



## **B Lab Controversial Issues Statement - Pharmaceutical Companies**

### **B Lab's Approach to Controversial Issues and B Corp Certification**

As for-profit companies that meet the most rigorous standards of overall social and environmental performance, accountability, and transparency, Certified B Corporations are leaders in the movement to use business as a force for good.

Whether through information a company provides in its [Disclosure Questionnaire](#), an issue raised by a third-party through B Lab's formal [Complaints Process](#), or public discourse on B Corp certification requirements and standards, difficult and complex questions regularly arise as to how controversial issues in the world of business should affect a company's eligibility for B Corp certification. Judgments on these issues are then determined by B Lab's independent [Standards Advisory Council](#) as part of a disclosure review process.

B Lab's Disclosure Questionnaire forms the basis of the disclosure review process, which covers sensitive industries, practices, outcomes, and penalties and is based on third party screenings and standards like the IFC Excluded Industries List and International Labor Organization Conventions. Recognizing that any list of sensitive issues may be incomplete, however, B Lab also reserves the right to conduct similar reviews on issues that are not currently featured in the Disclosure Questionnaire, but are deemed subject to material stakeholder concern and a potential violation of the B Corp movement's Declaration of Interdependence.

When new industries or issues where a decision making model has not already been developed arise, B Lab conducts research into the issue in order to guide the Standards Advisory Council's decision. Research is based on secondary sources compiled by B Lab staff, with the overall intent of identifying and understanding the different concerns related to the industry or issue and the different perspectives of stakeholders. This includes a review of press related to the industry and its impact, how the issue is covered by other standards, existing public policy and public policy recommendations from non-profit organizations and other topical experts, examples - potentially both good and bad - of actors within the industry, interviews with expert stakeholders and other public commentary and perspectives. This content is in turn used to develop the framework for Standards Advisory Council review, and determines the types of questions that individual companies are required to answer as part of their review.

Particularly when it comes to industries that are controversial, there is a natural and healthy tension between the inclination to exclude all companies in those industries from eligibility for B Corp Certification, and *the need for leadership* that has the potential to transform the culture, behavior, and impact of those industries. While B Lab and its [Standards Advisory Council](#) may determine that an industry as a whole is ineligible for certification because of its negative impacts or practices, they also recognize that in controversial industries it may be possible for companies to be meaningfully managing those potential negative impacts or controversies. In these circumstances, the need may be greatest to distinguish between good and bad actors, as well as good, better, and best performance by using rigorous standards of verified social and environmental performance, legal accountability, and public transparency. All stakeholders are best served by the existence of credible and transparent standards that facilitate improved policy, investment, purchasing, and employment decisions.

Along with the recognition that there are many diverse and reasonable perspectives as to what contributes to a shared and durable prosperity for all, B Lab and its Standards Advisory Council will make determinations regarding eligibility for B Corp Certification and, if eligible, will require companies in controversial industries, with controversial policies, or engaged in controversial practices to be transparent about their practices and how they work to manage and mitigate concerns. B Lab will also document and share these positions publicly in order to enable all stakeholders, including citizens and policymakers, to make their own judgments about a company's performance, as well as further thoughtful, constructive public discussion about important issues. Existing B Lab statements and frameworks on controversial issues are available [here](#).

These frameworks, like B Lab's standards generally, are works in progress, and we look forward to improving upon them in the future. B Lab invites other perspectives as it continues to refine its views and, hopefully, contribute to a constructive conversation about the role of business in society.

Independent of eligibility for B Corp Certification, all companies in any industry are able to use the [B Impact Assessment](#) as an internal impact management tool to assess and improve their overall practices, and/or adopt a stakeholder governance legal structure (such as [benefit corporation](#)) appropriate to the company's current corporate structure and jurisdiction.

If you have questions or comments about B Lab's approach to the below issues, please email B Lab's Standards Management team at [standardsmanagement@bcorporation.net](mailto:standardsmanagement@bcorporation.net).

## Pharmaceutical Companies and B Corp Certification

Although the pharmaceutical industry on its face would seem like an industry with a positive impact by developing products that save lives, several aspects of the industry's current business model are potentially controversial because of the potential of making profit-driven decisions that benefit the company while harming public health. Research & development (R&D) investment decisions determine which healthcare solutions are developed and often overlook health solutions for those most in need. The quality and safety of products are at risk of compromise depending on manufacturing and distribution practices, which can result in ineffective treatments or adverse effects on consumers. Pricing decisions directly affect the affordability and accessibility of products globally. At each stage of the pharmaceutical value chain, companies have a large potential impact on the state of global health.

In response to these controversies, 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:

*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.

*In order to be eligible, pharmaceutical companies must be able to demonstrate that they have the following practices in place and disclose them on their B Corp Profile:*

- 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.
- 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.
- 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.
  - 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.
  - 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<sup>1</sup> to improve access to such products in low- and middle- income countries (LMICs).
  - 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.
  - 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 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.*

## **Overview of the Pharmaceutical Industry, Associated Risks and Best Practices**

Companies in the pharmaceutical industry research, develop, manufacture and/or distribute medications.<sup>2</sup> Their products, used for various types of prevention measures, treatments and therapies, can be divided into brand or generic products derived from chemicals and products which enhance biotechnology (biologics).<sup>3</sup> The typical production and distribution process for

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<sup>1</sup> Examples of strategies might include equitable pricing strategies, patient assistance programmes, donations, voluntary licensing, etc.

<sup>2</sup> <https://www.britannica.com/technology/pharmaceutical-industry>

<sup>3</sup> <https://www.statista.com/markets/412/topic/456/pharmaceutical-products-market/#overview>

pharmaceutical products includes some version of research and development (R&D), manufacturing and sales, though each company may not be involved in every step of the process.

Pharmaceutical companies play a large role in global health outcomes. They conduct research and development (R&D) for dangerous and burdensome diseases and develop better treatments for chronic diseases, such as cancer and diabetes. They supply consumers with life changing and/or life saving solutions to serious illnesses.

Given the important nature of their services, their operations and business models also come with risks. While a company's specific risks will vary based on its role in the value chain, the most material risks related to the pharmaceutical industry can be broadly categorized as:

- R&D and intellectual property strategies that limit accessibility,
- Quality assurance risks,
- Aggressive marketing,
- Price gouging, and
- Lobbying against competition and affordability

Below is a summary of each material risk and some of the industry best practices related to managing them:

### *R&D and Intellectual Property Strategies that Limit Accessibility*

The initial discovery, clinical trials and approval process that are required to develop new medicines can be very expensive, thus the intellectual property system for pharmaceutical companies is based on the common practice of companies recouping the costs of R&D needed to develop new products through higher prices protected by 20-year competition-blocking patents/exclusivity terms.

The link between R&D decisions and revenue generating patents creates negative impacts on healthcare accessibility in two ways<sup>4</sup>:

1. Companies are not incentivized to invest in new products for low-income populations with low purchasing power, resulting in a void of R&D driven by the unique needs of low-income populations.
2. High prices protected by patents means that those who cannot pay high prices can't access potentially life-saving treatments.

In addition, companies are incentivized to find ways to extend their existing patents through 'evergreening', a process by which companies make small changes to a product so that they

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<sup>4</sup> <https://www.who.int/publications/10-year-review/chapter-medicines.pdf?%20ua=1>

can access a new patent or extend exclusivity terms.<sup>5</sup> Evergreening techniques include anything from filing for additional patents on methods of production and manufacturing, changing formulations or dosage schedules to obtain new patents, and even filing patents of questionable validity at the risk of lengthy litigation with generic companies to delay their entry.<sup>6</sup> From 2005 to 2015, 78% of the drugs associated with new patents were not new drugs, but existing ones.<sup>7</sup>

Aside from avoiding evergreening strategies, another best practice to address access issues is to develop equitable access plans for R&D projects addressing priority diseases. Companies, especially those that benefit from public funding for R&D, can develop such plans during the R&D process with specific strategies to improve the access of new medications for low-income groups. Strategies to facilitate equitable access include patient assistance programmes (providing financial assistance or free-of-charge medicines for a defined population with limited ability to pay), product donation programs, and voluntary licensing (granting alternative manufacturers licenses to produce patented products).<sup>8</sup>

### *Quality Assurance Risks*

Given the role that pharmaceutical products play in the global healthcare system, it is essential that pharmaceutical companies have manufacturing and distribution practices in place that preserve the quality of their products and the overall safety of consumers. Varying manufacturing and distribution practices pose a material risk because any inconsistencies in the quality of pharmaceutical products can cause material harm to consumers. Specific risks can include: unexpected contamination of products, causing damage to health or even death; incorrect labels on containers, which could mean that patients receive the wrong medicine; insufficient or too much active ingredient, resulting in ineffective treatment or adverse effects.<sup>9</sup> These risks are prevalent globally, but disproportionately burden low- and middle-income countries where an estimated 1 in 10 medical products are substandard or falsified.<sup>10</sup>

While regulations vary by region, the guidelines developed by the EMA, U.S. FDA, WHO, and International Council of Harmonisation (ICH) are generally recognized as the most rigorous global standards. Regulatory bodies generally refer to these principles as Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP). They include guidelines for manufacturing, processing, packing, inspections and quality risk management.<sup>11</sup> In addition, companies can adopt specific best practices to combat the risk of substandard or falsified medicines, including processes to ensure the quality and authenticity of active ingredients,

<sup>5</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3680578/>

<sup>6</sup> <https://academic.oup.com/jlb/article/5/3/590/5232981>

<sup>7</sup> <https://academic.oup.com/jlb/article/5/3/590/5232981>

<sup>8</sup>

[https://accessmedicinefoundation.org/media/uploads/downloads/5f08703db73dc\\_Methodology\\_Report\\_for\\_2021\\_Access\\_to\\_Medicine\\_Index.pdf](https://accessmedicinefoundation.org/media/uploads/downloads/5f08703db73dc_Methodology_Report_for_2021_Access_to_Medicine_Index.pdf)

<sup>9</sup> <https://www.who.int/news-room/q-a-detail/medicines-good-manufacturing-processes>

<sup>10</sup> <https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products>

<sup>11</sup> <https://www.sciencedirect.com/science/article/pii/S1319016413001114>

traceability and ongoing monitoring of the supply chain and distribution chain, special packaging and printing techniques, and rapid reporting of substandard and falsified medicines (e.g. to WHO's Rapid Alert system).

### *Aggressive Marketing*

Marketing and sales practices used to distribute products and increase revenue can cause severely adverse effects on stakeholders. For example, in the U.S. pharmaceutical and marketing companies targeted the medical community directly in order to increase the prescription of opioids, or highly addictive pain relief medications. Pharmaceutical companies intentionally misrepresented the risk and benefits of the medications through marketing campaigns that often featured doctors paid to convince other doctors to prescribe more opioid medications. The companies also incentivized their sales staff to be aggressive by tying bonuses to sales volumes.<sup>12</sup> The result has been a severe health crisis which has led to close to 50,000 overdose cases in 2019 and 1.7 million people in the United States suffering from substance use disorders related to prescription opioid pain relievers. The economic burden is estimated to be \$78.5 billion USD a year in healthcare, lost productivity, addiction treatment, and criminal justice involvement costs.<sup>13</sup>

Companies that enforce a strict code of conduct for marketing and sale of pharmaceutical products can minimize the adverse effects of aggressive sales practices. Companies can also remove the incentive to use aggressive sales practices by not having compensation structures that are tied to sales volume.

### *Price Gouging*

Unlike most industries where consumers can choose not to participate in a market based on a product's price, pharmaceutical products can be lifesaving. Thus demand for pharmaceutical products is inelastic to price; pharmaceutical companies are essentially able to set their products at any price with little impact on the demand. Coupled with the role that intellectual property rights play in constraining competition, the pharmaceutical industry has little exposure to market forces, which creates a high risk for monopolistic pricing.

Due to these factors, pharmaceutical product prices are regulated in many markets. Most OECD countries use specific methodologies to regulate prices such as internal reference pricing (reference to existing competitors within the country), external reference pricing (reference to what other countries pay), and value-based pricing (economic evaluation of the "value" patients and health systems gain from the product).<sup>14</sup> These pricing instruments are also conditionally recommended by the WHO as country-level pharmaceutical pricing policies.<sup>15</sup> The most notable

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<sup>12</sup> <https://www.washingtonpost.com/graphics/2019/investigations/opioid-marketing/>

<sup>13</sup> <https://www.drugabuse.gov/drug-topics/opioids/opioid-overdose-crisis>

<sup>14</sup> <https://www.oecd.org/els/health-systems/pharmaceutical-pricing-policy.htm>

<sup>15</sup> <https://www.who.int/publications/i/item/9789240011878>



exception among developed markets is the United States, where pharmaceutical pricing is largely unregulated.

There are cases where pharmaceutical companies have in fact taken advantage of the inelasticity of demand for pharmaceutical products and the lack of regulations in the U.S. to pursue profit at the expense of stakeholder wellbeing and access. For example, by engaging in a business strategy of buying old neglected drugs and turning them into high-priced “specialty drugs”, several times the previous price, as a quick means for profit.<sup>16</sup>

There is ongoing debate among stakeholders in the pharmaceutical industry over the pricing of pharmaceutical products, heavily due to lack of transparency around the pricing methodology and R&D practices of pharmaceutical companies. Transparency is essential in order to address accessibility issues in the industry. In addition, to further address accessibility issues, companies can adopt “equitable pricing strategies” by taking into account the ability of individuals and healthcare systems to pay at a local level.<sup>17</sup>

### *Lobbying Against Competition and Affordability*

There are numerous examples of pharmaceutical companies engaging in lobbying activities to influence both national and international regulations in an effort to protect industry profits. From 1999 to 2018, the pharmaceutical and health product industry spent \$4.7 billion, an average of \$233 million per year and more than any other industry, on lobbying expenditures at the federal level in the U.S., much of which was to counteract government efforts to lower drug costs.<sup>18</sup> Globally, the pharmaceutical industry has worked to extend its intellectual property rights through the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement which requires the member nations of the World Trade Organization (WTO), essentially all trading nations, to follow defined standards of intellectual property protection by making patents available for any invention. Members of the pharmaceutical industry continue to work against any provision that would allow countries, especially low-income countries, from bypassing patents in order to foster competition and decrease costs to address their public health needs.<sup>19</sup>

While pharmaceutical companies have the ability to lobby for policies that support their ability to maximize profit, the resulting risk to healthcare systems is significant. Companies engaged in lobbying for policies to keep the price of medications high and suppress competition and negotiation are prioritizing shareholder profits over stakeholder outcomes, which goes against the holistic stakeholder-focused approach of B Corp Certification.

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<sup>16</sup><https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html>

<sup>17</sup>[https://accesstomedicinefoundation.org/media/uploads/downloads/5f08703db73dc\\_Methodology\\_Report\\_for\\_2021\\_Access\\_to\\_Medicine\\_Index.pdf](https://accesstomedicinefoundation.org/media/uploads/downloads/5f08703db73dc_Methodology_Report_for_2021_Access_to_Medicine_Index.pdf)

<sup>18</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7054854/>

<sup>19</sup>[https://edisciplinas.usp.br/pluginfile.php/4232458/mod\\_resource/content/1/Barton\\_TRIPS%20and%20pharmaceuticals.pdf](https://edisciplinas.usp.br/pluginfile.php/4232458/mod_resource/content/1/Barton_TRIPS%20and%20pharmaceuticals.pdf)



**Rationale for the Standards Advisory Council Decision:**

Pharmaceutical companies have a significant role to play in contributing to global health outcomes; however, equitable health solutions for those most in need are rarely the most profitable business activities. Given this inherent tension between maximizing social benefit and maximizing shareholder returns, Certified B Corporations in the pharmaceutical industry should be able to demonstrate that their business model integrates a holistic, stakeholder-focused approach with an emphasis on health outcomes for its end beneficiaries and society in general. Given the wide range of company profiles in the industry, there is no single third party standard or set of best practices that is broadly applicable to all pharmaceutical companies. For this reason, the B Corp Certification requirements feature a prohibition of a few specific negative practices, while also expecting general management practices and transparency on the material risks identified above when relevant to the company's business model.

The minimum score requirement for companies listed on the ATMI recognizes the unique influence of multinational research-based pharmaceutical companies in driving global health outcomes, and establishes a threshold of current performance on the topic of medicine access in these companies' governance, R&D, and product delivery practices.

This recommendation does not specifically impose additional minimum requirements regarding other potentially material issues for pharmaceutical companies that are already sufficiently covered by B Corp Certification standards. All companies pursuing B Corp Certification, including pharmaceutical companies, must complete the Disclosure Questionnaire, which features disclosures on topics such as operating in a chemical-intensive industry, animal testing, litigation, and regulatory complaints. Any such topics raised in the Disclosure Questionnaire, as well as through B Lab's background check and public complaints processes, would be reviewed by B Lab and could result in additional disclosure requirements, remediation, or ineligibility in their own right.

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The decision of the Standards Advisory Council has been informed by independent research conducted by B Lab and stakeholder consultations including academic experts.

This statement is effective as of June 2021 until further judgment from the Standards Advisory Council.

Please send your feedback or questions to B Lab's Standards Management team at [standardsmanagement@bcorporation.net](mailto:standardsmanagement@bcorporation.net).