B Lab Statement on CNX Therapeutics Limited 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…"

CNX Therapeutics Limited 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
CNX Therapeutics Limited (CNX) is dedicated to the supply of essential medicines to wholesalers, hospitals and pharmacies. The company does not participate in drug development activities nor in the direct manufacturing process, all the products are manufactured by third party contractors.

CNX has a direct presence in the UK, Ireland and the Nordics, where they conduct direct product sales. CNX also has indirect operations throughout Europe, the Middle East, Latin America and Asia Pacific, where they work with partners for medicines distribution.

The company commercializes and distributes prescription-only essential medicines for Central Nervous System (CNS) disorders including schizophrenia, a range of medicines for use in critical care settings, and Oncology. The company's portfolio can be found here.

All products supplied by CNX are prescription-only medicines; 85% of the products are branded, and 15% are generics. The medicines therapy areas can be categorized by revenue: 70% CNS, 15% oncology, 10% hospital essential medicines, and 5% antibiotics.

CNX Therapeutics Limited (CNX) 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.

CNX Therapeutics 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.

CNX Therapeutics Limited 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.*

CNX Therapeutics is directly engaged in pharmaceutical supply chain and distribution activities. The company holds a UK Wholesale Dealers Authorization (WDA), issued by the UK Medicines and Healthcare products Regulatory Agency (MHRA). In order for a WDA to be granted, CNX has to comply with the requirements of Good Distribution Practice (GDP) to ensure that medicines are obtained from the licensed supply chain and are consistently stored, transported and handled under suitable conditions, as required by the Marketing Authorization (MA) or product specification. The MHRA carries out inspections to check that sites comply with GDP and CNX had its MHRA GDP inspection in November 2023, which was successfully approved.

CNX Therapeutics medicinal products are manufactured by third-party contract manufacturers. All of them must meet the standards of Good Manufacturing Practice (GMP) to ensure that products are of consistent high quality, be appropriate to their intended use, and meet the requirements of the Marketing Authorization (MA) or product specification.

As the product Marketing Authorization (MA) holder, CNX Therapeutics is responsible for ensuring its third-party contractors (including manufacturers, testing laboratories, storage and

distribution sites, release sites and all other regulated service providers) are meeting Good Manufacturing Practice (GMP) and/or Good Distribution Practice (GDP). To ensure this the company implements the following management practices:

- Initial qualification of a new third party service provider. This can be performed via audit or by completion of an assessment questionnaire.
- Obtaining the third party's certificates/licenses as issued by their local Healthcare Authority.
- Routine audit of their facility and Quality Management System. Frequency of audit is based on risk assessment and the nature of the activity being performed. • Agreeing and signing a Quality Technical Agreement (QTA) with all applicable third-party service providers that defines the responsibilities of each party.
- Routine review and assessment of all third-party service provider performance via review of Key Performance Indicators (KPIs), such as customer complaint volume, audit and inspection outcomes, compliance risk etc.

CNX Therapeutics also implements an electronic Quality Management System (eQMS) called DotCompliance, which is used to manage Customer Complaints, Deviations, Change Controls, Corrective Actions and Preventive Actions (CAPAs), audit schedules, risk assessments, QTAs, and document lifecycle review for Standard Operating Procedures (SOPs), Policies and Work Instructions. The Quality Management system is reviewed quarterly and results presented at Quality Management Review meetings. Quality KPIs and opportunities for improvement, along with third party contractor performance is assessed and discussed.

As the holder of the Wholesale Dealers Authorization (WDA), CNX Therapeutics fully adopts and implements the Falsified Medicines Directive (FMD) as required in the European Union (EU), and as required in the UK following the UK's departure from the EU. FMD was adopted in 2011 and introduced new harmonized measures to ensure that medicines in the EU are safe and that trade in medicines is properly controlled.

CNX has a written, approved Policy and Standard Operating Procedures (SOPs) that document the processes to be followed should a suspected falsified medicine be reported. In the event of a suspected falsified medicine being reported to CNX it will be captured in the eQMS as a deviation and an investigation performed, with associated CAPAs as required. Any suspected falsified medicine is immediately reported to the applicable contacts in the relevant Quality Technical Agreements, the relevant RP, releasing QP and/or MAH for thorough investigation. Furthermore, the relevant National Health Authority must immediately be notified.

CNX Therapeutics assures that all third-party contractors performing GMP / GDP activities are compliant with the FMD directive by documenting responsibilities in Quality Technical Agreements, and confirming during audits of third-party contractors that they have the relevant established documented procedures to be compliant with the FMD.

CNX Therapeutics only purchases pharmaceutical products from approved third party contractors, where the product batch has been released to market by an EU Qualified Person (QP) as amended on the Community Code relating to medicinal products for human use, and the Marketing Authorization. This assures that every batch of product has been manufactured to GMP and the registered product specification. CNX Therapeutics only sells pharmaceutical products to customers who have successfully passed a Bona Fide check to verify the legitimacy of the business.

All CNX Therapeutics products are, where required, labeled and traceable via serialization. This is the process of assigning a unique identification code to each individual package or unit of medication. This identification code allows the package to be tracked through the entire supply chain, from the manufacturer to the pharmacy or hospital and was designed to combat falsified medicine from entering the supply chain.

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.

CNX Therapeutics has a Code of Ethics/Conduct which sets up the main principles and values that govern its daily activity and that is applicable to all stakeholders covering topics such as anti corruption and bribery and conflict of interest resolution.

The company's ethical policies are applicable to all employees and critical third parties. The company provides annual mandatory compliance training to all employees and contractors via TalentLMS on the following topics: Anti-Bribery, Anti-Money Laundering, Code of Conduct, Whistleblowing, GDPR, Data Protection, Date Breaches and Unconscious Bias.

CNX Therapeutics has recently engaged the Supplier Ethical Data Exchange (Sedex) to provide detailed information on compliance and ethics within its supply chain. Whilst the company onboard Sedex, it provides a questionnaire to its suppliers and potential suppliers focused on the following key points:

- the ownership of the company and details of any persons of significant control.
- permits and government relations.
- conflicts of interest.
- financial information for credit check purposes.
- details of direct and indirect suppliers in their supply chain, how they are managed and the due diligence undertaken on them.
- policies and practices around modern slavery.

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- policies and practices on the environment.
- conduct and compliance, including whether anyone has been investigated for unfair business practices, breaches of any laws or bankruptcy information.
- copies of anti-bribery and anti-corruption policies, DEI policies, H&S policies, community engagement and other ESG policies.
- cyber security insurance and policies.
- various liability insurance limits.
- confirmation of business continuity plans.

Once the information is received, it is assessed internally by the relevant functions and a decision is reached as to whether to pursue a contract with the supplier.

CNX Therapeutics has a Whistleblowing Policy which forms part of its employee and contractor onboarding, and which has to be signed by employees and contractors when they join the company. A whistleblower channel is also in place for personnel and other stakeholders to report concerns.

CNX Therapeutics is not currently involved in marketing activities and is not a member of the ABPI (Association of the British Pharmaceutical Industry) anymore, but the company continues to comply with the provisions of the ABPI Code which includes provisions relating to lobbying and advocacy, and interactions with healthcare professionals (HCPs). The company's payments to its healthcare professionals are disclosed on its website: Declarations of Payments to Patient Organisations and Disclosure of Payments to Healthcare Professionals and Healthcare Organisations.

Although CNX does not currently undertake marketing activities, the company has recently contracted a consultant to advise on reviewing lobbying, advocacy and interactions with HCPs policies and updating them to ensure continuing compliance with the ABPI Code in the event the company does launch marketing activities for any of its products.

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 regard to political contributions, lobbying/advocacy on the company's behalf, revolving door policy, political contributions and donations.*

CNX Therapeutics confirms they do not undertake any lobbying/advocacy activities with government authorities/officials or political contributions and donations. The company's Charitable Donations Policy clarifies that charitable donations include financial contributions as well as contributions in-kind which may include, but are not limited to, donations of CNX's products or services, volunteering of employee time and the use of other CNX assets or resources.

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.*

CNX Therapeutics is not currently involved in research & development related 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).*

N/A

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.*

CNX Therapeutics works with and abide by regulations from government authorities on pricing and reimbursement in different geographies. In low- and middle- income countries (LMICs), the company works with partners to ensure fair and consistent distribution of medicine locally. The partners are chosen based on their local knowledge and expertise, as well as reputation.

In LMICs the company only sells licensed products that are registered locally. As part of the registration process the products go through a pricing and reimbursement process with the local authorities. This process takes into consideration the particular situation and requirements of each healthcare system and results in an approved price that is considered adequate by the local authorities. Neither CNX nor their local partners can unilaterally decide the pricing of the products in the markets.

The company also has internal Standard Operating Procedures (SOPs) for price changes that must be followed. Where a price change is proposed or pricing is to be agreed in advance of a tender submission, the Vice President - Commercial Operations prepares a proposal which may include, but is not limited to, price history, the NHS List Price (and history), IQVIA data on pricing, the rationale for the proposed change. This is reviewed by the CEO, CFO, COO and Vice President, Legal & ESG. The proposal is discussed and either agreed or further information is requested before a decision is reached.

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).*

CNX Therapeutics does not have direct sales teams and so do not have financial incentives tied to sales volumes. The company has overarching corporate objectives which include a target level of EBITDA (earnings before interest, taxation, depreciation and amortization) for its base business, not including new assets acquired. This is one of 5 elements that make up to 40% of the company bonus scheme. The remaining 60% is tied to areas including sustainability, culture and community initiatives, project management and integration of new assets. The company does not have practices that do, or could, incentivize overselling or other irresponsible sales practices.

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.

CNX Therapeutics is not currently listed on ATMI.