B Lab Statement on Medinsa 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…"

Medinsa 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
Medinsa belongs to the Aristo Pharma Group, which is a pharmaceutical group in the field of generic medicines mostly in different central and eastern European countries. Located in Spain, Medinsa is one of the five manufacturing sites of Aristo Pharma Group. Apart from Aristo Pharma portfolio products, Mendisa also manufactures medicine for other pharmaceutical European companies.

Approximately 70% of the medicine produced by Mendisa is for the Aristo Pharma Group. The company only sells its products to Aristo Pharma Group and European Pharmaceutical companies, which means that Medinsa does not sell its products directly to the final consumer.

All products produced by Medinsa are generic. Approximately 90% corresponds to prescription medicine and 10% to over-the-counter products. The company is not limited to specific therapeutic areas and Medinsa only manufactures oral solid dosage forms of medicine. All manufacturing and quality testing are performed on-site, while their active pharmaceutical ingredients are imported mostly from, India, China and Europe.

Medinsa'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.

Medinsa 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.

Mendisa’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.*

As a provider of generic pharmaceutical products, Medinsa starts their activity when patent protection comes to an end and they can develop and file for generic registration. Clinical trials are conducted by external, authorized Clinical Research Organizations (CRO) in order to show bioequivalence of their formulation versus the branded version.

Medinsa claims to be compliant with all legal requirements for the pharmaceutical industry in the jurisdiction where it operates. Their laboratory license is issued by the Health Authorities of Spain (Agencia Española de Medicamentos y Productos Sanitarios) and undergo regular inspection and audits for Good Manufacturing Practices (GMP), Good Distribution Practices (GDP) and Pharmacovigilance. The company is also audited by their clients and by the Ministry of Health of Republic of Armenia, the Ministry of Health of Kazakhstan, the Ministry of Health of the Republic of Belarus and the Ministry of Industry and Trade of the Russian Federation.

The company declares 100% traceability of each material that is being used in manufacturing. As part of its quality compliance, all materials, intermediate products, and finished products, are analyzed and controlled in Medinsa’s laboratories. In addition to that, Medinsa is compliant with the Track & Trace system which prevents counterfeit drugs and guarantees the traceability of every single product produced by the company.

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.*

Medinsa has a Code of Ethics which sets up the main principles and values that govern its daily activity and that is applicable to all employees, directors and managers covering topics such as anti-corruption, intellectual property rights, legality and conflict of interest resolution. The company also has a policy for interactions with healthcare professionals and organizations that sets limits to these interactions and how they should be documented. Regular training and engagement on the Code of Ethics is conducted across the organization by the compliance officer.

A whistleblower channel is in place to allow their personnel or other stakeholders to report possible violations of their policies and Ethical Code. Anonymous complaints are accepted by using an external website form which is fully compliant with EU Directives and Spanish 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.*

Medinsa's position on lobbying activities is conservative. Currently, the company is not performing direct lobbying activities related to the pharma business, including HCP's.

Moreover, Medinsa is not a member of any associations of pharmaceutical companies. They have their code of ethics in which they position themselves against any form of bribery to individuals, companies and authorities and political parties.

The company also confirms they have not engaged in any lobbying activities with government authorities/officials.

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.*

R&D at Medinsa is purely dedicated to the development of generic dossiers for the own group and to subcontracted services of galenical and analytical development of third-party projects. At Medinsa there are no R&D activities on innovative new molecules.

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).*

Medinsa is not currently involved in R&D for priority diseases, conditions, and pathogens identified in the Access To Medicine Index.

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.*

Medinsa does not sell their products directly to final consumers.

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).*

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