



Review Template - B Corp Requirements for Pharmaceutical Companies

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. For more information on the specific requirements, please refer to B Lab's position statement on Pharmaceutical Companies [here](#).

The following questions will be used to evaluate whether your company must meet the industry specific requirements for pharmaceutical companies to be eligible for B Corp Certification, as well as provide an initial indication whether your company is likely to be meeting them. Please feel free to add your responses directly to this document.

Depending on your company's responses, B Lab may request additional information and/or require a decision by B Lab's independent Standards Advisory Council to determine your eligibility.

Summary of Company

This will help determine which industry requirements are applicable to your company.

Diamante Società Benefit is a biotech company focused on research and development (R&D) of innovative drugs for autoimmune diseases, with a primary focus on rheumatoid arthritis. The company operates at the early stage of the pharmaceutical value chain, developing proprietary molecules and patented technologies. Diamante does not currently engage in large-scale manufacturing or direct drug sales; its core activities are preclinical and clinical development, with the goal of licensing its solutions to industrial partners for commercialization.

The company's Headquarters and main operations, including research and development, intellectual property management, and coordination of preclinical and clinical studies is located in Veneto, Italy.

The company also has collaborations with Contract Research Organizations (CROs) in United States, EU5 countries, India for preclinical and clinical studies, business development activities, and participation in international conferences to establish partnerships and licensing agreements.

The company focuses on autoimmune diseases, primarily:

- Rheumatoid Arthritis (RA)
- Potential expansion to other chronic inflammatory conditions.



Diamante is currently an R&D-driven company with no commercialized products. Its portfolio includes:

- Proprietary pipeline: An innovative drug candidate for rheumatoid arthritis in preclinical development.
- Patented technology: Focused on selective modulation of immune pathways.

As the company does not generate revenue from drug sales.

Diamante Società Benefit 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.*

Diamante Società Benefit 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.

Diamante Società Benefit Disclosure on Required Best Practices

In order to be eligible, pharmaceutical companies must be able to demonstrate that they have the following practices in place and disclose them on their B Corp Profile:

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.*



Diamante Società Benefit operates primarily in the **drug development stage**, focusing on preclinical and early clinical research. The relevant stages for our operations are:

- **Preclinical development**
- **Clinical development (early phase)**
- **Supply chain for research materials and investigational products**

Standards adhered to:

- **Good Laboratory Practice (GLP)** for preclinical studies
- **Good Clinical Practice (GCP)** for clinical trials
- **Good Manufacturing Practice (GMP)** for production for clinical studies
- **ICH Guidelines** for safety, quality, and efficacy
- **EU and Italian regulatory requirements** for investigational medicinal products

Risk management practices:

- Selection of certified CROs and suppliers compliant with GLP/GCP/GMP
- Internal SOPs for quality assurance and data integrity
- Vendor qualification processes and audits
- Secure tracking of investigational materials to prevent substandard or counterfeit products

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.*

Diamante has a **Code of Ethics** and supporting policies that apply to **all employees and critical third parties**, covering:

- **Anti-corruption:** Zero-tolerance policy aligned with Italian law and international standards
- **Lobbying and advocacy:** Activities limited to transparent participation in industry associations; no political contributions
- **Interactions with healthcare professionals/organizations:** Governed by ethical standards and transparency requirements
- **Ethical marketing:** Currently not applicable, as Diamante does not market products

Enforcement and adherence:

- Mandatory onboarding and annual training for employees
- Contractual clauses for third parties to comply with the Code (ongoing)
- **Whistleblowing channel** accessible via secure email and anonymous reporting system
- Periodic audits and compliance reviews

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.*

Diamante's approach to government affairs is based on **transparency and integrity**:

- **Lobbying/advocacy activities:** Limited to promoting innovation and patient access through participation in biotech/pharma trade associations (e.g., national biotech associations).
- **Material issues advocated for:** Research incentives, regulatory harmonization, and support for autoimmune disease innovation.
- **Controls in place:**
 - No political contributions or donations
 - No revolving door practices
 - All advocacy conducted through recognized associations with published codes of conduct

Required Best Practices - Companies Involved in R&D

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.*

Diamante Società Benefit's R&D strategy focuses on developing innovative therapies for autoimmune diseases, leveraging proprietary technologies to address unmet medical needs. Our approach includes:

- **Internal R&D:** Conducting preclinical research and early-stage development in-house, supported by collaborations with academic institutions and CROs.
- **Collaborative R&D:** Partnering with research organizations and industry stakeholders to accelerate development and ensure scientific rigor.
- **IP Management:** Protecting innovations through patents and trade secrets. Diamante has secured patents for its core technology and actively monitors global IP landscapes to maintain freedom to operate.



Public information on our R&D and IP approach is disclosed through press releases and scientific presentations (e.g., conference abstracts).

- 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).*

Diamante's current R&D pipeline targets **Rheumatoid Arthritis**, which is listed among priority conditions in the Access to Medicine Index We are currently in an early development phase, but our strategy includes partnering in the future with pharmaceutical companies that share our commitment to social impact and equitable access

Required Best Practices - Companies Involved in Sales

- 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.*

Diamante Società Benefit is not involved in sales.

- 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).*

This is not applicable to Diamante Società Benefit

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.*

This is not applicable to Diamante Società Benefit