

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

Laboratoires Expanscience is a French family-owned company specializing in the treatment of osteoarthritis and skin health. It sells branded pharmaceutical products (both prescription products and over-the-counter products) that account for approximately 30% of the company's annual revenue in the therapeutic areas of osteoarthritis, osteoporosis, and skin health. The company is no longer involved in research and development (R&D) activities for pharmaceutical products. 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 pharmaceutical products directly through its subsidiaries in France, Turkey, and Mexico, with a majority of products for sale in France only. The company also has indirect sales of its product Piasclédine 300, used for the treatment of osteoarthritis, through contracts with distributors in 44 countries across 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.

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

For the Operator:

- Public health code;
- BPPV & GVP (Good Pharmacovigilance Practices) Europe;
- BPF GMP (Good Manufacturing Practices) for medicinal products for human use;
- BPD GDP (Good Distribution Practices);
- HAS (French Health Authority) charter and repository for information activity through canvassing or prospecting aimed at promoting drugs;

For the Manufacturer:

- Guide of BPF (Good Manufacturing Practices)
- European GMP (Good Manufacturing Practices) (Part I & II);
- BPDG (Good Distribution Practices);



• European Pharmacopoeia;

Each site holds an Opening Authorization, issued by the French National Agency for the Safety of Medicines:

- For the Operator: Operator of drugs other than investigational drugs and wholesale distributor operations,
- For the Manufacturer: manufacturer / importer and a certificate of compliance with good manufacturing practices (GMP) for medicinal products for human use.

These 2 sites are regularly inspected by the health authorities. In addition, the Manufacturer site is audited by its principals or foreign health authorities and 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.

Laboratoires Expanscience's Pharmaceuticals and Cosmetics Department and the Corporate 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. Before a drug can be distributed, it must have a Marketing Authorization (MA) which is issued by a health authorization (in France this is the French National Agency for the Safety of Medicines). The issuance of an 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. In the countries of the European Union, there are 3 European procedures and 1 national procedure for obtaining a marketing authorization. In countries outside Europe, the country's local regulations apply to register a drug.
- II. All stages of production are documented in a batch file, in accordance with specific procedures corresponding to each stage of production, including cleaning and line emptying. During the manufacturing or packaging process, production operators carry out ongoing checks, in accordance with internal procedures and production instructions. At the end of production, each batch produced is controlled by the quality control department and Quality Assurance proceeds to the marketing of batches of drugs in view of the conformity of the documents (batch records and analytical / microbiological results) in accordance with the MA dossier. Where the manufacturing and packaging operations are subcontracted, the subcontractor must meet certain quality and specific authorization criteria, moreover a quality contract is issued so that the respective



commitments are respected and in particular to provide a drug that complies with its Marketing Authorization.

- III. Medicines can only be placed on the market by persons trained and authorized by the responsible pharmacist.
- IV. 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 products placed on the market. Pharmacovigilance makes it possible to monitor and prevent 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 it can present:
 - 1. A product quality defect (with or without impact on public health),
 - 2. A potential or proven public health problem,
 - 3. A discontinuation of the marketing of a specialty,
 - 4. At the request of the competent health authorities.
- V. In the complaint management process (patients, healthcare professionals), the company systematically assesses whether it is a counterfeit or not, and in its production processes uses serialization to mitigate the risk of counterfeiting.
- 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.

Laboratoires Expanscience has a compliance program that includes a code of business ethics, third-party assessments, an internal whistleblowing system, training programs about anti-bribery and prevention of conflicts of interests, and a specific focus on the interactions with healthcare providers and professionals (including an in-house "anti-gift and transparency manager" dedicated to this role).

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 Laboratoires Expanscience affiliates on topics such as gifts and hospitality, relationships with business partners, intermediaries and customers, conflicts of interest, lobbying, donations and



sponsorship. The company has an internal whistleblowing channel that is administered by an external service provider and allows employees to confidentially report potential violations of the Code of Ethics.

Training on compliance (anti-bribery, conflicts of interest, GDPR, etc.) is conducted for all new employees and when procedures are updated. In addition, employees in roles that engage the company with third parties receive additional training at least every two years.

Regarding its business partners, the principles of Laboratoires Expanscience's Code of Ethics and specific anti-bribery and anti-corruption clauses are included in and enforceable through its formal agreements with said partners. In addition, all Significant Partners (defined as contracts exceeding a predetermined value) and partners presenting specific risks (such as country risk of corruption) are subject to an additional verification procedure conducted by the Compliance Unit. Third-party assessments are conducted at the onboarding stage to identify risks of fraud, sanctions, and/or corruption.

Regarding responsible marketing, all messages are pre-clinical or clinically proven. Commercial communication for the pharmaceutical sector for patients and healthcare professionals is subject to validation by a regulator organism such as the French National Agency for the Safety of Medicines in France, ANVIS-Brazil, Cofepris-Mexico, etc. In most of the countries, Laboratoires Expanscience is not permitted to market directly to consumers, only to HCPs. Regulator organisms limit and frame the content and targeting of the company's communication campaigns, regulating each and every marketing tool.

In 2009, the company signed the advertisers charter for responsible consumption, which evolved into the <u>FAIRe program</u> and reports every year an action plan on responsible communication within the framework of the FAIRe program of the Union des Marques, and has a program to train employees about responsible communication.

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.

Laboratoires Expanscience does not engage in any direct lobbying activities outside of its industry associations. Laboratoires Expanscience is a member of the LEEM (pharmaceutical trade association) 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. 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.

Regarding policy advocacy activities, Expanscience has been involved in 2018 when the President of Expanscience participated in the government mission on the elaboration of the French law PACTE (Plan d'Action pour le Croissance et la Transformation des Entreprises - Action Plan for the Growth and Transformation of Companies), to give his vision on how company can serve general interest of the society.

4. 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 Laboratoires Expanscience products follow the pricing defined by the national authorities (such as for France the Economic Committee for Medicinal Products (CEPS)), which are regulated according to reference pricing and/or value-based pricing methodologies. This includes sales in the company's only direct LMIC market, Mexico, where its offerings are one of the cheapest on the market.

In LMIC countries, Laboratoires Expanscience can fix a price with its distributors who will take 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 (Arthrocoach App, Let's Talk OA, Vivir sin limites website). They include educational programs, such as well-being, nutrition, adapted physical activities to improve quality of life.

5. 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).



Laboratoires Expanscience seeks a balance of "sell in" (sales to retailers) and "sell out" (sales to customers) sales objectives. The company's sales representatives can have bonuses based on their turnover, but there is no incentive to sell beyond the turnover objective to avoid overselling, and the turnover objective is set based on sales from the previous year.

In addition, in 2020 the company introduced a CSR target-based bonus based on inventory analysis and recommending practices to reduce high inventory levels and reduce waste.