topics.

- Ferrer has a Corporate Whistleblowing Management System and whistleblowing channel available for employees and third parties. Any potential non-compliance may be reported through this channel.

Furthermore, the company has not received a complaint of non-compliance over the past five years (2017-2021).

As already mentioned, Ferrer supports the WHO's global public health recommendation calling for exclusive breastfeeding for the first six months of age and continued breastfeeding up to two years and beyond, combined with the safe introduction of appropriate complementary foods.

Ferrer is adhered to ANDI Code and follows strictly its requirements as well as other applicable sectoral codes. According to the FTSE4Good standards Spain is considered a low risk country. Additionally, Ferrer is aligned with EU and ES legislation.

As stipulated by the requirements for B Corp Certification, as long as the company continues to earn >1% of its annual revenue from the sale of BMS products, Ferrer is committed to updating its BMS marketing policy by its next recertification date in order to meet the immediate expectations of the [BMS Call to Action](#), which requires that the company's policy and practices (including promotion to consumers and healthcare providers) are Code-aligned for all products marketed as suitable for infants between birth and 12 months of age. Ferrer is also committed to achieving full Code compliance by 2030 in order to maintain its certification.