B Lab Statement on UPSA'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…"

UPSA 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

Founded in 1935, UPSA is one of France's largest industrial pharmaceutical companies which is active in both prescription and non-prescription drugs mainly for pain products. As a mid-sized pharmaceutical company, UPSA is Europe's leading producer of paracetamol-based medicines.

UPSA is engaged in the development activities for new product formulations or galenic forms. The company's main direct operations, including sales and marketing organizations, are in France (43.8%), Belgium (10.6%), Switzerland (7.5%) and Italy (1.9%). In other markets, UPSA products are sold through third-party distributors (36.4%), mainly in continental Europe, French Speaking Africa and Vietnam. The company manufactures close to 100% of its products in its 2 manufacturing sites located in Agen, France. The primary road to market is direct sales to pharmacies or wholesalers with no direct sales to customers. UPSA distributes all of their production directly from their two distribution centers also located in Agen.

UPSA is present across the entire value chain, from production to distribution. In the value chain of the pharmaceutical industry, companies like UPSA are key to making available essential drugs for day-to-day ailments, both through the prescription and over-the-counter channel.

UPSA products are available in the following main therapeutic areas:

- Pain & Fever
- Cold & Flu

- Digestion
- Sleep Induction
- Vitamins and Well-being

The main product category is Paracetamol containing products which make up 74% of revenues. Paracetamol is an essential drug (as per WHO standards) for the treatment of pain and fever which is widely available and not patent protected. In France, paracetamol is available both with a prescription status (82%) and an over-the-counter status (8%). In other countries, paracetamol may be available with a medical prescription, but mostly with an over-the-counter / non-reimbursed status. The cold & flu category (10%) is available over-the-counter and consists of various branded drugs combining different ingredients.

The digestion, sleep induction and vitamin categories account for 16% of revenues and are also available over-the-counter without medical prescription. UPSA is selling only branded products, which are based entirely on non-patent protected active ingredients.

UPSA'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.

UPSA 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.

UPSA'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.*

   UPSA is a full-scope pharmaceutical company controlling its entire value chain from sourcing active ingredients to product formulation and final pharmaceutical manufacturing. UPSA also controls its distribution to third party platforms (direct to pharmacies, wholesalers, export partners).

   UPSA is subject to, adheres to and acts in line with all national and European laws and regulations applicable to the pharmaceutical industry which strive to guarantee 100% product quality and safety for all patients and customers.

   UPSA is the subject of regular audits by competent authorities in France to verify and certify that it acts in line with all current Good Manufacturing Practices, Good Distribution Practices and all rules governing the life-cycle of products, including pharmacovigilance and the rules for promotion in line with legal and ethical standards.

   UPSA has put in place a strict and robust Quality Management System that ensures that all operations (manufacturing, testing, release, promotion) are carried out in strict compliance with applicable rules, in line with ICH Quality Guideline Q10 on Pharmaceutical Quality Systems.

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.*

UPSA is governed by the Code of Ethics of its parent company (Taisho Pharmaceutical Company Ltd) and has implemented a comprehensive set of company policies and procedures, including amongst other:

- Anti-corruption and bribery
- Conflicts of interests
- Fair Competition, Competitive Intelligence and Professional organizations
- Interactions with healthcare professional / organizations and Transparency Disclosure
- Whistleblowing process
- Contracts / Purchasing
- Privacy

All policies are applicable to all UPSA employees. When dealing with critical third parties, UPSA contractually imposes equivalent standards to be respected by all subcontractors. UPSA carries out compliance checks and due diligence on all critical business partners to ensure compliance with its own compliance standards.

UPSA has a comprehensive compliance program in place by which all employees must certify that they have read and understood all applicable company policies. Specific trainings are dispensed to all exposed employees in specific areas:

- Anti-corruption & bribery
- Privacy
- Pharmacovigilance

UPSA has a whistleblowing line in place for all employees and all third parties which enter in relation with UPSA. All such activities comply with the requirements of the French SAPIN 2 anticorruption Law.

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.*

UPSA is subject to the French Law on Transparency regarding all its lobbying activities and interactions with public or governmental bodies. A transparency disclosure is carried out each year directly on the portal of the competent Authority (Haute Autorité pour la Transparence de la Vie Publique).

In addition, UPSA personnel responsible to interact with public or governmental bodies are holding detailed records of their interactions. No hospitality is granted under any circumstance.

No political contributions or donations are made; no lobbying on behalf of UPSA is mandated; no public officials are recruited.

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.*

   No R&D activities are carried out by UPSA. UPSA products and product developments are not patent protected.

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).*

   No R&D activities, including those for priority diseases, are carried out by UPSA. UPSA products and product developments are not patent protected.

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.*

In its home market – France – UPSA is subject to a highly regulated pricing environment. 80% of its revenues in France are generated by reimbursed products. Prices of reimbursed products are determined by the competent authority (in France: CEPS). It may be noted that prices of paracetamol products are set at a very low level.

In other markets (or other product categories) UPSA products are available over-the-counter and the pricing is free. It means pricing is based on the competitive environment with other manufacturers offering the same or similar products.

Generally speaking, over-the-counter selfcare medication products are cheap and affordable. This is true also in low / middle income countries where UPSA products are being distributed, in particular in French Speaking Africa. UPSA products are available together with other competing products, including generics, at competitive / affordable prices.

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).*

In France, which is UPSA's primary market for sales related activities, it must be noted that activities of sales teams are disconnected from activities of medical information / promotion from a regulatory point of view. Promotion of pharmaceutical products to healthcare professionals, indeed, is restricted to a specific category of individuals, medical representatives, who undergo specific training from the products characteristics, medical background but also legal and ethical rules point of view.

The primary mission of sales teams is to visit pharmacies, present the UPSA product portfolio and negotiate commercial conditions of sale. By definition, orders of pharmacies are based on their needs / needs of their own customers and ability to supply the same. Storage capacities of pharmacies are generally very limited and pharmacies need to be able to hold stocks of all products from all manufacturers in all product categories / indications. From that perspective, risks of overselling / overstocking are very limited.

UPSA's business model in France is mainly based on a direct to pharmacies distribution model (91%). Sales to wholesalers and hospitals are limited (9%) and only general terms and commercial conditions apply.

All activities are governed by Industry standards and company internal rules. Sales teams undergo specific training related to interactions with healthcare professionals and anti-bribery. All medical representatives and sales agents have a legal and industry standard / company obligation to promote the “right usage of medicines”.

While the remuneration package of sales agents does provide an element linked to the evolution of sales versus overall market performance, the framework does not create a risk of overselling in that context.