



## **B Lab Statement on Provepharm Life Solutions' 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..."*

Provepharm Life Solutions 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**

Provepharm Life Solutions is a French international and private pharmaceutical company, pioneer of the 3rd way, based on the principle of innovation of mature and known molecules, intended for hospital use. Provepharm's product portfolio corresponds to 58% of branded products and 42% of generics in the following areas: antidotes, diagnostics, injectable vitamins, metabolism, and neuroscience. 100% of the company's drugs and medical products require prescription. With 25 years of experience in R&D, the company relies on the expertise of more than 120 employees based in France (Marseille) and in the United States (Philadelphia) and achieved revenues of 77 million euros in 2022.

### **Provepharm Life Solutions' 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.

Provepharm Life Solutions 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.

### **Provepharm Life Solutions' 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.*

Provepharm Life Solutions maintains a list of standards and guidelines that they take into account at each stage of the life cycle of their medicines and medical devices. The company complies with Good Manufacturing Practices, Regulation (EU) 2017/745, validation of competent authorities, clinical evaluation, Fitness for use ISO 62366, Risk Management ISO 1971, ICH, Good Clinical Practice, ISO 13485, BPD, BPV and Falsified Medicine Directive.

For each of the standards, their departments carry out training, regulatory and normative monitoring gap analysis to ensure compliance with all applicable standards. They are also regularly audited by the competent authorities and their customers. Provepharm audits their critical and important suppliers based on these standards, on a regular basis as well.

To manage the risk of substandard or counterfeit medicines, Provepharm has a certified quality management system that complies with the standards stated above, which includes the following procedures: (i) Risk Management Procedure for Medical Devices, (ii) Risk assessment procedure (risk analyses are reviewed annually), (iii) Release procedures, (iv) Annual Product Review, (v) Procedure for managing clinical studies, (vi) Serialization procedure, (vii) Procedure for managing the risks of ruptures and ruptures, (viii) Complaints procedure (including declaration of 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.*

Provepharm is fully committed to complying with applicable regulations and to act with honesty and integrity.

As such, Provepharm Life Solutions has an [Ethical and Anti-Bribery Charter](#) which sets up the main principles and values that govern its daily activity and that is applicable to all employees, directors and management covering topics such as respect to competition, corruption and influence peddling, transparency, patients, and marketing. In regards to interactions with healthcare professionals, French authorities establish minimum standards and expectations on how pharmaceutical companies should conduct these activities ([De l'activité d'information par démarchage ou prospection visant à la promotion des médicaments](#)). Provepharm is certified to meet those requirements.

Complementary to their Ethical and Anti-Bribery Charter, the company has a [Supplier Code of Conduct](#) that is applied to their manufacturers and third-party distributors identified under the category of important and critical suppliers. The code covers topics such as transparency, environment, and working conditions. Additionally, the company has an [Ethical and Responsible Commercial Charter](#) to inform health professionals of their practices and guide their relationships.

To ensure adherence to the above policies for employees and critical third parties, an alert platform has been set up. The alert platform is part of an ethical system comprising several tools made available to employees and stakeholders. The platform is accessible [online](#) and it is available in two different languages. Anonymity is completely preserved when a report is made, unless the declarant voluntarily provides personal information.

Training on ethical topics is also provided to all Provepharm employees annually since 2022 and an Ethics Committee has been set up to handle alerts and violations to the company's policies and principles. The themes addressed in 2022/2023 during training offered includes sponsorship, conflict of interest, anti-gifts, anti-money laundering and anti-corruption topics. The online training modules are designed by a specialized company whose work is validated by the French Anti-Corruption Agency.

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.*

Provepharm Life Solutions' position on lobbying activities is conservative. Currently, the company is not performing direct lobbying activities related to the pharma business. Provepharm is a member of LEEM, Adelphes, INPI, Eurobiomed, UPE 13, Novachim and United Nations Global Compact.

The mission of LEEM is to represent and defend the pharmaceutical industry, conduct conventional policy with the State, negotiate with social partners, promote and defend ethics. Le Leem, groups together companies in the pharmaceutical industry in France.

As part of the implementation of the AGECE law, Provepharm is a member of Adelphes to follow developments and benefit from the tools and working groups offered by Adelphes. As for Eurobiomed, it brings together an ecosystem of more than 400 industrial players, large groups, SMEs and start-ups, research laboratories and universities who work together to develop and market innovative products and services to generate growth and jobs in buoyant markets.

The Union for Businesses of Bouches-du-Rhône (UPE 13) is the inter-professional organization which brings together all businesses from all sectors of activity, whatever their size, structure or profession. Novachim is the network of companies and research laboratories in the "Chemistry and Materials" sector in the South Provence-Alpes-Côte d'Azur region.

Provepharm has also been a member of the United Nations Global Compact since 2016.

Provepharm does not participate in lobbying or advocacy actions carried out by these organizations but they believe that the actions carried out by them have a positive impact for the world by contributing to the compliance with the 10 principles of the United Nations Global Compact and the achievement of the Sustainable Development Goals, the evolution of the eco-design of products and the evolution of waste standards, and to conduct a health policy focused on patient needs that takes into account both the return of therapeutic innovations and the objective of controlling health expenditure.

*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.*

In the last fiscal year, 23% of the company's revenue was dedicated to R&D, which means that approximately 17 million euros was invested in the development of new products. In 2022, the



main therapeutic area of investment was injectables, allowing the detection of the sentinel gland in patients with tumors.

The most attractive therapeutic area for provepharm at present are antidotes. They base on old molecules and aim to maximize their potential by improving their purity, stability, specifications, indications presentation, among others. For this, Provepharm relies largely on the literature of these products known for a long time and for which the company has a lot of perspective on their safety (e.g. methylene blue). This approach allows them to bring drugs to market faster by limiting costs, the negative impact that the development of a new product can have and at the same time offering better quality products.

Provepharm has an innovative committee with multidisciplinary composition that consists of the “think-tank” of the company, being responsible for mapping people’s needs and technological advances in the industry. Ideas are developed and explored in the innovative committee to then become innovative projects. During the development stages, Provepharm conducts ROI studies to understand the benefits of the development of the proposed idea or project. Then, the teams of different areas are involved to collaborate and execute the project.

When a collaborator declares to have developed a new product or technology, Provepharm’s Patent Committee conducts studies and analysis to understand the potential of this product. The teams and collaborators involved in the project are then recognized by the company through bonuses. After the analysis of the project is finalized, if the company identifies potential for its production and development, Provepharm can either impose secrecy regarding the new discovery or proceed with the patent application. Currently, Provepharm has 126 patents and patent applications divided into product families. All patents are publicly available on [Espacenet](#).

*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).*

Provepharm has been involved for several years in the fight against Malaria. The publication of work on the efficacy of methylene blue against the disease paved the way for a long research process. It is with this in mind that Provepharm has registered, with the objective of evaluating methylene blue, for approval by the health authorities of the countries of the endemic zone.

Provepharm designed an innovative chemical synthesis pathway, patented internationally, for Methylene Blue, “Proveblue®”, which is the only Active Pharmaceutical Ingredient (API) approved in the US, and fully compliant with all requirements of the current pharmacopeias



USP, Ph. Eur. and relevant ICH Guidelines. Provepharm's IV injectable Methylene Blue has been approved by FDA for the treatment of pediatric and adult patients with acquired methemoglobinemia (ProvayBlue®), as well as in EMA-related countries, and Australia, New-Zealand, South Korea and Japan (Proveblue®).

Already available pre-clinical and clinical data support the therapeutic potential of Methylene Blue for the treatment of Malaria, and Provepharm, as a part of its internal Social Responsibility and Environment Policy, is now seeking to support the further assessment of Methylene Blue for the treatment of Malaria in developing countries of the endemic zone.

In this context, Provepharm initiated with the US Army Walter Reed Institute of Research (WRAIR) a joined effort project in 2017, with the support of an international board of scientific experts in Malaria, which was dedicated to defining the orientations to follow for carrying on at best the development of Methylene Blue in Malaria.

The objectives of this joined reflection was to (i) review and take stock of already available data on Methylene Blue in Malaria; (ii) identify the key steps toward the regulatory approval of Methylene Blue for the treatment of Malaria in endemic countries, within a "no gain no loss" approach by Provepharm, i.e.: Provepharm not looking to reap any financial gain from this endeavor, but hoping to minimize its external costs, while proposing its support to the scientific community effort, including the possibility of providing clinical supply of its product, Proveblue® .

International Key Scientific Experts in the domain joined this project by participating in the first Consortium Meeting held in Paris in June 2019, which kicked-off the process of building a Development Plan. Two key steps which were clearly identified by the scientific board were:

1. The need for a comparative assessment of the parasite clearance under treatment with Proveblue® in order to illustrate the medical need among the already available therapeutic arsenal.
2. Better anticipation of the safety profile of Proveblue® in G6PD-deficient patient population, given that this genetic anomaly is of higher prevalence in developing countries of the endemic zone.

Provepharm carried on supporting the preclinical assessments of Methylene Blue, notably on different stages of the parasite, by providing Proveblue® to the scientific community in order to implement the knowledge of Methylene Blue potential in Malaria. Provepharm is also working with the scientific community on a clinical study protocol to propose for the comparative assessment of the parasite clearance under Methylene Blue treatment in malaria-infected patients.



This initiative was crowned by the Galien MedStartup prize in the category "Best collaboration or partnership for a disruptive solution dedicated to developing countries". Provepharm intends to federate the global community of methylene blue experts in Malaria, in order to build a development program and mobilize investors to finance this program, as part of a "no gain, no loss" business model for the company.

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.*

On the private market, Provepharm has standard price grids for each of their products that they adapt in coordination with local partners, taking into account the competitive environment of the country in order to establish a price that is consistent with the market of the country in which Provepharm operates. For low- and middle-income countries, prices are set in agreement with their local distributor considering the purchasing power (population of the country) and competitive environment.

Provepharm is in a direct sales model in France and plays a key role in terms of market access by declining by 20 to 50% its catalog price in order to make their portfolio affordable to a larger number of customers.

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).*

Incentive programmes promoted by Provepharm, when allowed by local authorities and rules established to the pharma industry, consider two different aspects: training program to HCPs in order for them to use Provepharm portfolio according to the indication of the product, and sales targets. Provepharm's sales targets considers contracts are built with their local distributors and, in order to avoid any risk of overstocking and overselling, they provide for a minimum stock of 3 to 4 months in the country. No more than that. Qualitative incentives are also used to balance quantitative sales incentives. These qualitative incentives include educational programs on products and scientific environments offered to healthcare professionals.

Provepharm has obtained certification for its information activities by canvassing or prospecting aimed at promoting medicines (according to the [HAS standard of March 2017](#)). To be certified, the company has to demonstrate that they meet the minimum expectations for ethics, and



training and evaluation of professionals involved in promotion and sales of medicines. These minimum expectations are standards created and validated by the French health authorities.