

# **Medichem**

Disclosure Report Date Submitted: March 10th, 2025

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## **Disclosure Materials**

Certified B Corporations must complete a Disclosure Questionnaire to identify potentially sensitive issues related to the company (e.g. historical fines, sanctions, material litigation, or sensitive industry practices).

This component does not affect the company's score on the B Impact Assessment. If the company answers affirmatively to any items in the Disclosure Questionnaire that B Lab deems relevant for public stakeholders, then, as a condition of their certification, the company must:

- Be transparent about details of the disclosure issues identified on the company's public B Impact Report
- 2) Describe how the company has addressed this issue
- 3) Demonstrate that management practices are in place to avoid similar issues from arising in the future, when necessary.

In all cases, the Standards Advisory council reserves the right to refuse certification if the company is ultimately deemed not to uphold the spirit and integrity of the community.

In addition to the voluntary indication of sensitive issues in the Disclosure Questionnaire, companies pursuing Certification also are subject to a background check by B Lab staff. Background checks include a review of public records, news sources, and search engines for company names, brands, executives/founders, and other relevant topics.

Sensitive issues identified through background checks may or may not be within the scope of questions in the Disclosure Questionnaire, but undergo the same review process and are subject to the same possible review by the Standards Advisory Council, including ineligibility for B Corp Certification, required remediation, or disclosure.

#### **B Lab's Public Complaints Process**

Any party may submit a complaint about a current B Corp through B Lab's Public Complaint Process. Grounds for complaint include:

- 1) Intentional misrepresentation of practices, policies, and/or claimed outcomes during the company's certification process
- 2) Breaches of the B Corp Community's core values as expressed in our Declaration of Interdependence

This document contains a copy of the company's completed Disclosure Questionnaire and related disclosure documentation provided by the company.



# **Disclosure Questionnaire**

#### **Industries and Products**

#### Yes No Please indicate if the company is involved in production of or trade in any of the following. Select Yes for all options that Animal Products or Services $\overline{\mathbf{A}}$ **Biodiversity Impacts Chemicals** $\overline{\mathbf{A}}$ **Disclosure Alcohol Disclosure Firearms Weapons** $\boxed{}$ **Disclosure Mining** $\boxed{}$ **Disclosure Pornography** $\boxed{}$ **Disclosure Tobacco** $\boxed{}$ **Energy and Emissions Intensive** $\overline{\mathbf{A}}$ <u>Industries</u> Fossil fuels $\square$ Gambling **Genetically Modified Organisms** $\overline{\mathbf{A}}$ Illegal Products or Subject to $\overline{\mathbf{A}}$ **Phase Out** Industries at Risk of Human $\square$ **Rights Violations Monoculture Agriculture** $\square$ **Nuclear Power or Hazardous** $\square$ **Materials** Payday, Short Term, or High **Interest Lending** Water Intensive Industries $\square$ **Tax Advisory Services**

#### **Outcomes & Penalties**

	Yes	No	
Please indicate if the company has had any formal complaint to a regulatory agency or been assessed any fine or sanction in the past five years for any of the following practices or policies. Check all that apply.			
Anti-Competitive Behavior		<b>V</b>	
Breaches of Confidential Information		N	
Bribery, Fraud, or Corruption		V	
Company has filed for bankruptcy		V	
Consumer Protection		V	
Financial Reporting, Taxes, Investments, or Loans		V	
Hazardous Discharges Into Air/Land/Water (Past 5 Yrs)		N	
Labor Issues			
Large Scale Land Conversion, Acquisition, or Relocation		N	
Litigation or Arbitration	V		
On-Site Fatality		$\searrow$	
Penalties Assessed For Environmental Issues		V	
Political Contributions or International Affairs		N	
Recalls	$\checkmark$		
Significant Layoffs		V	
Violation of Indigenous Peoples Rights		V	
Other		$\checkmark$	



#### **Practices**

	Yes	No
Please indicate if the following statements are true regarding whether or not the company engages in the following practices. Check all that apply. If the statement is true, select "Yes." If false, select "No."		
Animal Testing		K
Company/Suppliers Employ Under Age 15 (Or Other ILO Minimum Age)		V
Company prohibits freedom of association/collective bargaining		
Company workers are prisoners		$\searrow$
Conduct Business in Conflict Zones		$\checkmark$
Confirmation of Right to Work		V
Does not transparently report corporate financials to government		$\searrow$
Employs Individuals on Zero-Hour Contracts		K
Facilities located in sensitive ecosystems		N
ID Cards Withheld or Penalties for Resignation		\
No formal Registration Under Domestic Regulations		V
No signed employment contracts for all workers		V
Overtime For Hourly Workers Is Compulsory		V
Payslips not provided to show wage calculation and deductions		V

	Yes	No
Sale of Data		V
Tax Reduction Through Corporate Shells		V
Workers cannot leave site during non-working hours		Ŋ
Workers not Provided Clean Drinking Water or Toilets		$\supset$
Workers paid below minimum wage		N
Workers Under Bond		$\checkmark$
Other		$\checkmark$

## Supply Chain Disclosures

	Yes	No
Please indicate if any of the following statements are true regarding your company's significant suppliers.		
<b>Business in Conflict Zones</b>		$\vee$
Child or Forced Labor		$\vee$
Negative Environmental Impact		$\checkmark$
Negative Social Impact		$\vee$
Other		$\checkmark$



**Disclosure Questionnaire Category: Animal Testing** 

Topic	Company is required to undergo mandatory animal testing by law
Summary of Issue	Medichem is a pharmaceutical company that produces Active Pharmaceutical Ingredients (APIs) and Finished Dosage Forms (FDFs) that are required to be tested on animals under by law in the markets where they operate.
	Medichem has conducted animal testing on a few occasions, always related to value-added medicines development that, from a regulatory-legal - point of view required animal testing before starting clinical studies in humans.
	Directive 2010/63/EU1 and a Joint Ad Hoc Expert Group (the JEG 3Rs) recognize that certain types of data can only be generated by means of animal studies. The European Medicines Agency plays a key role in eliminating repetitious and unnecessary animal testing in the European Economic Area (EEA), in collaboration with other European organisations such as the European Directorate for the Quality of Medicines & HealthCare (EDQM). Medichem follows the legislative and regulatory guidance changes to avoid, to the maximum extent possible, animal testing in its pharmaceutical development.
	The company does not carry out animal testing internally. The few studies in animals Medichem has conducted were outsourced to duly certified Contract Research Organizations (CROs).
Size/Scope of Issue (e.g. \$ financial implication, # of individuals affected)	The company had zero products in the market that underwent animal testing in the last fiscal year. The company had one product in the research and development phase that had undergone animal testing, which represents less than 1% of the total products in the research and development phase.
Impact on Stakeholders	Animal testing and experimentation are widely used to develop new products and to test the safety of other products. Many of these experiments can cause pain to the animals involved or reduce their quality of life in other ways.



# Implemented Management Practices

Medichem has conducted studies in animals only where there are no alternatives, i.e., when it was legally mandatory for the approval of its products and no alternative study would be acceptable for the approval of the medicine.

Medichem checks that the studies are carried out in CROs that guarantee the well-being of the animals and, to the maximum extent possible, are committed to the 3Rs initiative (Replacement, Refinement, Reduction) or equivalent standards seeking to reduce the use of animal testing.

Medichem requests the relevant accreditations from the CRO. Examples of the requested accreditations:

- CCSEA Registered Committee for Control and Supervision of Experiments on Animals (CCSEA)
- AAALAC Accredited Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC)
- Approved by Office of Laboratory Animal Welfare (OLAW), Public Health Service, National Institute of Health, Department of Health & Human Services, Maryland, USA

As an internal policy, Medichem does only contract with CROs that ensure working procedures in adherence to the <u>European Union Directive (2010/63/EU)</u> for the protection of experimental animals.



Disclosure Questionnaire Category: Litigation, Arbitration, and/or Penalties

Issue Date	2020 - 2025
Topic	Tax penalties
Summary of Issue	In the last 5 years, the company has had 12 minor tax administrative penalties related to VAT voluntary regularization, late payment of taxes, and social security payments.
Size/Scope of Issue (e.g. \$ financial implication, # of individuals affected)	The aggregate financial value associated with the 12 cases the company had is 273,000 euros, corresponding to less than 1% of the company's revenue.
Impact on Stakeholders	In addition to the many different aspects of value that business provides to society, business has an obligation to contribute their share of taxes. This is because business exists within the context of society; its proper role is to serve society, not the other way around. Moreover, healthy businesses can only exist over the long term in a healthy society. A healthy society depends upon public expenditures made possible by taxes.
Resolution	All cases are settled.
Implemented Management Practices	Medichem reviews all new business operations in different countries with the legal and supply chain departments to understand the fiscal requirements and responsibilities. The company also shared that it has changed internal procedures to reinforce compliance and internal controls.
Related Incidents (Yes/No)	No



### **Disclosure Questionnaire Category: Chemical Intensive Industry**

**Medichem** is involved in the production/sale of products or is part of an industry that can potentially be classified as chemical intensive, meaning that they are more likely to have significant impacts on the environment, such as pollution of air, land, and water, as well as potential human health risks to those exposed to harmful chemicals if the use and disposal of chemicals are not properly managed. Certified B Corps are required to make transparent their involvement in such activities or industries.



### Disclosure Questionnaire Category: Energy and Emissions Intensive Industry

**Medichem** is involved in the production/sale of products or is part of an industry that can potentially be classified as energy and emission-intensive, meaning that they are more likely to have significant impacts on the environment based on their carbon emissions associated with their operations and their contribution to climate change. Certified B Corps are required to make transparent their involvement in such activities or industries.



### **Disclosure Questionnaire Category: Water Intensive Industry**

**Medichem** is involved in the production/sale of products or is part of an industry that can potentially be classified as water-intensive, meaning that they are more likely to have significant impacts on the environment, such as water stress or depletion of local water sources, if water use is not appropriately managed. Certified B Corps are required to make transparent their involvement in such activities or industries.



### **Disclosure Questionnaire Category: Recalls**

**Medichem** reported conducting one voluntary recall in the past five years, representing 1% of the company's products for the same period. When a product is recalled, various stakeholders such as customers, suppliers, investors, commercial partners, and local communities, may face negative impacts, including health and safety risks, financial losses, loss of trust, damage to credibility, and other inconveniences. Certified B Corps must make their recalls transparent under their B Corp Profile.