



### **B Lab Statement on Laboratoires Expanscience'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..."*

Laboratoires Expanscience - 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**

Expanscience is a French family-owned company specializing in Dermo-Cosmetics, Joint well-being and Rheumatology, Dermatology, Cosmetic Active Ingredients. It sells branded pharmaceutical products (both prescription products and over-the-counter products) that account for approximately 27% of the company's annual revenue in the therapeutic areas of osteoarthritis, osteoporosis, and skin health. The company has no drug development activities. It carries out manufacturing activities for some of its pharmaceutical products at its primary manufacturing site in France and engages with subcontractors to manufacture the remainder of its pharmaceutical products. It sells distributes pharmaceutical products directly through its subsidiaries in France, Turkey, and Mexico, with a majority of products for sale in France only. The drug portfolio is also distributed through distributor contracts in 45 countries in Africa, the Middle East, Asia, Latin America and Europe.

### **Laboratoires Expanscience'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.

Laboratoires Expanscience 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.

### **Laboratoires Expanscience'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 our products are produced in accordance with relevant European law regulation and standards facilities are monitored by relevant regulatory bodies and inspected by the relevant authorities listed below, in order to confirm quality, efficacy and safety of our products and compliance with applicable regulations.

The Operator (based at Paris La Défense) and Manufacturer (based in Epernon) sites of Expanscience comply with the regulations in force, in particular:

For the Operator:

- Code de la Santé Publique (French Public Health Code)
- BPPV in France & GVP (Good Pharmacovigilance Practices) in Europe
- BPDG in France & GDP (Good Distribution Practices) in Europe
- HAS (French Health Authority) charter and repository for information activity through canvassing or prospecting aimed at promoting drugs
- ANSM recommendations for Drug Advertising
- EMA guidelines for Medicinal Products
- ANSM guidelines for Medicinal Products

For the Manufacturer:

- BPF in France & GMP (Good Manufacturing Practices) for medicinal products for human use in Europe;
- BPDG in France & GDP (Good Distribution Practices) in Europe



- European Pharmacopoeia
- 21 CFR 210-211 General Current GMP for Finished Pharmaceuticals

Each site holds an Opening Authorization, issued by the French Health National Authority:

- For the Operator: comply with GDP requirements, i.e. Wholesaler distribution (supply, export, exploitation of medicinal products other than investigational products),
  - For the Manufacturer: manufacturing operations and importation of medicinal products
- These Opening Authorization reflect the compliance status of the premises of the Operator and the Manufacturer, with a specific period of validity for each one.

These 2 sites are regularly inspected by French Health Authorities. In addition, the Manufacturer site may also be regularly inspected by foreign Health Authorities depending of the exportation areas of the Medicinal Product.

The Operator site is audited as part of the certification of the promotional information activity.

The reports emanating from these inspections and external audits are used as a source of continuous improvement and control of the sites' compliance with the relevant standards.

Expanscience's Regulatory, Vigilance and Quality Department guarantees the compliance, safety and quality of drugs over the entire life cycle of a drug from its manufacture to its distribution in the territories concerned:

- I. Prior any distribution of Medicinal Product, the Product must get a Marketing Authorization (MA) issued by a Competent Authority (in France this is the French National Health Authority ANSM). The issuance of a MA is based on the examination of the benefit / risk balance of the product, and more precisely on the examination of:
  - its effectiveness,
  - the foreseeable adverse effects,
  - the quality of the medicinal product as well as the quality of the manufacturing process.
- II. Production of Medicinal Products is documented in a batch file, in accordance with specific procedures corresponding to each stage of production, including cleaning and line clearance. During the manufacturing or the packaging process, production operators carry out In Process Controls, in accordance with internal procedures and production instructions. At the end of the production, each batch produced is controlled by the quality control department and the Quality Assurance department certifies all the batches according to the marketing authorization and GMP. Where the manufacturing and packaging operations are subcontracted, the subcontractor complies with GMP according to a Technical Agreement and a quality audit is carried out according to a yearly risk analysis. Medicines can only be released on the market by authorized Pharmacists by delegation of the Responsible Pharmacist.
- III. Once the drug is marketed, different services are in charge of post-market surveillance, including:



- A. Pharmacovigilance: responsible for identifying, evaluating and preventing the risk of adverse effects from drugs or distributed products. Pharmacovigilance monitors and prevents the risk of side effects from drugs in order to optimize their proper use.
  - B. Management of quality complaints,
  - C. Management of a withdrawal / recall when necessary in case of:
    - 1. A critical product quality defect,
    - 2. A potential or proven public health problem,
    - 3. If requested by a competent health authority.
  - IV. In the complaint management process (patients, healthcare professionals), the company systematically checks the absence of risk of counterfeit or not.
  - V. In order to avoid counterfeit Medicinal Product, the Manufacturer performs serialization and aggregation if requested.
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.*

Expanscience has a compliance program that includes a code of business ethics (1), an internal whistleblowing system (2), third-party assessments (3), training programs (4), and contractual provisions (5).

- 1) The Code of Ethics applies to all of the company's affiliates (salaried employees, temporary workers, trainees, external personnel, and executive corporate officers) as well as its Business Partners. It sets out the minimum ethical requirements for Expanscience affiliates on topics such as gifts and hospitality, relationships with business partners, intermediaries and customers, conflicts of interest, lobbying, donations and sponsorship.
- 2) The company has an internal whistleblowing channel allowing employees to confidentially report potential violations of the Code of Ethics. The reporting of a violation could not trigger a sanction against the person who reported the alleged breach.
- 3) To reduce its exposure to anti corruption risks, Expanscience conducts screening (so-called "Know Your Customer" screens) on its clients and suppliers located in countries most exposed to corruption risks. To do so, Expanscience uses an external



tool called indueD. Such third-party assessments are conducted before signing any contract; they aim at identifying the risks of fraud, sanctions, and/or corruption.

- 4) To familiarize its employees with compliance matters, Expanscience makes available on its internal e-learning platform two e-learning modules (available in several languages), covering (i) corruption and influence peddling and (ii) GDPR. These two modules are compulsory for all employees and are part of the onboarding package for new hires. Additional compliance training is also conducted to the most exposed employees. They include courses focused on interactions with healthcare providers and professionals (“anti-gift and transparency management”) and training on competition laws.
- 5) Anti-corruption clauses are included in most of our contracts to reflect the principles set forth in Expanscience’s Code of Ethics. This provision clearly outlines that any anti corruption practice amounts to a contractual fault that could trigger the early termination of the contract.

Regarding responsible advertising, all messages are supported by clinical evidence. Every communication or advertising material —whether physical or digital— is internally reviewed by the Medical and Regulatory Affairs departments. In France, advertising for medicinal products must be submitted to the French Health Authorities and receive formal approval before being used with healthcare professionals or patients. In most countries, Expanscience is not allowed to market directly to consumers and may only address healthcare professionals. Regulatory bodies strictly define and limit the content and targeting of the company’s communication campaigns, overseeing every marketing tool.

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.*

Expanscience does not engage in any direct lobbying activities outside of its industry associations, whose purpose is to represent the interests of the industry before the public authorities and to advocate/coordinate the industry’s efforts and actions towards consumers and patients.

Moreover, political contributions are strictly prohibited in the company’s Code of Ethics and the Code also outlines expected conduct when engaging in lobbying activities, which prohibits any gifts or benefits of any kind to public officials.



## 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.*

Expanscience has no R&D on pharmaceutical activities.

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).*

Expanscience has no R&D on pharmaceutical activities.

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.*

The majority of Expanscience products follow the pricing defined by national authorities (such as, for France, the Economic Committee for Medicinal Products (CEPS)), so they are regulated according to reference pricing and/or value-based pricing methodologies.

This includes sales in the company's LMIC subsidiaries, Mexico and Turkey. In Mexico, the company's products are among the most affordable on the market, while in Turkey, prices are set by the government. In LMIC countries where products are marketed by distributors, Expanscience sets a price with its distributors who takes into account different criteria, including that of competing specialties present in the market, daily treatment costs, market players, distributors' profitability, international recommendations, and inflation.

To reinforce the access to osteoarthritis treatment globally, the company has developed therapeutic educational tools that are free of charge for HCP's and patients such as webinars, podcasts, websites, applications (Martha App, Arthrolink, OASIS, Vivir sin limites website). They



include educational programs, such as well-being, nutrition, adapted physical activities to improve quality of life.

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).*

Expanscience sales representatives have a combination of financial incentives based on both sales volume and qualitative objectives, that ensures that sales activities are in line with the company's strategy. For sales volumes, they are encouraged to seek the right balance between sell in (sales to retailers) and sell out (sales to customers), and they have been incentivized over the past years to reduce customer stock levels (e.g., in pharmacies). This approach helps prevent overstocking, overselling, and waste by having a better balance between sales and actual needs. There also have incentives on qualitative objectives such as training or services granted to customers.

For other business functions benefiting from a bonus system, sales-related objectives, whether in terms of turnover or volume, have been removed. Instead, incentives include performance indicators that ensure the right profitability to keep the company and business sustainable over time, as well as impact objectives (such as % of carbon emission reduction).

8. *[IF APPLICABLE] 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*

This is not applicable to Expanscience.

### **B Lab's Public Complaints Process**

Any party may submit a complaint about a current B Corp through [B Lab's Public Complaint Process](#). Grounds for complaint include:

1. Intentional misrepresentation of practices, policies, and/or claimed outcomes during the [certification process](#), or
2. Breach of the core values articulated in our [Declaration of Interdependence](#) within the B Corp Community.