



B Lab Statement on Herbarium'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..."

Herbarium 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

Herbarium is a pharmaceutical company involved in Research & Development, Product regularization, acquisition of inputs, production, marketing, distribution and Pharmacovigilance. The company has direct operations in Brazil and indirect operations such as distribution of products, in Guatemala, Nicaragua, El Salvador, Honduras, Costa Rica, Panama, Ecuador, Bolivia and Paraguay.

Herbarium focuses, but is not limited to, the following therapeutic areas; stomach disorders, biliary tract disorders, multivitamins, derm protectors, dermatological and gynecological products, erectile dysfunction, antidepressants, sedatives, mood stabilizers, and more. The company currently has 100 products in their portfolio with 72.12% classified as prescription (RX) medicine, 22.76% as over-the-counter (OTC), and 5.11% as hygiene, beauty and nutrition (HBN).

Herbarium'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.

Herbarium 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.

Herbarium’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.*

The relevant steps that Herbarium adopts for the life cycle of products are those established both in the ICH Q10 Guide (International Conference on the Harmonization of technical requirements for the registration of medicinal products for human use – Pharmaceutical Quality System), and in the guidelines of Resolution RDC 658/2022 and its complementary regulations:

1. Pharmaceutical development:
 - a. Development of medicinal substances;
 - b. Development of formulations (including container/closure system);
 - c. Manufacture of products under investigation;
 - d. Development of delivery systems (when applicable);
 - e. Development and expansion of manufacturing processes;
 - f. Development of the analytical method.



2. Technology Transfer:
 - a. Transfers of new products during development through Manufacturing;
 - b. Transfers within or between manufacturing and testing sites for commercialized products.
3. Commercial Manufacturing:
 - a. Acquisition and control of materials;
 - b. Provision of facilities, services and equipment;
 - c. Production (including packaging and labeling);
 - d. Quality control and assurance;
 - e. Release;
 - f. Storage;
 - g. Distribution.
 - h. Post-market monitoring – customer service, market complaints, benefit-risk assessment
4. Product discontinuation:
 - a. Retention of documentation;
 - b. Sample retention;
 - c. Continuous product evaluation and reporting.

All relevant decisions, from the conception of the formulations to the discontinuation of the product, are based on established internal procedures, in addition to being approved by the company's leadership – quality management. Specifically, the stages of approving input materials (inputs), controlling the production process and approving the quality of the finished product guarantee compliance with established quality requirements. Furthermore, if process deviations are identified that could impact quality requirements, occurrences and non-conformities are recorded to conduct an analysis of the cause and establish a mitigating action plan, in order to address the identified cause, eliminating recurrences.

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.*

Herbarium has a Code of Ethics that includes a statement on anti-corruption and bribery, lobbying and advocacy activities, company interactions with healthcare professionals/organizations, and ethical marketing. There is mandatory training for all employees through their Virtual Teaching platform to review this material. In addition, suppliers



also receive a Code of Conduct that they must agree upon prior to conducting business. This code of conduct includes the same information as the Code of Ethics and also includes information about the company's Integrity Guarantee Channel which is a safe channel for offering complaints.

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.*

Herbarium is not engaged in any government affairs, political contributions or lobbying activities.

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.*

Herbarium currently has more than 24 projects in their development pipeline in different stages of maturity, including radical and incremental innovations, within the segments of herbal medicines, natural cosmetics, health products, etc. The company also has an innovation program that aims to develop partnerships with universities, integrating Brazilian plant researchers and Herbarium, for the development of new technologies and products. However, for reasons of the company's strategy, this information is not publicly linked. The company's annual investment in R&D activities in the last fiscal year was approx. 1.7 million reais (\$301,348.97 USD).

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).*

Herbarium does not currently have any products for priority diseases, conditions, and pathogens identified in the Access to Medicine Index (ATMI).

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.

Herbarium is part of the pharmaceutical market, and in Brazil this market has its prices regulated by a government body. CMED - Medicines Market Regulation Chamber, is responsible for establishing criteria for defining and adjusting medicine prices in the country. Among the main responsibilities of this body:

- imposing limits on the price list for medicines;
- adoption of rules that encourage competition in the sale of medicines;
- fixing the price ceiling.

CMED annually approves adjustments in medicine prices and defines the MAXIMUM CONSUMER PRICE (PMC). This regulation aims to guarantee the population's ability to access medicines. Herbarium is part of this context of market regulation.

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).

The company has a monthly variable remuneration program, known as the Sales Award. The sales indicator takes into account what we call " *Sell In* ", direct sales to the distributor or network, however, to ensure healthy sales, the company uses two resources:

- the sales plan is carried out through a *Sell Out analysis* , that is, the target is defined according to the output for the consumer.
- all employees in the sales area have *sell out on their performance indicator panel* , that is, their performance is also measured by the output of the product to the consumer.

With this model Herbarium guarantees that there is no overselling in the market. In addition to these internal tools, the market itself has the practice that products with products close to their expiration date are returned to our company at no cost to our customer, this makes us guarantee that the product on the market is only sold if there is demand.