



B Lab Statement on Corporación J. Uriach S.A'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 in the pharmaceutical industry:

"B Lab and its independent Standards Advisory Council have determined that pharmaceutical companies are eligible for B Corp Certification if they have not engaged in specific prohibited practices in the last five years AND are meeting additional industry specific practice requirements outlined below..."

Corporación J. Uriach S.A is required to disclose a summary of how it complies with these industry requirements as a part of its B Corp Certification. For more information on the specific requirements, please refer to B Lab's position statement on Pharmaceutical Companies [here](#).

Summary of Company

Corporación J. Uriach S.A (hereinafter, "Uriach") is a European company that believes in the power of nature, enhanced by science, as the best way to improve human health and wellbeing. That's why Uriach is not considered a major player in the pharmaceutical industry as just 9% ~ of the revenue is related to the pharmaceutical industry, specifically over-the-counter products (hereinafter "OTC"). The rest of the revenue (91%) is related to the Natural HealthCare Industry.

Also, most OTC products are not directly manufactured by the company rather by their Contract Manufacturing Organizations (CMOs). The company's latest OTC product was launched in 2022 under a license agreement from a 3rd party. While Uriach is not currently involved in research and development (R&D) processes, minor R&D activities exist, related to the maintenance of the current regulatory dossiers, or to explore the possibility of moving the product into natural-based ingredients thus abandoning the OTC-drug status.

All products from Uriach that can be considered pharmaceutical are branded and over the counter (9% ~ of the total revenue of the last fiscal year 2023). In general terms, Uriach has businesses that operate directly in the European Union, specifically within Spain, Italy, Portugal, Germany, Austria, Switzerland, and Romania. OTC drugs direct operations are mainly present in three locations: Germany, Spain and Portugal.

Therapeutic areas of focus of Uriach's OTC drugs and associated brands are the following:

- Travel Sickness (e.g. Biodramina, Vomisaft)
- Cough & cold and allergy symptoms (e.g. Emser Salz, Emser Nasenspray, Melhoral)
- Attenuation of gastrointestinal flatulence in adult populations (e.g. Aero Red)



- Scalp Antifungal (e.g. Bioselenium)
- Prevention of magnesium deficiency states (e.g. Magnogene)
- Nasal congestion (e.g. Utabon)

Uriach's Disclosure on Prohibited Practices

Pharmaceutical companies engaged in the following practices in the last five years, as demonstrated through company disclosures or through material, justified, and unresolved stakeholder concerns, are currently ineligible for B Corp Certification:

- Companies engaged in any form of lobbying or policy advocacy that endanger consumer safety, promote an anti-competitive environment (e.g. by opposing increased transparency measures), inhibit affordable pricing, or limit equitable access to medicine. This includes membership, Board involvement, or funding of industry associations that engage in such lobbying activities.
- Companies utilizing intellectual property strategies for branded products to influence an unjustified delay to the introduction of an authorized generic product to the market (e.g. "evergreening" patents).
- Companies engaged in price gouging as evidenced by significant and unjustified year-over-year price increases to their products.

Uriach has been reviewed in accordance with B Corp Certification's Disclosure Questionnaire and background check requirements, including disclosure of its involvement in lobbying and advocacy activities, intellectual property strategies, and price changes in order to verify it is meeting the above requirements regarding prohibited industry practices. The company's approach to managing these material topics to the industry are further detailed below.

Uriach's Disclosure on Required Best Practices

1. *Adherence to credible national and/or international standards of safety, quality, and efficacy covering all relevant stages of the drug life cycle (i.e. drug development, supply chain, manufacturing, and distribution), which should include explicit systems to manage the risk of substandard medicines.*

All of Uriach's products are subject to strict quality supervision and regulation. Uriach has a quality management system where they establish control and assurance mechanisms on all of their products and suppliers to ensure that they meet the highest standards, specifically, the regulatory standards for medical devices and food and cosmetic supplements followed are detailed below:



- ISO 13485 for medical devices
- ISO 22000 for food supplements
- ISO 22716 for cosmetic products.

In Germany, internal operations and quality systems meet the requirements and standards of the field detailed below:

- Quality Management System certified to ISO 13485:2016.
- Production plants are certified according to Good Manufacturing Practice (GMP) compliance as indicated in art. 111 (5) of directive 2001/83/EC.
- We have several certifications for the manufacturing and/or marketing of our products that reaffirm our compliance with quality standards.

Along the same lines, all suppliers – including OTC products suppliers - have Good Manufacturing Practice and are evaluated annually. For pharmaceutical products, CMOs and active ingredient manufacturers are audited at least every 3 years. For the others, audits are based on the criticality of the risk and are carried out based on an annual evaluation..

Pharmacovigilance or Cosmetovigilance:

One hundred percent of our products, regardless if they are medicines, food supplements, medical devices, or cosmetics, are assessed for their impact on the health and safety of their consumers. The current legislation in the area, both at Spanish and European level, requires the company to keep a record of all adverse reactions that occur, as well as to carry out an exhaustive evaluation of them. To monitor this compliance, Uriach reports to the health authorities on a regular basis and whenever necessary on the safety of each of the products we market. At Uriach we have several communication channels to receive information on cases of adverse reactions, such as those reported by health professionals, users, and social networks.

In addition, training is provided to all the people who join Uriach and regular refresher sessions are held to raise awareness among all collaborators about the importance of channeling this information to those responsible for the organization. During 2021, 2022, and 2023, there have been no cases of non-compliance with regulations on the safety of products marketed by Uriach resulting in fines, sanctions, or warnings.

2. *A Code of Ethics and/or other policies applicable to all company employees and critical third parties that establish minimum expectations with regard to anti-corruption and bribery, lobbying and advocacy activities, company interactions with healthcare professionals/organizations, and ethical marketing (where applicable). The company must also have clear processes to enforce the Code, including an accessible whistleblowing channel, and regular training of staff and third parties on the Code.*



Uriach has a Code of Ethics which is the highest-level regulatory instrument in the company's regulatory structure and aims to establish the ethical and responsible principles of all the stakeholders and employees. The Code of Ethics is published on the [Uriach website](#) and is available to any third party who wishes to know its content.

The Code of Ethics is complemented by a wide range of internal regulations. In terms of anti-corruption, Uriach has the following regulations:

- **Crime Prevention and Compliance Model:** The aim of the Crime Prevention and Compliance Model is to define the crime prevention and compliance guidelines that all companies belonging to Uriach must follow. This regulation includes, among other issues, the structure and corporate bodies governing compliance, their responsibilities and functions and the principles that should govern their daily activity.
- **Anti-corruption Policy:** is developed in the different protocols detailed below:
 - **Protocol for Gifts and Hospitality:** determines the principles of action required when offering and receiving gifts and hospitality when interacting with public officials, customers, and suppliers to prevent corrupt behavior.
 - **Money Laundering Prevention Protocol:** Its objective is to protect the integrity of the company's financial system and economic activity.
 - **Donations and Sponsorship Protocol:** establishes the obligation to verify the genuine destination of donations made to non-profit associations and foundations. It also covers the supervision of the destination of sponsorship projects, patronage or any other charitable, cultural, scientific, social project or any area outside of daily work.
 - **Conflict of interest protocol:** Defines the procedure for action by collaborators so that the interests of Uriach prevail over personal interests. This Protocol establishes the rules on how to identify, avoid or resolve such conflicts.

These anti-corruption principles are also applicable to third-party partners, such as manufacturing companies, distributors, and other crucial stakeholders in the supply chain. Other policies or instruments available on the [web](#) such as Supplier Code of Conduct, Donations and Sponsorship Regulation, Ethical marketing guidelines, etc.

Additionally, Uriach conducts general practices to ensure proper governance and management of potential breaches such as:

- From the highest level of governance, the Board of Directors has appointed a delegated Commission of the Board, specifically dedicated to Audit & Compliance, which is responsible for ensuring a proper level of budget allocation and following up on the compliance activities and plans to be carried out within the group. The execution of these plans is led by the Risk and Compliance Committee.



- **Risk and Compliance Committee:** is responsible for ensuring compliance with the annual action plans, which aims to identify risks in all areas, provide mitigation plans to the identified risks and advise and guide on the best way to implement necessary controls. This Committee manages among others the preparation of annual risk maps, the development of policies and protocols, training on the internal regulations and the handling of the whistleblowing channel.
- **Whistleblowing Channel:** available online so that any stakeholder can report any breach on the aforementioned policies or protocols or the applicable law, including the possibility of raising a concern anonymously.

3. *Public disclosure detailing the company's approach to government affairs, inclusive of lobbying/advocacy and political activities. This should include disclosure of the material issues that the company lobbies/advocates for, their trade associations, and the controls they have in place in regards to political contributions, lobbying/advocacy on the company's behalf, revolving door policy, political contributions and donations.*

Uriach discloses annually in a public way its participation in this type of activities, as required by the non-financial reporting law in Spain. Specifically, the company reports about:

- Grants received by the government (pages 106-107 of the last non-financial report).
- Donations amount and beneficiaries (pages 66 of the last non-financial report)
- Entities with which the company collaborates (pages 65-68 of the last non-financial report).

Likewise, it is important to note that, according to the internal Code of Ethics, the company has been formally committed to not collaborating with political institutions and parties (page 17).

Regarding advocacy practices, the company belongs to sectoral organizations that support consumer healthcare products (amongst which there are OTC Drugs); however, these organizations are very general and also support cosmetics, medical devices, and food supplements, and mostly inform us about regulatory changes. The company is not directly involved in specific advocacy practices regarding OTC drugs. In contrast, the company does have an internal Advocacy Plan generated for its main products (Food Supplements), which are not considered pharmaceuticals.

The internal Advocacy Plan focused on Food Supplements has been designed to work with two target audiences:

- Regulatory and Public Institutions with the aim of understanding present and future regulation for Food Supplements.



- Educational Institutions to promote Natural Consumer Health Science amongst healthcare professionals.

4. *For companies involved in research & development, public disclosure of its R&D and intellectual property strategies and disclosure of annual resources invested in both internal and collaborative R&D activities.*

Uriach does not have a specific strategy for R&D or IP management for OTC products but focuses on expanding other natural health product lines such as food supplements, topical creams, phytopharmaceutical products, etc. Uriach dedicated in 2023 a total of 4.4Mill Euros to R&D activities. Of those, 14% were R&D activities to support the categories of OTC Drugs and Phytopharmaceuticals. The majority of our R&D spend (86%) supports the company's core business categories of food supplements, cosmetics, and medical devices; the projects in this area are varied and mostly support launches of new products.

Uriach does not hold active patents on its OTC products, nor do they plan on acquiring new ones.

5. *For companies involved in research & development for priority diseases, conditions, and pathogens identified in the Access To Medicine Index, R&D processes for both internal and collaborative R&D activities must include a framework to develop equitable access plans for such projects. Access plans must be project-specific and include detailed commitments and strategies to improve access to such products in low- and middle- income countries (LMICs).*

Uriach is not currently involved in R&D for priority diseases, conditions, and pathogens identified in the Access To Medicine Index.

6. *For companies involved in sales, public disclosure of its approach to pricing which, at a minimum, utilizes pricing instruments that are generally accepted by public health agencies to set prices in all markets (such as internal reference pricing, external reference pricing, and value-based pricing). Additionally, for sales in LMICs, pricing strategies must prioritize the payer's ability to pay across different segments of a country's population and aim to improve access to those in need.*

Uriach's OTC products have prices that are determined by market forces as they have many competitors. Price fluctuations occur due to several reasons such as energy costs, inflation, or market demand. The company does not base their pricing strategy on market access or government subsidies.



Uriach monitors and adjusts their prices twice a year based on market dynamics such as competition, sales, price elasticity and consumer willingness to pay, as well as cost and production changes. They do not hold any monopoly in any market/category for their products, and therefore have not made any significant or unjustified price increases that could limit access to their products or be based on a monopolistic position within the market. Although there have been price increases, it has always been justified by market or cost criteria and have not been significant.

It is important to note that in the OTC market, the margin applied by the pharmacy (which is the final distributor) is regulated. However, the company's price is not regulated as it is governed by market dynamics, having always alternative options available in the market.

Regarding distribution and commercialization, the company strictly adheres to the applicable regulations for commercialization and sale practices. This includes following the limits and requirements outlined in both Spanish and European legislation, as well as the industry codes of conduct to which we are accountable as members. According to the regulations, offering bonuses, incentives, discounts and similar commercial practices on food supplements or cosmetics is prohibited when, directly or indirectly, they may constitute a prohibited commercial practice with respect to pharmaceutical products. Uriach guarantees that they do not engage in any cross-action between OTC drugs and food supplements that would violate the law, as well as other prohibited practices such as advertising through celebrities or influencers, for example.

Finally, in addition to specific regulations that apply to each product category, the company's Legal & Compliance Department oversees and ensures compliance with general regulations related to the marketing of their products. These include regulations pertaining to the Law for the Defense of Competition, the Law of Unfair Competition, the General Law of Advertising, the General Law for the Defense of Consumers and Users, and other complementary laws.

Uriach does not directly sell over the counter (OTC) products to countries determined to be low or middle-income. The company does not own or have any control over the registration or final pricing of these products in the market.

7. For companies involved in sales, companies have financial incentive structures for sales agents/teams designed to encourage responsible sales practices and minimize the risk of overselling (for example, by decoupling bonuses from sales volume).

Natural Healthcare Products are playing a more prominent role in Uriach's sales strategy. Nevertheless, Uriach has commercial agents who receive bonuses based on sales volume. The salesforce that sells OTC drugs only visits pharmacies and not doctors. This salesforce sells both OTC drugs and all other product categories within Uriach's portfolio. The variable



incentives for Uriach's sales force that visits pharmacies are linked to aggregated sales. This means that the incentives are based on the total sales of the affiliate or the aggregated sales of a category that includes SKUs from all regulatory categories (e.g. category "large brands" or category "cough and cold").

The company does not reward or compensate with sales bonuses the sale of OTC products in particular, but all total sales (in terms of category or affiliate), which mostly consist of natural healthcare products, which is the core of the business; and do not bear a risk of overselling since its focus is on wellness and health prevention.

Additionally, Uriach strictly adheres to the applicable regulations for commercialization and sale practices. This includes following the limits and requirements outlined in both Spanish and European legislation, as well as the industry codes of conduct to which they are accountable as members. According to the regulations, offering bonuses, incentives, discounts and similar commercial practices on food supplements or cosmetics is prohibited when, directly or indirectly, they may constitute a prohibited commercial practice with respect to pharmaceutical products. Uriach guarantees that they do not engage in any cross-action between OTC drugs and food supplements that would violate the law, as well as other prohibited practices such as advertising through celebrities or influencers, for example.

Finally, in addition to specific regulations that apply to each product category, Uriach's Legal & Compliance Department oversees and ensures compliance with general regulations related to the marketing of our products. These include regulations pertaining to the Law for the Defense of Competition, the Law of Unfair Competition, the General Law of Advertising, the General Law for the Defense of Consumers and Users, and other complementary laws.

Required Best Practices - Companies Listed on ATMI

8. In addition to the above requirements, companies listed on the Access To Medicine Index must also achieve a score of 2.50 or higher in each of the Index's three specific topic areas. If listed, B Lab will review your company's scorecard in order to verify this requirement.

Uriach does not appear in the Access to Medicine index as it commercializes OTC products for non-severe health conditions where there is a wide access to potential substitutes.