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SUSTAINABLE IMPACT FRAMEWORK

Medical Products & Devices

Sectors:

- Biotech
- Pharmaceuticals
- Life Sciences Tools & Services
- Health Care Equipment
- Health Care Supplies

Last updated: July 2024

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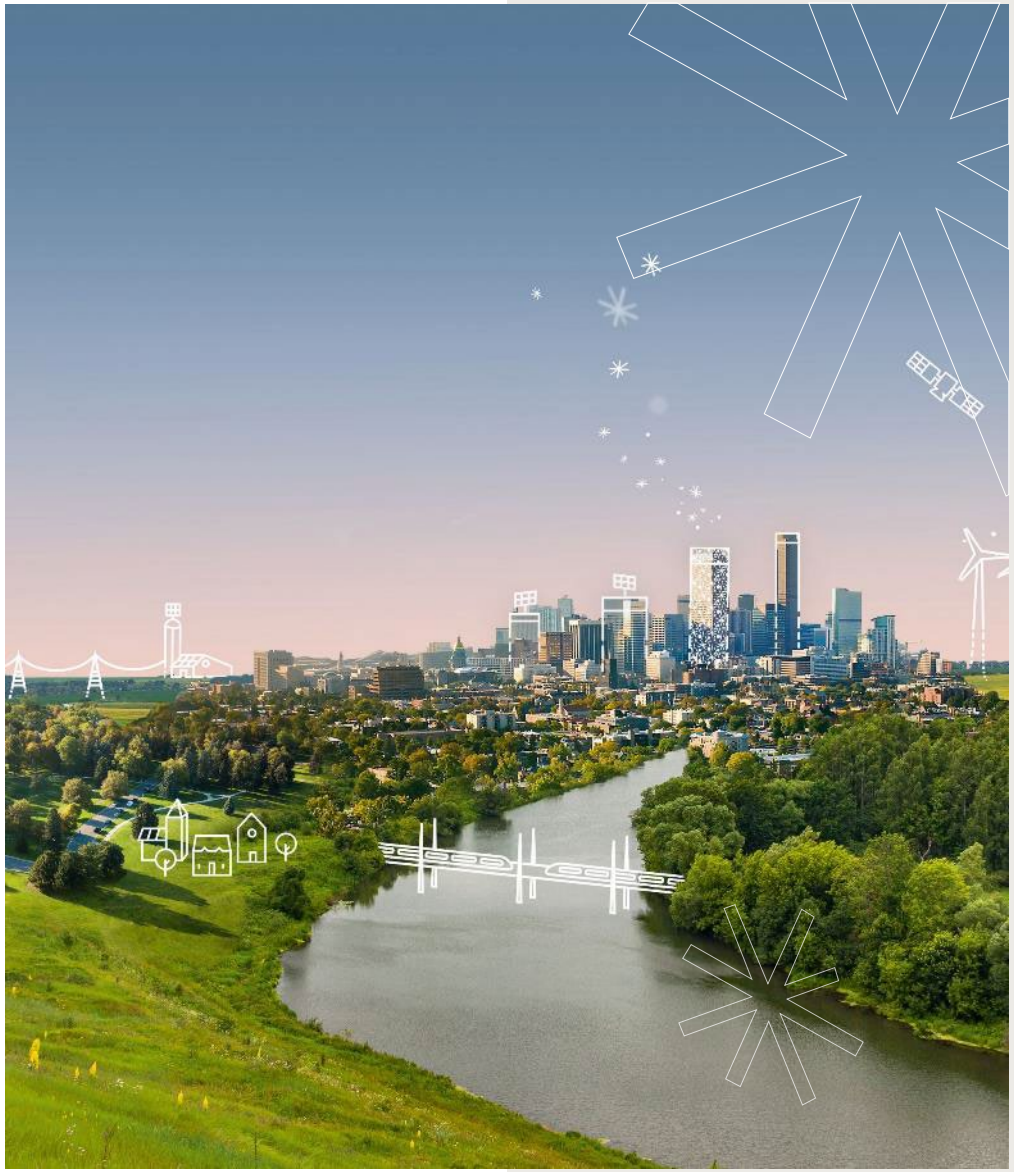
Executive Summary



Medical products and devices

Companies operating in the healthcare sector and, more specifically, those involved in research, manufacturing and distribution of medical products, are positioned to address some of our society's challenges, including rare diseases, tropical diseases or unmet needs, but also medical conditions arising from changing lifestyle habits, urbanization, climate change and aging. The COVID-19 pandemic highlighted that companies in the sector can rapidly adjust the prioritization of R&D projects to tackle the most pressing threats. Yet, the pandemic also illustrated the complexity of the sector, and some of its weaknesses. The decentralization of the medical treatments' supply chain has indeed raised concerns over continuity and safety of treatments distribution.

Global life expectancy has increased by more than 6 years between 2000 and 2019[1]

Globally, major socioeconomic indicators used to measure countries' development, such as life expectancy, are still progressing. However, these indicators fail to illustrate inequalities between low- and high-income countries, notably regarding access to diagnostics and prevention, medical treatments and efficient care services. In higher income countries, the burden of out-of-pocket spendings also pushes people into poverty every year. In addition, threats such as noncommunicable diseases (heart, cancer, diabetes, etc.), mental health issues or emerging pathologies resulting from antimicrobial resistance or climate change (which increases the frequency of extreme weather events or disruptions of food systems) are not captured in these global indicators.

Healthcare is responsible for 4.4% of global emissions and expected to triple by 2050[2]

The environmental footprint of the industry has long been overlooked. Yet, on the one side, the production of active pharmaceutical ingredients (main medicine ingredient that produce the intended effect) is often carbon intensive and water is an essential raw material in the drug manufacturing process. Not only these processes are resource intensive, but they also generate heavily polluted and toxic wastewater that require complex and costly treatments. Pharmaceutical ingredients released in the environment may cause disruption of local ecosystems and antimicrobial resistance. Robust water stewardship policies encompassing water quantity and quality are therefore key to transition towards more sustainable practices. On the other side, the environmental footprint of MedTech and life sciences companies results from sourcing of components including electronics, and the use of the equipment.

77% of the $2.2billion recovered by the US Justice in False Claims Act settlements involved the health care industry[3]

Product safety is a major risk for companies in the healthcare industry. Supply chain management is notably key for companies to reduce the risks of contamination but also to make sure clinical trials are conducted according to the company's specifications. In addition, companies in the sector have long been under scrutiny due to past controversies resulting from inappropriate business practices. The range of controversies in the sector was large and has included misleading product marketing, biased clinical trials, or corruption of healthcare professionals or authorities. The industry is now evolving towards a model following strict compliance rules and audits, robust trainings and enhanced monitoring of salesforces. A track record of past controversies and corrective measures implemented may still provide relevant signals on the company efforts to ensure ethical behaviors.

Drivers of contribution and obstruction to sustainability goals

	Activities	Practices
Positive Impact	**Sustainable Activities** MEDICAL TREATMENTS DIAGNOSTICS, EQUIPMENT AND DEVICES PRODUCTS & SERVICES FOR GENDER EQUALITY SUSTAINABLE AGRICULTURE (ANIMAL HEALTH)	**Advanced Practices** HUMAN CAPITAL MANAGEMENT • Diversity and inclusion • Job quality CLIMATE BIODIVERSITY *Advanced governance models*
ESG Risks	**Harmful Activities*** *No frequent exposure to harmful activities*	**Risk Mitigation** WORKING CONDITIONS : HUMAN RIGHTS & HEALTH AND SAFETY PRODUCT SAFETY MEDICAL ETHICS BIODIVERSITY & CLIMATE FOOTPRINT GOVERNANCE : • Governance of sustainability • Business ethics • Taxes

* As defined in: Minimum standards and exclusions, Mirova

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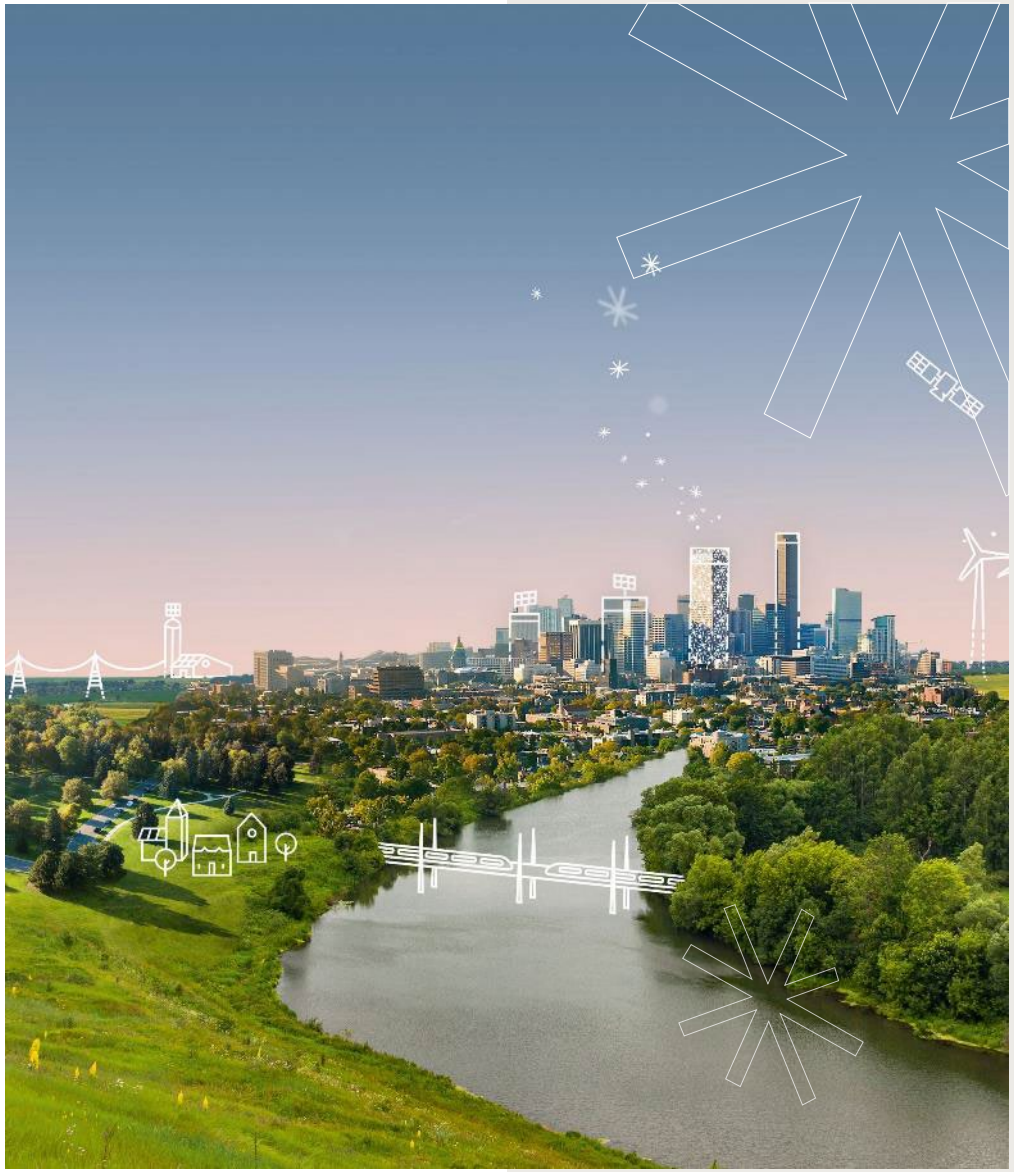
Positive Impact



Sustainable Activities

SOCIAL OPPORTUNITIES

CONTEXT

Globally, major socioeconomic indicators used to measure countries' development are still progressing. For example, life expectancy has increased by more than 6 years between 2000 and 2019[1]. However, these indicators fail to represent inequalities between low- and high-income countries, notably regarding access to diagnostics, medical treatments, and efficient care services.

While on average we are living longer, one cannot ignore threats such as non-communicable diseases (heart diseases, cancers or diabetes), mental health issues or emerging health threats resulting from antimicrobial resistance or climate change that increase the frequency of extreme weather events or disrupts food systems. For example, cancer is the second leading cause of death globally, accounting for an estimated 9.6 million deaths (i.e. 1 in 6 deaths) in 2018[1].

SUSTAINABLE ACTIVITY

Medical treatments and diagnostics, equipment and devices

Development, manufacturing, and/or distribution of accessible treatments, prescribed medicines, vaccines, diagnostic products; healthcare equipment and devices.

IMPACT CRITERIA

Exposure to medical products enabling treatment, prevention or better detection of :

- **Rare diseases, neglected tropical diseases or unmet needs.**
- **Leading causes of death** (such as, but not limited to, heart diseases, cancers, respiratory infections, strokes), notably focusing on personalized medicine, immuno-oncology and/or solutions aiming to reduce the burden of the disease.
- **Emerging health threats** including antimicrobial resistance or infectious diseases aggravated by climate change

Analysis of the number of products with FDA program designations such as **Breakthrough Designation, Orphan designation, Fast track** and their European equivalent that validate the quality of the clinical pipeline. These programs have been designed to expedite the development of drugs for serious conditions, unmet needs, or providing significant improvement over available therapies.

Analysis of the pricing strategy based on local regulation, local healthcare systems, and reimbursement systems.

For this pillar, the positive contribution of activities is analyzed through a combination of revenues exposure, R&D investment and other indicators to qualify the innovative nature of the activities and the population targeted/met.

For products supporting medical research and services (instruments, small medical equipment, etc.), met medical needs / mature technologies:

LOW POSITIVE IMPACT

> 10% to 100% revenues from sustainable activities

For unmet needs, leading cause of deaths or emerging threats:

MODERATE POSITIVE IMPACT

> 10 to 100% revenues from sustainable activities without robust pricing strategy.

HIGH POSITIVE IMPACT

> 10% to 100% revenues from sustainable activities **with a transparent pricing policy aligned with purchasing power of the patient pool,**

Sustainable Activities

SOCIAL OPPORTUNITIES

CONTEXT

Evidence shows that in 2021, around 9% of women in the reproducing age had an unmet need for contraception[1] globally and, in low-income countries, less than half of the need for family planning was met[1]. Unintended pregnancies are likely to exacerbate inequalities, and usually expose women to more health complications.

Beyond family planning, which is a crucial pillar for women empowerment, some health conditions such as autoimmune diseases, anxiety, depression or migraines disproportionately affect women. Others, such as endometriosis, are directly related to female conditions. All attract much less funding in proportion to the burden they exert on the global population. For example, endometriosis is estimated to roughly affect 10% of reproductive age women and girls globally[1] , yet only a very little share of the population receives treatment.

Most clinical trials tend to be conducted on males, generally from a higher socio-economic status. This creates biases and impacts clinical trials results, which can eventually lead to underestimation of pathologies or safety risks for some patients based on their gender, ethnicity, age, etc.

SUSTAINABLE ACTIVITY

Products for equality

Development, manufacturing, and/or distribution of affordable sexual and reproductive health products and women's health (treatment and diagnosis of diseases and conditions that affect a woman's physical and emotional well-being).

IMPACT CRITERIA

Exposure to medical products enabling treatment, prevention or better detection of conditions particularly relevant for women such as gynecological conditions including endometriosis and menopause, women's cancers, autoimmune diseases, anxiety and depressive disorders, etc.

Exposure to sexual and reproductive health products including, but not limited to, contraception (incl. oral contraceptive pills, implants, etc.), abortive products, HIV prevention and management, as well as fertility, etc.

Qualitative analysis of the company's integration of diversity aspects in the conduction of clinical trials, including, but not limited to:

- Measures to overcome financial and language barrier in clinical trials recruitment,
- Measures to overcome low health literacy and distrust of healthcare systems,
- After trials support including patient assistance programs to pay for treatments that are comparable or replace trial medications.

For this pillar, the positive contribution of activities is analyzed through a combination of revenues exposure, R&D investment and other indicators to qualify the nature of the activities. For medical segment considered as unmet needs, the market share, and the size of population targeted and effectively met is considered in the analysis.

For products supporting medical research and services (instruments, small medical equipment, etc.), met medical needs / mature technologies:

LOW POSITIVE IMPACT

> 10% to 100% revenues from sustainable activities

For products targeting medical conditions disproportionally affecting underrepresented population. OR sexual and reproductive health:

MODERATE POSITIVE IMPACT

> 10% to 100% revenues from sustainable activities without robust pricing strategy.

HIGH POSITIVE IMPACT

> 10% to 100% revenues from sustainable activities with robust pricing strategy.

Sustainable Activities

SOCIAL OPPORTUNITIES

CONTEXT

Despite recent progress, many treatments, diagnostic tools, and other essential healthcare products remain unaffordable and unavailable in many regions of the world. It is estimated that billions of people still struggle in accessing the medicines they need[1], although most of these products exist.

In low-income regions, the main hurdle to advance human health is the lack of quality infrastructures and basic healthcare services yet, even where medical treatments or drugs are available, the pricing strategy of the company may no be aligned with the purchasing power of the country, which severely limits its access.

In higher-income regions where infrastructure tend to be more available, patients usually depends on local governments or private insurance to support the cost of treatments or prevention. Yet, the coverage is still not uniform across population and out-of-pocket payments may still be a burden for patients. It is estimated that almost 5% of the population globally was pushed into poverty in 2017 due to out-of-pocket payments (latest data available)[2].

SUSTAINABLE ACTIVITY

Access to basic needs

Development, manufacturing, and/or distribution of affordable treatments, prescribed medicines and vaccines such as biosimilars and generics, as well as diagnostic products; healthcare equipment and devices.

IMPACT CRITERIA

Exposure to low-cost product portfolio including biosimilars and generics.

Exposure to list of Essential Medicines defined by the WHO, that include, but is not limited to products preventing or treating diarrhea, HIV/AIDS, influenza, malaria, or reproductive health.

Qualitative analysis of the company's access strategy including targeted pricing policies, cooperation with local governments and the definition of an access to medicine strategy, that should include access-related goals for senior, transparency about potential sharing of intellectual property as well as voluntary licensing and efforts to ensure continuous supply of medicines in low-income countries where the burden of the disease is high.

For this pillar, the positive contribution of activities is analyzed through a combination of revenues exposure, R&D investment and other indicators to qualify the nature of the activities.

LOW POSITIVE IMPACT	MODERATE POSITIVE IMPACT	HIGH POSITIVE IMPACT
	For products analyzed as life-saving and affordable specifically targeting conditions particularly relevant for low- and middle-income countries:	
	> 5% to 15% revenues from sustainable activities	Above 15% revenues from sustainable activities
	For products offering affordable alternatives for treatments or diagnostics with high price burden.	
10% to 20% revenues from sustainable activities	20% to 50% revenues from sustainable activities	> 50% sustainable activities

Sustainable Activities Focus : Medical treatments for animals

CONTEXT

One Health is an approach that recognizes the close link and interdependence of human health, domestic and wild animals, plants, and the wider environment (including ecosystems). While the health, food, water and energy sectors all have specific concerns, the collaboration across sectors and disciplines contributes to protect health and the integrity of our ecosystems as well as food security. Animal health is thus one of the pillar of the One Health approach, and animal medicines are, in many instances, necessary. Yet, intensive agriculture models have been supported by and led to the extensive use of antibiotics. Notably, global meat production accounts for 70% of all antibiotic use and is projected to increase by 11.5% between 2017 and 2030[1]. This use of antibiotics is explained by the pressure from proteins producers to achieve higher slaughter weights and prevent cattle from contracting diseases caused by unhygienic and crowded conditions. Yet, the misuse and overuse of antibiotics is causing various concerns for our ecosystems and human health. It is leading to Antimicrobial Resistance (AMR) and, as many of these antibiotics are also used to cure human illnesses, it may reduce the effectiveness of existing treatments. In addition, when entering the environment, antibiotics contaminate water and soil, and disrupt our ecosystems. **In order to deliver a positive impact, companies exposed to animal health products will have to clearly demonstrate their efforts to support the transition towards a more sustainable agriculture, mainly through the development of alternatives such diagnostics, prevention, vaccines, etc. Products analyzed as supporting intensive agriculture models including but not limited to efficiency driven products (i.e. drugs used to increase milk production efficiency) would be excluded.**

POSITIVE IMPACT

SUSTAINABLE ACTIVITY	IMPACT CRITERIA
Sustainable agriculture Animal medical treatments for the prevention of diseases (alternative to antibiotics, etc.)	Exposure to medical products enabling treatment, prevention or better detection of animal diseases (excl. companion animals). Qualitative analysis of measures implemented to inform, train and support farmers in the use of antibiotics alternatives and transition towards sustainable agriculture models.
HIGH POSITIVE IMPACT	> 50% from solutions and alternatives for animal health with robust stewardship to support agriculture transition.
MODERATE POSITIVE IMPACT	> 20% to 50% from solutions and alternatives for animal health.
LOW POSITIVE IMPACT	> 10% from solutions and alternatives for animal health.

CONDITION FOR ELIGIBILITY

- If exposed to antibiotics, reduction in the share of antibiotics revenues overtime and increase in R&D focusing on alternatives.
- Qualitative analysis of portfolio to avoid any treatment or equipment prevalent in intensive agriculture systems (including reproductive genetics, vitamins for animals evolving in dark warehouses, etc).
- Robust governance of antibiotics products including trainings of farmers, marketing strategies, transparency around risks, and stedwardship on AMR.

Sustainable Activities

	CONTEXT	SUSTAINABLE ACTIVITY
SOCIAL OPPORTUNITIES	Unsafe food containing harmful bacteria, viruses, parasites or chemical substances is the leading cause to more than 200 diseases[1], ranging from diarrhea to cancers. Every year, an estimated 600 million people fall ill after eating contaminated food and 420 000 die, which results in the loss of 33 million healthy life years[1]. Life science companies are usually heavily involved in R&D projects related to the testing and monitoring of new molecules, and usually apply these resources to the detection of food contaminants as well. R&D in the field is all the more important since emerging food safety risks occur. These risks result from potential endocrine-disrupting chemicals (notably in packaging), hybrid strains of pathogenic E. coli, microplastic in marine-derived foods.	**Food Safety** Food meters and testing devices, hygiene products, decontamination devices, etc.
BIODIVERSITY	There are an estimated 350,000 different types of manufactured chemicals on the global market[2]. These include plastics, pesticides, industrial chemicals, chemicals in consumer products, antibiotics and other pharmaceuticals. They are called “novel entities” and have largely unknown effects on the environment. Significant volumes of these novel entities enter the environment each year and the cocktail of chemical pollution now threatens the stability of global ecosystems. A crucial step to address the issue is to improve our ability to detect and monitor them. Life science companies are particularly well positioned to improve our understanding of these substances and their impacts. For example, to address widespread contamination, various companies are developing innovative solutions to extract toxic PFAS (per- and polyfluoroalkyl substances) chemicals from water supply or are developing tools to better detect microplastics.	**Eco products and processes** Testing equipment for pollution and toxicity management (air/water/soil quality, toxic content detection in products, etc.) Environmental and process monitoring services

For this pillar, the positive contribution of activities is analyzed through a combination of revenues exposure, R&D investment and other indicators indicated below. Companies will be valued based on the revenues generated as well as the quality of innovation and how they improve the current standards of detection and monitoring.

LOW POSITIVE IMPACT	MODERATE POSITIVE IMPACT	HIGH POSITIVE IMPACT
> 10% sustainable activities	> 20% to 50% sustainable activities	> 50% sustainable activities

Advanced Practices

HUMAN CAPITAL

CONTEXT	Actions/measures expected:	Impact indicators examples:
Job Quality Employees working in pharmaceutical companies tend to be considered on average as highly-skilled workers, notably in Research and Development (R&D) and sales or marketing. Most often, the employee turnover rate is relatively controlled in the industry and lies around 10-12%[1]. Companies are usually constrained to offer continuous trainings notably to ensure alignment with the regulatory landscape and avoid safety issues. In the sector, internal promotion is a crucial pillar of employee development, and the approach of most companies is to offer employees opportunities to work in different business units prior to offering leadership positions. This can really support employees' development. In addition, large pharmaceutical companies tend to pursue external acquisition strategies. Thus, human capital management policies should also include harmonization of corporate culture, implementation of high ethical conduct and promotion of common career path opportunities. It will contribute to retain talent and be incremental to the success of medical research projects and innovation.	• **Develop employees' skills recognized on the labor market and anticipate shifts in skills.** • **Ensure fair remuneration and social benefits are sufficient for good living conditions.** • **Ensure employee satisfaction and wellbeing.**	• Training hours per employee, % of workforce trained. • Qualitative analysis of the training offering including, upskilling programs, mentorships focused on young talents, leadership development…). • Creation of internal universities / academies targeting actionable skillsets and accessible to most employees. • Analysis of employees', executives' and shareholders' remunerations. • Existing and effective employees' association mechanisms. • Workplace wellbeing measures: flexible work arrangements, mental health support, counselling etc.
Diversity & Inclusion As women in the healthcare industry account for around 50% of the workforce (while average MSCI World is 38%[2]), the challenge is not really to attract women but rather to provide the structure to enable them to access leadership positions and to be equally represented across different business units. There is still progress to be made as women only account for 25% of the Executive Committee of this industry[2]. Diversity and inclusion do not only pertain to gender. A particular attention should be paid to the economic social background of employees, their age, making sure that the working environment is inclusive for every employee regardless of their minority profile. To do so, diversification of recruitment pools to ensure equal opportunities in terms of professional development, and to raise awareness of employees and management on this subject. The analysis also considers geographical and cultural difference to assess the quality of practices, notably regarding benefits and social dialogue matters.	• **Improve female and diverse representation especially at management/leadership level.** • **Ensure equal opportunities and increase awareness to overcome inequalities.** • **Ensure adapted and flexible career options.**	• Percentage of women in the Executive Committee, difference between women representation in the workforce and Executive Committee, C-Suite female representation (CEO, CFO, CIO, CCO). • Wage gap or credible target to reach pay equality & unadjusted pay gap. • Succession planning including at least one woman as a possible candidate for every Senior position. • Roadmap to improve recruitment of minorities and ensure unbiased recruitment. • Gender-neutral leave policy. • Provision of daycare options (affordable and/or paid by the company) and work flexibility options.

LOW POSITIVE IMPACT

➢ Advanced practices - Medium Stake* topic

> Credible strategy to achieve advanced practices

MODERATE POSITIVE IMPACT

> Advanced practices - High Stake* issues

POSITIVE IMPACT

Advanced Practices

	CONTEXT	ADVANCED PRACTICES	
		Actions/measures expected:	Impact indicators examples:
CLIMATE	The carbon footprint of pharmaceutical companies is mainly driven by Scope 3 emissions, which account for over 80% of their total carbon footprint[2]. A drug manufacturing process is divided into two major stages: the production of the active pharmaceutical ingredient (API), and the transformation of the active drug into a product suitable for administration. For most pharmaceutical companies, the API manufacturing process is outsourced to suppliers and the overall carbon footprint of the product depends on various factors, including the nature of the drug (made of synthetic or biological chemicals), and the quality and resource efficiency of manufacturing processes (including solvent recycling, power used in the factories etc.). Medtech and equipment companies tend to have a smaller decarbonization leverage and a significant share of the footprint occur in the use phase. Conducting life-cycle analyses and committing to eco-design is key to improve the energy- and resource- efficiency of the product, as well as its reparability and recyclability.	**Implement robust decarbonization strategy on all three scopes**	• GHG[1] emissions reduction targets on the all 3 scopes, preferably aligned with the Science Based Target Initiative (SBTi) and effective reduction in emissions. • Scope 1 & 2[3] : Absolute reduction of scope 1 and 2 emissions, significantly increase renewable energy power for manufacturing sites. • Scope 3[4] : transparency on API decarbonization strategy, measures to recycle solvents, objective to reduce dependency on plastic packaging, improve energy efficiency of products, and design lifecycle analysis to reduce footprint related to the use of products.
BIODIVERSITY	The impact of the industry on the biodiversity is resulting both from input raw materials (water and chemicals mainly) and downstream impacts of the process and the drug its. Not only the quantity of pure water necessary for the process is substantial, but these processes may also generate heavily polluted and toxic wastewater that require complex and costly treatment. While these processes are expected to be heavily regulated in most countries, a lack of control along the supply chain, lack of enforcement of these regulations and a lack of understanding on the impact of certain pharmaceutical residues in the environment is concerning. As of today, there are limited number of large-scale studies truly identifying the impact on wildlife and biodiversity of most of these residues. Nevertheless, antibiotic water contamination have already had consequences, including antimicrobial resistance (AMR). AMR is now presented as a global health crisis and drug resistant infections already cause an estimated 700,000 deaths each year globally[5]. Releases in the environment do not only happen in the manufacturing process but also results from the misuse and overuse of antibiotics, notably in agriculture. Yet, it is estimated that up to 50% of the antibiotics prescribed for human use are considered unnecessary[6], thus information, training and support to doctors is also crucial to address the threat.	• **Limit water and soil pollutions** • **Preserve input resources (water and biobased ingredients)** • **Limit end of life pollutions and waste**	• Assessment of sites and suppliers' sites to biodiversity and water scarcity sensitivity. Implementation of relevant plans based on the assessment. • Audit of critical API manufacturers and contract manufacturing providers based on PSCI[7] or other relevant frameworks. • Transparency on Risk Quotient on API discharges from sites and suppliers' site or/and PNEC[8] levels met, • Transparency about water withdrawal quantities from areas of water scarcity and implementation of a robust water stewardship plan. • Use of biobased ingredients and implementation of sustainable sourcing strategy (including regenerative agriculture sourced ingredients). • Targets to reduce waste and use of plastic in packaging.

LOW POSITIVE IMPACT

> Advanced practices - Medium Stake* topic

> Credible strategy to achieve advanced practices

MODERATE POSITIVE IMPACT

> Advanced practices - High Stake* issues

The information provided reflects Mirova's opinion/the situation as of the date of this document and is subject to change without notice. 1. Greenhouse gases. 2. The Shift Project, 2021 3. Direct emissions created by a company's activities and Emissions from the electricity a company uses in its operations. 4. Indirect emissions from a company's supply chain, distribution, use of products, and product disposal. 5. OECD, 2018. 6. European Journal of Internal Medicine. 7. Pharmaceutical Supply Chain Initiative. 8. Predicted No Effect Contamination Source: Mirova

Advanced governance model

CONTEXT

Mirova aims to promote the development of a corporate vision focused on the creation of collective value over the long term. Corporate governance should be shaped to include the interests of its key stakeholders. We believe that the creation of wealth requires a long-term perspective, which takes into account sustainability issues.

Mirova encourages companies to include environmental and social issues in its purpose, and to adapt their articles of association accordingly. We feel that shareholders have a role to play in spreading this vision of what a company should be.

Thus, we are promoting the development of a long-term shareholder base, the creation of governing bodies that serve all stakeholders and address CSR[1] issues, the introduction of a compensation policy which is not only fair to its stakeholders, but which also promotes sustainable growth, and -increased transparency and a better quality of both financial and extra financial information, through annual audited reports covering all these issues.

Advanced governance practices only foster sustainability but is not a standalone driver of impact.

ADVANCED GOVERNANCE MODEL DETAILS

Practices/measures expected:	Impact indicators examples:
Commitment to long-term and shared value creation	• Demonstrate how value created is shared fairly amongst company stakeholders. • Strive towards the model of a purpose-driven organization or/and a B-Corp organization.
Integration of stakeholders in the decision-making process	• Create of a Sustainable Development Committee or sustainability representative at Board-level, with regular meetings throughout the year. Sustainability items systematically integrated into the board agenda.
Fair taxes	• Provide country-by-country reporting on tax payments.

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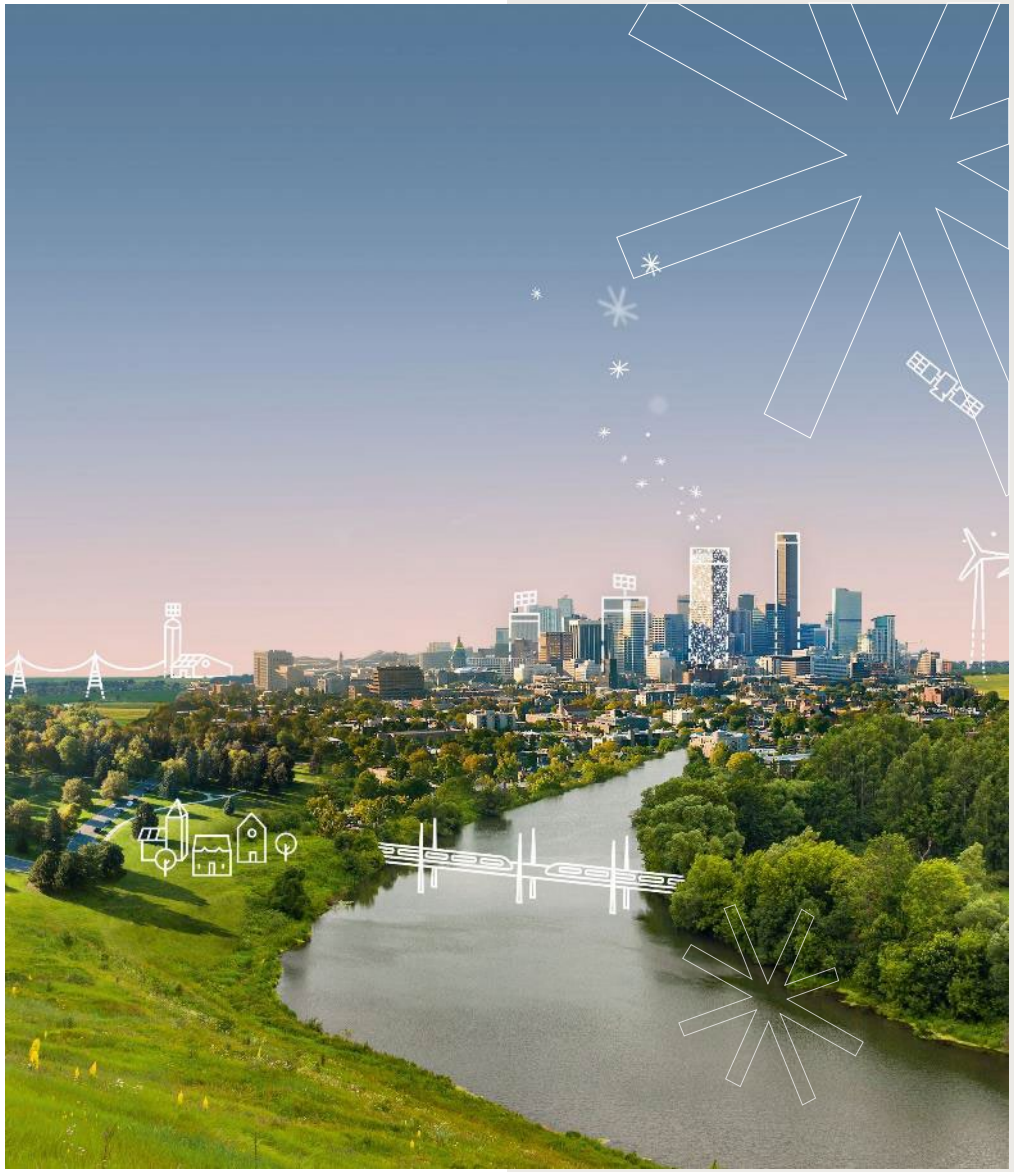
ESG Risks



Product Safety

CONTEXT

A company with a highly fragmented supply chain and little oversight over their suppliers' practices might be at higher risk of product safety controversy. Indeed, most safety issues result from the outsourcing of the various steps in the process: clinical trials, manufacturing, packaging, transportation and/or distribution. Recalls are usually frequent and voluntary and might be a good signal of the effectiveness of the pharmacovigilance process.

The US Federal Drug Administration has set different severity levels for recalls. A Cass I recall is the most severe and refers to a reasonable probability of death. Yet, most recalls are Class II or III. While severe product safety controversies are usually difficult to anticipate, the frequency and severity of recalls can be a signal of potential concerns over the ability of the company to implement robust quality management processes.

Finally, the industry is more and more exposed to the risk of counterfeited drugs notably due to the emergence online pharmacy services. Although pharmaceutical companies are not directly responsible for the development and distribution of counterfeited drugs, they carry at least the responsibility for monitoring the market as part of the pharmacovigilance process, for ensuring their packaging difficult to counterfeit and for informing patients in case of suspicion.

MINIMUM STANDARDS

Type of ESG risk:	Risk assessment indicators examples:
Clinical trial management	• Transparency about quality management process and patient safety mechanisms during clinical trials. • Use of written protocol for conducting clinical studies according to the Helsinki Declaration as well as the Good Clinical Practices guidelines.
Manufacturing process	• Audits of suppliers on quality standards including reference to the Good Manufacturing Practices (which validate among others the cleanliness and sanitizing of plants and equipment, qualification of the personnel, storage and labelling of raw materials etc.). • Number of FDA enforcement actions taken in response to violations of current Good Manufacturing Practices.
Pharmacovigilance	• Number of product recalls and transparency on class I recalls (explanation of the reasons and action plans/corrective measures implemented). • Qualitative analysis of fines and regulatory actions related to product safety. • Transparency about efforts to monitor, avoid and communicate about counterfeit drugs.

Animal testing

Research and development (R&D) activities are at the core industry's activities. After a drug is discovered, companies are generally required by law to undertake both pre-clinical tests on animals as well as clinical tests on humans (healthy volunteers) before seeking registration and marketing approval from healthcare authorities. Pre-clinical trials are usually conducted on animals, mostly small mammals such as mice, rabbits or monkeys to determine the suitability of the new medical compound to become a drug and their safety for continued testing on humans. During this phase, the potential toxicity as well as the effectiveness of the new candidate drug is analyzed over an average period of two years. Although the actual effectiveness of animal testing may be debated, no strict regulation banning the use of animals in pharmaceutical clinical trials exists, and most regulations currently in place fail to really promote animal welfare.

The most reliable approach for now has been the voluntary implementation of the three "Rs" policy (Reduction, Refinement, Replacement) by companies. This approach entails the minimization of experiments on animals whenever substitute tests are possible, efforts to avoid animal suffering and commitments towards the development of alternatives to animal testing such as, but not limited to, in vitro methods or advanced computer-modeling techniques.

Working conditions

CONTEXT	MINIMUM STANDARDS	
	Type of ESG risk	Risk assessment indicators examples
Manufacturing pharmaceutical products involves exposure to chemicals, toxic fumes, flammable materials, and other hazardous agents may cause hazard for workers. These ingredients are not harmful for patients, as the concentration of these substances in the final product is usually limited but it may become a health hazard in a context of a repeated heavy exposure without proper protection. Thus, companies in the sector are expected to focus on maintaining a high level of workplace safety and eliminate workplace accidents, especially focusing on air quality. The robustness of the policy/strategy will be determined by the ambition of the goals and the scope, the availability monitoring tools, trainings & prevention program.	**Health and safety**	• Frequency and severity of accidents (direct workers and contractors), number of fatal accidents in the last few years. • Measures to promote fair working conditions and a sustained social dialogue in countries with less stringent regulations. • Anonymous reporting channel to report non-ethical behaviors in the workplace.
Medical products companies rely on highly complex supply chains comprising thousands of suppliers around the world. As a result, the monitoring of all suppliers' labor standards may be complicated. Companies should ensure decent working conditions in their supply chain with appropriate due diligence and monitoring, as well as participation in collaborative efforts to drive harmonized standards.	**Human rights in the supply-chain**	• Transparency and traceability of the supply chain of high-risk ingredients. • Audit of suppliers based on collaborative scheme such as International Pharmaceutical Supply Chain Consortium audit program or equivalent third-party audit programs for integrity of supply chain and ingredients. • Violation of UNGC principles and OECD guidelines for Multinational Enterprises and implementation of corrective measures. • Implementation of a policy to monitor compliance with UNGC principles or OECD guidelines for multinational enterprises. • Number of identified cases of severe human rights issues and incidents. **PAI #10** **PAI #11** **PAI #16**

Climate & Biodiversity

CONTEXT

For many years, the carbon strategy of companies in the industry remained aligned with expectations set by local regulations. Recently, most companies have started to design more robust and comprehensive decarbonization strategies, yet the transparency and maturity is still heterogenous notably between geographies and subsectors. For example, the MedTech subsector remains lagging. For companies analyzed as lagging, we expect the implementation of at least the evaluation of their carbon footprint of the activities and the implementation of a robust action plan.

The sector relies heavily on biodiversity resources, which provide a rich and unique source of bioactive lead compounds, especially in the field of anti-cancer and anti-infective agents. For example, about two-thirds of these agents are derived from natural products. The Convention on Biological Diversity (CBD) in 1992 marked a turning point in the industry. Prior to this date, it was common practice to freely collect plant and microbial sources from around the world for research purposes. Through the CBD, countries now maintain sovereignty over their genetic resources and may limit access to these. Pharmaceutical companies, among other users of biological resources, are expected to aligned with the laws surrounding biodiversity protection and share the benefits derived from their discoveries.

MINIMUM STANDARDS

Type of ESG risk:	Risk assessment indicators examples:	
Climate footprint	• Calculation of GHG Emissions on all 3 scopes or ongoing evaluation (PAI 1 / PAI 2). • Share of non-renewable energy consumption and production (PAI 5) - Energy consumption intensity per high impact climate sector (PAI 6). • Definition of a decarbonization strategy to reduce major sources of emissions.	PAI #1 PAI #2 PAI #5 PAI #6
Environmental risks in the supply-chain	• Existence of a code of conduct for suppliers that includes environmental considerations, especially for API procurement. • Participation in multistakeholder industry initiatives and promote the development of ambitious environmental standards in the supply-chain (ex: Health Systems Task Force etc.).	
Biodiversity footprint	• Adopt the Convention on Biological Diversity (CBD) and the Kunming-Montreal Global Biodiversity Framework. • Transparency about quantity of genetic resources used for research, identification of protected natural substances (CITES list) and efforts to develop alternative solutions. • Adhesion to the Nagoya Protocol principle of sharing benefits generated with countries that give access to their natural resources, as well as with local populations having specialized know-how. • Emissions to water (PAI 8) - Hazardous waste and radioactive waste ratio (PAI 9).	PAI #8 PAI #9

Medical Ethics

CONTEXT

Medical products are designed and manufactured with the aim to improve global health. In most cases, researchers, practitioners, and users abide by strong ethical standards. In some rare cases, risks of product misuse or unethical research projects may arise. For example, while innovation around DNA sequencing or genome editing has enabled the detection and treatment of major diseases including cancers or rare diseases, it may also raise issues around such as data privacy, consent, stereotyping and stigmatization, genetic modifications etc. We expect companies to apply robust ethical standards and ensure due diligence with their suppliers and consumers to avoid any detraction.

MINIMUM STANDARDS

Type of ESG risk:	Risk assessment indicators examples:
Product Responsibility	• If relevant, companies should formally express potential risks of misuse, such as, but not limited to, identification of ethnicity or other physical characteristics. • Robust policies to exclude sales and direct relationships with local governments/ stakeholders suspected of misuse of the product. If possible, control distribution channels and product tracking to avoid illegal reselling. Ensure that any misuse can result in the end of the relationship. • Ensure inclusion of medical ethics in Code of Business Conduct and Ethics. All directors, officers, and employees of the Company should be responsible for reviewing this Code and certifying annually. All employees are given annual training on specific Code elements to ensure they have a complete understanding of what is expected of them.

Stem cells

Stem cells refer to cells that can be self-renewed, multiply infinitely and differentiate into all types of human cells. Stem cells research carry the potential to actively contribute to addressing unmet medical needs by improving the understanding of a disease occurrence or by offering opportunities in the development of transplant and regenerative medicine, diabetes, Parkinson's or Alzheimer's diseases treatments. As of today, only a small number of stem cells treatments have been authorized by national regulators. A remaining lack of scientific evidence of stem cells therapy's safety should also justify caution.

Most stem cells are collected from embryos or fetal tissues. Indeed, while adult stem cells exist, they may not produce all other cell types, remain sensitive to environmental hazards or may contain errors resulting from the process of cells replication. The development of "induced pluripotent stem (IPS) cells" (cells which have been reprogrammed back into an embryonic state) is promising, yet such cells still struggle in delivering similar benefits. No relevant other alternative has been identified to conduct this research and International bodies such as the World Health Organization are still calling for stronger international regulation on stem cells research and therapies. The International Society for Stem Cell Research (ISSCR) issued specific Guidelines. While they lack in political enforcement, we consider many of these guidelines as essential to ensure minimum standards of ethics.

- Existence of a scientific oversight process to review and to raise potential bioethics dilemma about, among others, procurement of embryos.
- Informed consent: Voluntary informed consent should always be provided by donors. Perfect transparency on the origin of stem cells is necessary to initiate research.
- Ethical sourcing of stem cells: fetal tissue should strictly rely on donation following an abortion or stillbirth. In what regards research should only be conducted from in vitro embryo for which parental project would have been abandoned. The creation of a stem cell line can be approved for the study of specific pathologies but should remain under the control of the oversight body.
- No incentive should exist to encourage women to donate embryos or fetal tissues. No remuneration or compensation should be allowed to encourage the harvesting of embryos.

Governance

CONTEXT

The industry has a long history of business ethics related controversies and between 1999 and 2016, the pharmaceutical industry paid out more than $33 billion in settlements for misconduct to state and federal authorities in the United States[1]. Among the controversial practices, corruption, marketing, lobbying and fiscal practices have been the most pointed out. Over the past decades, corruption scandals notably involved kickbacks and off-label promotion. Such issues have highlighted the need to change the way sales representatives are incentivized, with a shift towards a more qualitative approach. In addition, companies have paid greater attention to training and monitoring of their sales representatives' alignment with their code of conduct.
Regarding lobbying, while it is perfectly legal in both the EU and the US, some practices may remain questionable, especially when they tend to go against the interest of consumer groups. Finally, corporate inversion tax regulations are among the key areas of focus for pharmaceutical lobbying in recent times. While tax credits have been allowed in most countries to incentivize innovation, some companies may be still active in high end tax optimization scheme benefiting from the opacity around the topic.

MINIMUM STANDARDS

Type of ESG risk	Risk assessment indicators examples	
Governance of sustainability	• Existing governance structure enabling the mitigation of environmental and social risks. • Disclose breakdown of value among stakeholders, improving transparency around employee remuneration and payroll. • Integration of ambitious and binding sustainability criteria – assessed through pre-determined, quantifiable metrics– into the variable compensation of top executives. • All Board members are trained on sustainability topics. • Presence of employee representatives at board level (beyond regulatory requirements). • Unadjusted gender pay gap and board gender diversity.	PAI #12 PAI #13
Business Ethics	• Robust Business ethics policies covering lobbying practices, anti-corruption, anti-competitive and bribery policies. • Anonymous whistleblowing channel to report non-ethical behaviors in the workplace, mechanisms applicable to all employees and third parties and presence of a third-party ombudsman, number of severe cases and correctives measures. • Systematic training on Company's and Suppliers' Code of Conduct. • Transparency on remuneration scheme of employees in sales-related functions with efforts made to make the fixed part most of the remuneration. • Transparency about lobbying practices and objectives. • Number of convictions and number of fines for violation of anti-corruption and antibribery laws.	PAI #17
Tax practices	• Effective tax rate vs. equal statutory tax rate. • Absence of controversies or evidence of aggressive tax optimization practices.	

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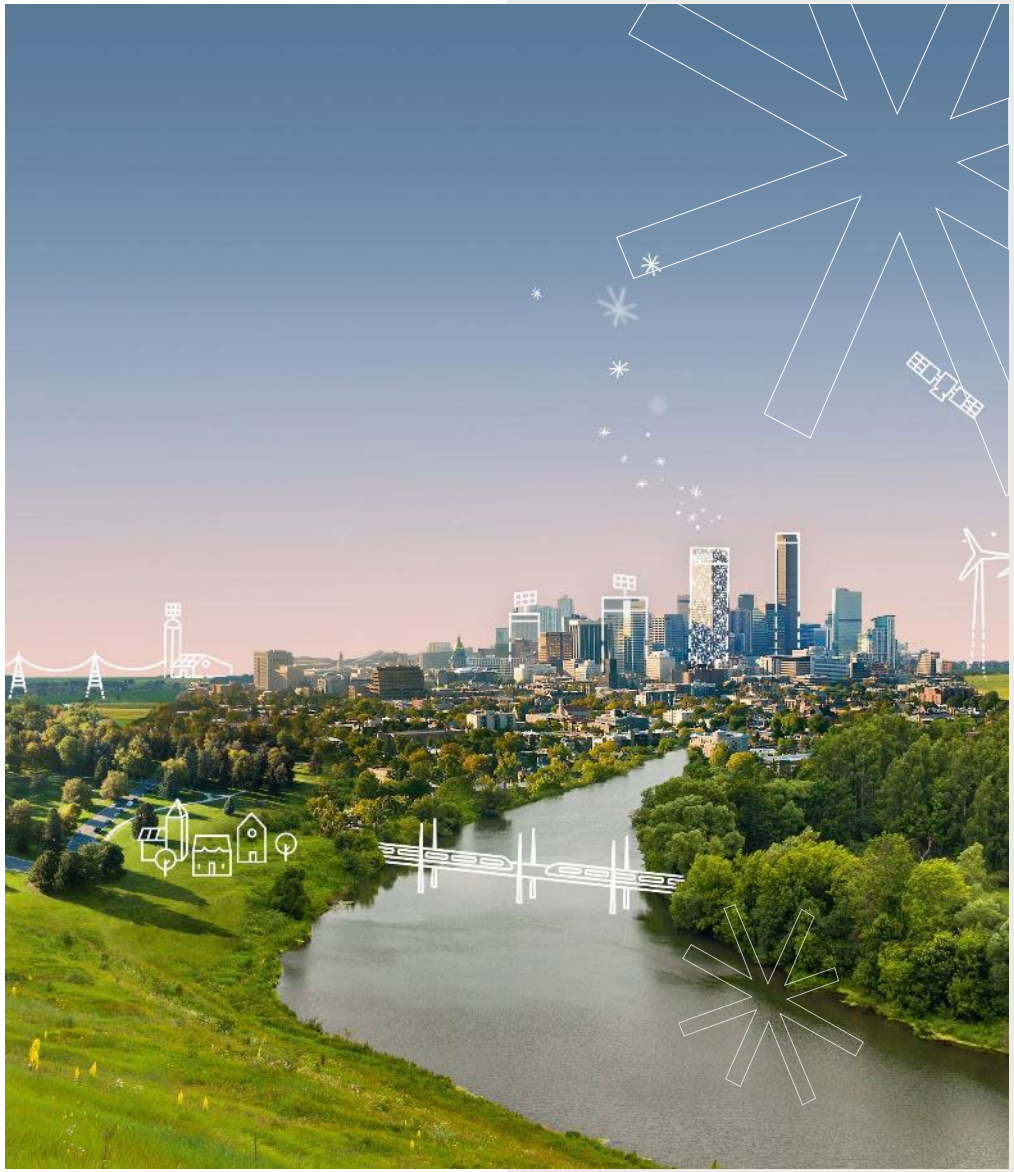
Appendices



Positive Impact

According to Mirova's internal methodology, contribution to the SDGs can be grouped into two main categories, which are often complementary.

- The **"activities"** i.e.. the products and services they offer.
- The "**practices**" i.e.. the way operations can contribute to create sustainable and inclusive jobs, or by having strong commitments to net zero targets beyond their green products offerings, etc.

ACTIVITIES	Marginal or no exposure to sustainable activities.	From 10% to 20% revenues from sustainable activities.	From 20% to 50% revenues from sustainable activities.	> 50% revenues from sustainable activities.
	The positive contribution is mainly analyzed through revenues exposure but not only. We complement this exposure with a qualitative review of the solution's impact. ESG KPIs to assess the level of impact generated can include mainly the innovation profile of the products, affordability and access.			
PRACTICES	Absence of advanced practices.	One or more **Advanced practices** on Medium Stake issues. or credible strategy to transition to advanced practices.	One or more **Advanced practices** on High Stake issues.	
	For the purpose of defining High/Medium Stakes, Mirova relies on external classifications, to the extent possible. Indicative High Stake sectors are defined as follows, but may be adapted on a case-by-case basis, notably depending on a company/project effective exposure to high stake activities. • Climate: Mirova relies on the list defined by NZIF and retains Nace codes A to H and J to L as High Stake. • Biodiversity: Mirova relies on the definition of its supplier Icerbeg Datalab and retains all GICS except from GICS 5020, 4510, 5010 and 3510 as High Stake. • Human Capital: Mirova considers sectors that are most exposed to arduous working conditions as High Stakes and all GICS except from GICS 5020, 4010, 4020, 4030, 4510, 3520, 6010 and 6020.			

ESG risks

SECTOR INHERENT RISK LEVEL: MEDIUM/HIGH

Product safety is one of the most crucial issue for the all actors in the healthcare industry. Alongside, although medical products can significantly improve people's quality of life, such benefits may be counteracted by inappropriate business practices that range from product marketing and clinical trials, to corruption of healthcare professionals or authorities.
The environmental footprint of the industry has long been overlooked. Yet, manufacturing healthcare products, including equipment or treatments has a rather high environmental footprint. Drugs manufacturers relies on active pharmaceutical ingredients which can be very carbon and water intensive. The risk of pharmaceutical releases in the environment is more and more concerning due to their disruptive power on biodiversity and due to increased antimicrobial resistance. Medtech companies, the sourcing of electronics components and the energy efficiency feature of the devices is to be considered. Finally, the increasing fragmentation of the industry requires to ensure high quality standards of social practices along the entire supply chain.

COMPANY INHERENT RISK LEVEL

A company inherent risk level may differ from the inherent risk level of the sector.
The definition of the company inherent risk level may also be determined by the specificities of the business model, the nature of the activities and their locations as well as that of their suppliers (incl. country specific risks).

MAIN ESG RISKS FACTORS

Working conditions : human rights & health and safety

Product safety

Medical ethics

Biodiversity & climate footprint

Governance :

- Governance of sustainability
- Business ethics
- Taxes

RESIDUAL ESG RISK LEVEL

LOW RESIDUAL RISK	Satisfactory management of the company's or project's main sustainability risks on most material issues.
MEDIUM RESIDUAL RISK	Current management in place does not fully cover all ESG risks but these are considered as moderate and current practices are deemed acceptable.
HIGH RESIDUAL RISK	Companies demonstrating significant mitigation efforts operating in sectors with industry-wide complex and unaddressed challenges - systematically under targeted engagement.
SIGNIFICANT HARM	Not eligible for investment.

Principal Adverse Impact Indicators

ADVERSE SUSTAINABILITY INDICATOR		MOST RELEVANT	THRESHOLDS / CRITERIA
CLIMATE AND OTHER ENVIRONMENT-RELATED INDICATORS			
Greenhouse gas emissions	1. GHG emissions	X	Systematic integration in qualitative internal analysis and systematic engagement with the largest emitters to strengthen their Net Zero commitments.
	2. Carbon Footprint	X	
	3. GHG intensity of investee companies		Not applicable
	4. Exposure to companies active in the fossil fuel sector		Not applicable
	5. Share of non-renewable energy consumption and production	X	Systematic integration in qualitative internal analysis and systematic engagement with the largest emitters to strengthen their Net Zero commitments.
	6. Energy consumption intensity per high impact climate sector	X	
Biodiversity	7. Activities negatively affecting biodiversity sensitive areas		Exclusion of companies or projects significantly harming biodiversity sensitive areas.
Water	8. Emissions to water	X	Systematic integration in qualitative internal analysis and systematic engagement with relevant investee companies on this issue.
Waste	9. Hazardous waste and radioactive waste ratio	X	
INDICATORS FOR SOCIAL AND EMPLOYEE, RESPECT FOR HUMAN RIGHTS, ANTI-CORRUPTION AND ANTI-BRIBERY MATTERS			
Social and employee matters	10. Violations of UN Global Compact principles and Organization for Economic Cooperation and Development (OECD) Guidelines for Multinational Enterprises	X	Exclusion of companies violating UNGC and OECD principles and monitoring of exposure to violations as part of controversy monitoring process. Systematic integration in qualitative internal analysis.
	11. Lack of processes and compliance mechanisms to monitor compliance with UN Global Compact principles and OECD Guidelines for Multinational Enterprises	X	
	12. Unadjusted gender pay gap	X	Systematic integration in qualitative internal analysis and systematic engagement with relevant investee companies on this issue.
	13. Board Gender Diversity	X	
	14. Exposure to controversial weapons (anti-personnel mines, cluster munitions, chemical weapons and biological weapons)		Exclusion of companies or projects exposed to controversial weapons leads to and involved in the production of re-exportable weapons.
INDICATORS FOR SOCIAL AND EMPLOYEE, RESPECT FOR HUMAN RIGHTS, ANTI-CORRUPTION AND ANTI-BRIBERY MATTERS			
Human Rights	16. Number of identified cases of severe human rights issues and incidents	X	Systematic integration in qualitative internal analysis and monitoring of exposure to violations as part of controversy monitoring process.
Anti-corruption and anti-bribery	17. Number of convictions and number of fines for violation of anti-corruption and antibribery laws	X	

The information provided reflects Mirova's opinion/the situation as of the date of this document and is subject to change without notice. Our minimum standards policy also provides more information on thresholds for Principal Adverse Impacts Indicators : Mirova Minimum standards Source: Mirova.

Useful Resources

SFDR

- Sustainable Finance Disclosure Regulation (SFDR): positioning of Mirova Funds
- Description of the principal adverse impacts on sustainability factors

POLICIES AND METHODOLOGIES

- Our approach to impact
- Our approach to impact & ESG assessment
- Minimum standards
- Voting and Engagement policies
- Temperature alignment of listed investment portfolios
- Transparency codes
- Our Taxonomy for Sustainable Solutions

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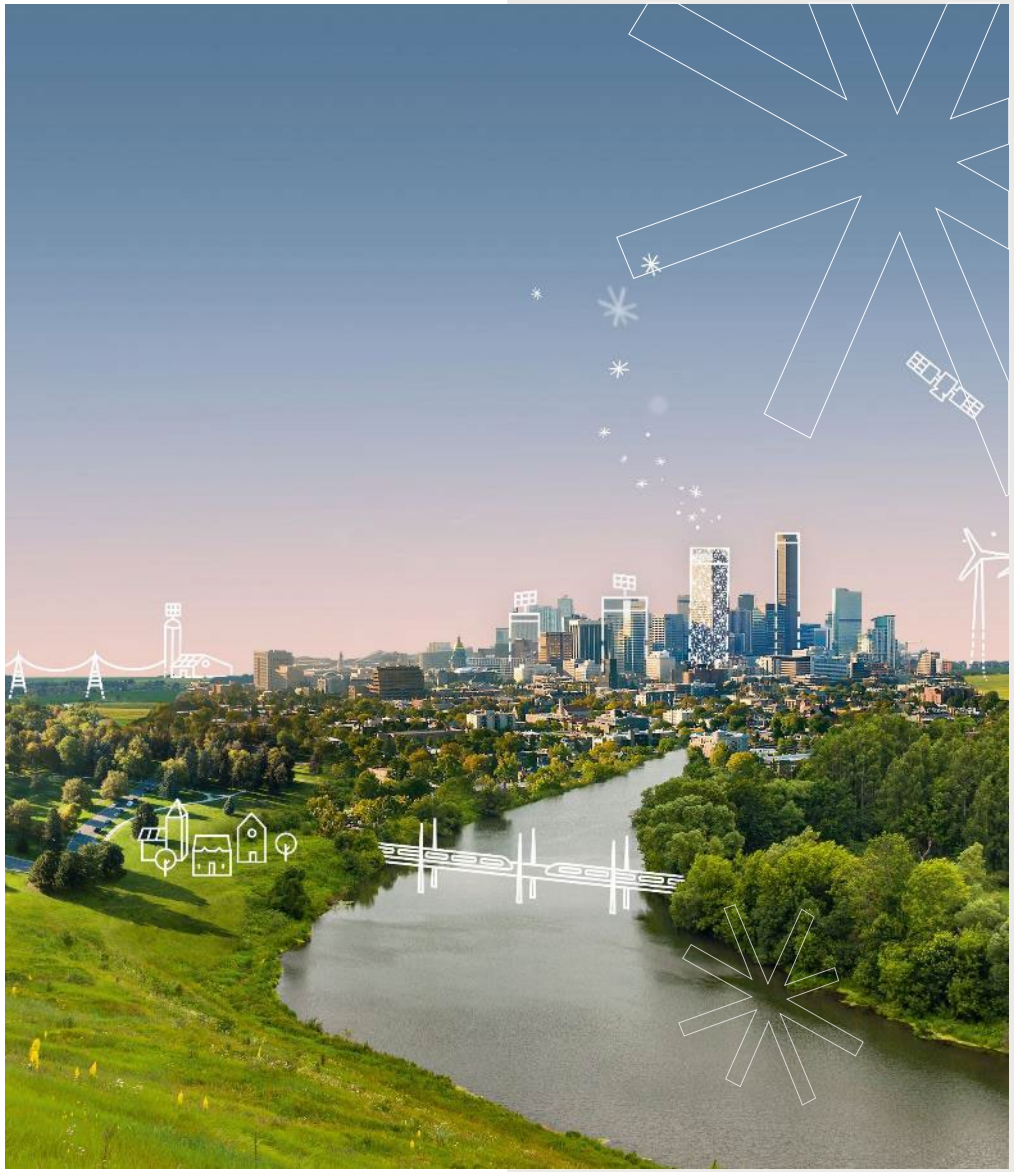

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MAIN RISKS

ESG Investing Risk & Methodological limits

By using ESG criteria in the investment policy, the relevant Fund's objective would in particular be to better manage sustainability risk and generate sustainable, long-term returns. ESG criteria may be generated using Mirova's proprietary models, third party models and data or a combination of both. The assessment criteria may change over time or vary depending on the sector or industry in which the relevant issuer operates. Applying ESG criteria to the investment process may lead Mirova to invest in or exclude securities for non-financial reasons, irrespective of market opportunities available. ESG data received from third parties may be incomplete, inaccurate or unavailable from time to time. As a result, there is a risk that Mirova may incorrectly assess a security or issuer, resulting in the incorrect direct or indirect inclusion or exclusion of a security in the portfolio of a Fund.

Sustainability risks

The Sub-Funds are subject to sustainability risks as defined in the Regulation 2019/2088 (article 2(22)) by environmental, social or governance event or condition that, if it occurs, could cause an actual or a potential material negative impact on the value of the investment.

Sustainability Risks are principally linked to climate-related events resulting from climate change (i.e. Physical Risks) or to the society's response to climate change (i.e. Transition Risks), which may result in unanticipated losses that could affect the Sub-Funds' investments and financial condition. Social events (e.g. inequality, inclusiveness, labour relations, investment in human capital, accident prevention, changing customer behaviour, etc.) or governance shortcomings (e.g. recurrent significant breach of international agreements, bribery issues, products quality and safety, selling practices, etc.) may also translate into Sustainability Risks. Sustainability factors consist in environmental, social and employee matters, respect for human rights, anti-corruption and anti-bribery matters (the "Sustainability Factors"). Portfolio investment process includes binding and material ESG approach to focus on well rated securities from an ESG viewpoint in order to mitigate potential impact of Sustainability Risks on portfolio return. More information on the framework related to the incorporation of Sustainability Risks is to be found in the sustainability risk management policy of the Management Company on its website.

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Non-contractual document, issued in July 2024.

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