B Lab Statement on Medichem'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…"

Medichem 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

Medichem is a vertically integrated chemical-pharmaceutical company headquartered in Spain, specialized in the development and manufacture of Active Pharmaceutical Ingredient (APIs) and Finished Dosage Form (FDFs) for the global generics industry. Generic medicines are pharmaceutical products that contain the same active ingredients as their branded counterparts and are designed to be bioequivalent. These medications are produced after the original manufacturer's patent on a drug expires or is revoked, allowing other companies to manufacture and sell the generic versions of such products at an affordable price compared to brand-name drugs.

As a chemical pharmaceutical "B2B" business, Medichem is focused on the development of generic APIs and FDFs and their related regulatory and industrial activities and has no direct relationship, sales or influence with either doctors, pharmacists, prescribers, patients (or patient associations), consumers or even wholesalers. Medichem's clients and partners are mostly generic pharmaceutical companies that have global reach, and which purchase APIs and/or FDFs from Medichem and incorporate them into medicines which they commercialize under their own brands and their own distribution, promotion and sales channels.

Medichem develops and manufactures APIs and FDFs in the following 4 European Union locations:

- Pharmaceutical development site for FDFs in Sant Joan Despí (Barcelona - Spain)
- API development, production and quality control site in Celrà (Girona - Spain)
- APIs and FDFs production plants in Hal Far (Malta)

- Injectable FDFs manufacturing site under construction in Llanera (Asturias - Spain). As it is under construction, currently there is no operational activity in this company.
- Headquarters are located in Sant Joan Despí (Barcelona - Spain)

As a B2B company Medichem has no direct consumer operations and Medichem's products are not sold directly to the end consumers by the company. Medichem sells their APIs and FDFs to international pharmaceutical companies operating globally which manufacture and/or distribute their own medicines (several of them developed and manufactured by Medichem). Medichem's clients are pure pharmaceutical companies which use Medichem's goods in their operations, production processes, or for resale to other businesses, hospitals or patients or consumers. Those entities are subject to the regulation of entities that interact with physicians and patients.

Medichem's main clients are based in the European Union, the United States, India, United Kingdom and Canada. For those products that Medichem cannot manufacture in its own plants (currently injectable and respiratory medicines, one high potency oral solid and packaging with certain features), Medichem uses third parties that provide contract manufacturing services (CMOs). Medichem's CMOs are located in Turkey, Italy, Spain, Germany and The Netherlands.

The products that Medichem develops and manufactures address a range of therapeutic areas such as the central nervous system, cardiovascular, oncology, dermatology, metabolic diseases and respiratory diseases. Approximately 60% of Medichem's revenue comes from the development and manufacturing of generic APIs sold to third party pharmaceutical companies that incorporate those APIs as an ingredient to their own products and distribute them under their own brands. Approximately 40% of Medichem's revenue corresponds to generic prescription drugs FDFs: prescription- retail (19.62%) and hospital drugs (19.90%).

Medichem also produce Chlorohexidine, an antiseptic used in hospitals to prevent healthcare-related infections. It is used in different formulations for skin antisepsis, oral care, patient bathing, and hand hygiene. In addition, Chlorhexidine is impregnated in vascular catheters and wound dressings that contribute to reducing exposure to hospital germs. Medichem produces Chlorhexidine as part of its API portfolio and also as non-prescription FDF antiseptic with marginal sales (0.04% of sales).

Medichem'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.

Medichem 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.

Medichem’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.*

Medichem has a Quality Manual in place, which applies for all sites of the company (Spain and Malta) and is periodically inspected by EU, US and national Regulatory Authorities, as well as for the clients, that corresponds to the highest-level document of the Quality Management System, issued to describe the company’s processes implemented to ensure full compliance with the applicable GMP (good manufacturing practices for APIs and FDFs) regulations related to the activities carried out in the different sites, covering the development, manufacturing, analysis, holding, release and/or supply of the products. Once inspected, GMP Certificates by site and activity (Celrà API and FDF, Barcelona FDF and Malta API and FDF sites) are issued and periodically renewed.

Apart from GMP inspections carried out by National Health Authorities, which are covered by the US Food and Drug Administration (FDA) based on the Mutual Recognition Agreement with the EU since 2017, Medichem sites also receive regular inspections by foreign Authorities to

verify the compliance with the relevant applicable guidelines and requirements (PMDA, Korean FDA, Brazil, Libya, Belarus, among others) and the corresponding GMP certificates are issued.

Additionally, API manufacturing plants have implemented an Environmental Management System in compliance with ISO 14001 standard to reduce the environmental impact of their activities, and the corresponding ISO 14001 Certificate is issued. Sites are annually audited, and the certificate is renewed every 3 years.

Medichem has formal procedures, within the Quality Management System, to receive, manage and evaluate customer complaints. Those are investigated to find the corresponding root-cause and apply the appropriate mitigation actions, if required. Periodical KPIs are collected to measure and analyze the process performance and implement the considered improvement measures based on the obtained results.

Furthermore, apart from several KPIs established within the Quality Management System to evaluate indirectly the customer satisfaction (from the supply and quality point of view, among others), Medichem has in place a formal procedure to monitor customer satisfaction level, acquiring data from periodical surveys submitted to our customers. The obtained information is evaluated, and actions are implemented to improve the client's experience and interaction with Medichem's team.

Moreover, Medichem has a periodic revision as control mechanism of the commercialized products in place, named Periodic Safety Update Report (PSUR), which is a pharmacovigilance document intended to provide an update of the worldwide safety experience of the commercialized medicinal products.

Medichem is committed to avoiding counterfeit medicines. Both the EU and the US have stringent regulations and Medichem has the systems in place to safeguard the integrity of the drug supply chain and protect public health from the dangers of counterfeit medications: Medichem complies with the following:

A. European Union EU Falsified Medicines Directive, which requires Safety Features (unique identifiers and tamper-evident packaging for prescription medicines). Medichem is further part of the European Medicines Verification System (EMVS), a pan-European system for verifying the authenticity of medicinal products and Medichem adheres to Good Distribution Practices (GDP) Guidelines, which ensure that products are consistently stored, transported, and handled under suitable conditions.
B. Regarding the US, Medichem complies with Title II of the Drug Quality and Security Act (DQSA) of 2013, which establishes requirements for product tracing, verification, and identification, and Serialization requirements, which mandate that manufacturers and

re-packagers affix or imprint a product identifier on each package and case to avoid 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.*

Medichem has a clear commitment to generating a positive impact on society and the environment and to developing their business in an ethical and compliant way. Medichem has in place a Compliance System (or compliance program) aligned with national and international compliance standards.

The Compliance System is applicable to all Medichem employees, regardless of their position and/or location (Spain and Malta). The system consists of a set of policies, procedures and controls that establish specific action guidelines for all employees, helping to build trust with third parties with whom Medichem maintains business relationships.

The main goals of Medichem Compliance System are:

- Promoting a culture of ethics and regulatory compliance
- Zero tolerance for non-compliance with regulations
- Establishing control measures to prevent non-compliance
- Maintaining a relationship based on ethics and compliance with collaborators and third parties with whom Medichem interacts
- Providing training for all employees

Medichem has an Internal Code of Conduct in which it establishes the general obligations to be assumed by all Medichem employees, who are expected to conduct themselves in accordance with the general principles contained therein, the legislation in force and respect for the protection of Human Rights, anti-corruption and bribery, among others. The Code of Conduct is supplemented by other internal policies such as Compliance Policy, Human Rights Respect Policy, and Anti-corruption Policy, Protocol on Fraudulent and unfair conducts, among others. Regular training and engagement on the Code of Conduct and the other policies are periodically conducted across the organization.

In order to prevent and react against potential non-compliances, Medichem has an Ethical Channel that allows for confidential, anonymous communications and ensures no-retaliation

conducts. Medichem also has a Code of Conduct for Third Parties, that establishes the main principles and values that govern its relationships with third parties.

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.*

Medichem does not engage in direct lobbying activities at a company level related to the pharmaceutical industry. Medichem is a member of the European trade associations listed below, both incorporated under the Belgian laws and subject to the European Union transparency rules for trade associations.

- Medicines for Europe Medicines For Europe | Better Access. Better Health
- European Fine Chemical Group home - EFCG (cefic.org)

The material issues those associations advocate for are available at their respective websites, but can be summarized as follows: fostering timely competition and sustainable uptake of generic, biosimilar and value added medicines, support pro-competitive measures in the pharma and intellectual property legislations, especially to stop delays to generic and biosimilar entry, invest in affordable off-patent innovation to solve healthcare and patient challenges, improve supply chain security and reduce shortage risks, tackle the economic root causes of medicine shortages, create a more level playing field on quality regulations and, more importantly, their enforcement, and create a fertile environment for investments and innovation for industry in Europe.

Medicines for Europe requires all of its members to adhere to its own Code of conduct WHO WE ARE – CODE OF CONDUCT | Medicines for Europe which includes various standards, procedures and requirements for its members such as the prohibition of advertising of prescription-only medicines to the general public. Both trade associations are listed in the EU Transparency Register, which requires detailed information about the association's activities, funding sources and expenditures, meetings with EU officials etc.: organisation detail - European Union (europa.eu) and organization detail - European Union (europa.eu)

Furthermore, at an internal level, Medichem has set up a monitoring body (the Ethics and Compliance Committee) responsible for ensuring compliance with the Medichem's Code of Conduct and other internal regulations related to risk prevention and compliance at Medichem. The Code of Conduct and the Fraudulent and Unfair Conducts Protocol includes policies on anti-bribery and anti-corruption.

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.*

Medichem's R&D strategy is focused on providing greater access to pharmaceutical treatments to the global population as well as ensuring that value-added products are available to patients. With the objective to ensure timely availability of generics, the highly qualified personnel engage daily in technically challenging projects, combining the use of new technology platforms, added-value design-arounds and freedom to operate IP strategy (i.e. ensuring that Medichem's developments will not conflict with third party's intellectual property rights). Medichem's R&D also aims at ensuring the highest level of quality, a robust supply chain (which goes from the use of vertical integration to the careful selection of 3rd party suppliers), and transparency in the decision-making process. In agreement with Medichem's positioning with regards to the environmental impact, R&D is committed to providing products that minimize environmental impact.

15% of the total number of employees on 31 December 2023 (446 people) belong to the R&D team, i.e. 66 people. Medichem devoted an amount of 10.2M€ to R&D projects in 2023. The R&D data are publicly available at the annual sustainability report.

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).*

The Access to Medicine Index ranks 20 of the world's largest originator (research-based) pharmaceutical companies, based on market capitalization and the relevance of their product portfolios to diseases in LMICs. Medichem is not an originator (research-based) company and is focused on the development and manufacture of generic APIs and FDFs to increase access worldwide. Medichem is therefore not directly involved in R&D projects for drug discovery (i.e

new molecules) to address priority diseases, conditions and pathogens as identified in the Access to Medicine Index.

Medichem's R&D teams develop generic and value-added products that address diseases and conditions (such as schizophrenia, bipolar disorder, anxiety disorders, epilepsy, kidney disease and diabetes).

The global IP framework poses challenges to the access of generic medicines in LMICs, but Medichem's regulatory and commercial strategy considers on a routine-basis opportunities of providing access in LMICs where Medichem's generic products can legally be supplied because either there is no patent protection or the innovator company's patent rights expire earlier than in highly regulated regions such as Europe and the US.

When certain national regulatory restrictions limit the importation of products into LMICs, Medichem also considers technology-transfer agreements to other stakeholders to allow local manufacturing that make the product available to meet demand locally in LMICs.

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.*

As a generic medicines B2B (business-to-business) company, Medichem has very limited or no influence on pricing. The generic medicines market is often highly competitive, with multiple manufacturers producing similar products as soon as the patent covering the product expires or is revoked. In such an environment, price erosion and competition are fierce, and the most common pricing strategy is responding to price pressures by leveraging economies of scale, optimizing supply chain efficiency. Cost of production, including raw materials, manufacturing processes directly impact pricing and need to be optimized.

Medichem does not set prices for its products to the pharmaceutical market. Medichem's customers or commercial partners are the holders of the regulatory approvals for the drugs and therefore the ones who oversee the pricing and reimbursement proceedings from the regulatory authorities. Most countries use a reference pricing system to control drug costs, including the pricing of generic medicines. It involves setting a benchmark price, or reference price, for a group of interchangeable drugs, typically including both branded and generic versions of the same medication. The reference price is typically set based on the lowest price within the group.

Medichem sets prices to cover its R&D, production, quality and regulatory compliance costs and obtain a reasonable commercial margin but has no discretion to set pricing policies depending on the territories, being at the mercy of market competition fluctuations in different countries.

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).*

As a B2B company, Medichem does not have a team of sales representatives that can influence demand for our products by encouraging prescription by doctors. Therefore, our commercial team interacts only with other companies.

Medichem's commercial team has its own sales incentive structure with mainly quantitative targets but also qualitative targets. Their performance is limited to an achievement of 150%, which is equivalent to 120% of payout and it is reviewed twice yearly (mid and year end), with the possibility of annual regularization. Medichem has a sales incentive control committee integrated by CEO, CHRO, CFO and Commercial Directors. This Committee is responsible for the correct definition and evaluation of targets and payment of the related compensation to the commercial team. Furthermore, Medichem's Code of Conduct ensures that all employees including the commercial team commit to adhering to a rigorous and coherent set of values and protocols.

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.*

Medichem is not currently listed on the Access To Medicine Index.