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Investing in sustainability

Health: Medical Devices and Services

Sustainable Development Sector Analysis Framework

May 2021

This is a methodological document aimed at clarifying how Mirova considers sustainable development issues in the framework of the environmental, social and governance analysis of each sub-sector of activity.

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The medical services and devices sector encompasses companies involved in various activities related to health care. Indeed, it includes healthcare facilities (hospitals, nursing homes etc.), companies providing medical equipment (surgery robotics, hearing aids, implants etc.) and supplies (needles, pads, surgical packs and small instruments etc.) as well as services providers enabling, among others, the digitalization of the sector. While these companies have various business models, they all face potential for disruption. Indeed, personalization of patient care, changing lifestyles and demographic trends will influence the type of products and services delivered by these companies. Moreover, these trends will shape patients and stakeholders' expectations including sustainability related features.

In this changing context, companies in the sector carry the opportunity to address numerous social challenges. Among others, innovations in the field of artificial intelligence and machine learning can help in decreasing healthcare costs thanks to improved efficiency across the value chain. Moreover, the recent evolution of the EU and US regulations will increase the administrative burden for most devices companies while strengthening patient safety. The responsibility of companies in ensuring product safety is more than crucial and is to be monitored through relevant quality standards.

Alongside, other relevant sustainability issues remained to be tackled by companies in the sector. First and foremost, business ethics controversies have tarnished stakeholders' trust, and companies are encouraged to improve transparency on remediation and corrective measures. The sector is also expected to scale up its ability to tackle emerging risks from different nature. Indeed, environmentally related risks, such as end-of-life management, antimicrobial resistance, as well as cybersecurity risks are receiving an increasing scrutiny as awareness around such challenges is rising.

In 2020, in the context of the COVID19 crisis, the sector has been in the spotlight and has demonstrated its ability to play a critical role in global health. Indeed, companies working in the industry have rapidly gathered resources to reorganize their operations, ensuring continuous medical consumables and equipment production, continuous operations in healthcare facilities, and enabling patients to receive necessary treatments, which has saved numerous lives.

Sectors: Health Care Facilities, Managed Health Care, Health Care Equipment, Health Care Supplies, Health Care Services

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Healthcare Sector: answering the SDGs at its core

Products offering solutions to the 3rd SDG

Since World War II, according to the WHO, global average life expectancy at birth has increased by about 25 years, from a little less than 50 years to over 70 years today. However, health disparities across regions are growing, with Sub-Saharan Africa experiencing significantly higher probability of premature adult death than more developed, low-mortality regions (WHO, 2017).

Figure 1: Life expectancy at birth (years - both sexes)

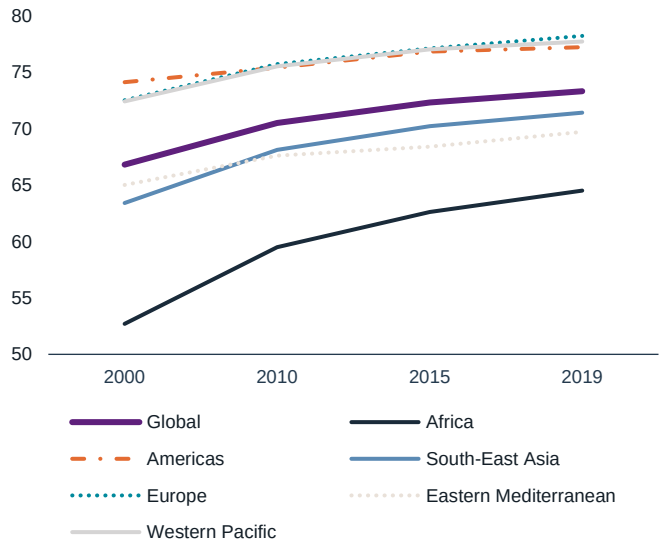
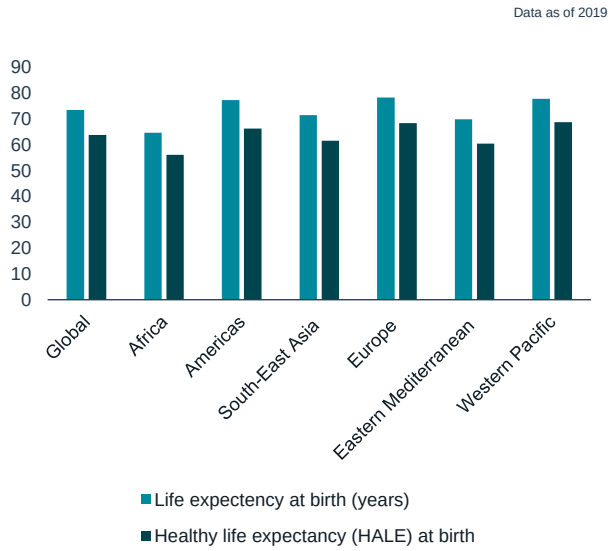


Figure 2: Life expectancy at birth and Healthy Life Expectancy (HALE) at birth per region (years)



Source: Mirova/ (WHO, Global Health Observatory data repository, 2019)

Global health indicators such as life expectancy at birth and healthy life expectancy (HALE) at birth, which reflects the number of years expected to be lived in full health at birth, show modest improvements since the early 2000s. Indeed, global life expectancy at birth rose about 10% since 2000 and the global HALE rose by +9%. Nevertheless, a significant gap across countries persists (Figure 1). For example, the average life expectancy at birth is about 78 years in Europe, yet, 71 in South-East Asia, and down 64.5 in Africa. HALE indicators also vary widely across regions and countries: while this is unsurprisingly lower than average in most African countries, the indicator drops below 60 years and may even attain less than 50 years in some African countries. As a result, finding a solution to unmet medical needs remains a global priority, especially in least developed countries.

As responsible investors, we thus look at the global healthcare sector as directly addressing the Sustainable Development Goal 3 (i.e. SDG3) - ensure healthy lives and promote wellbeing for all at all ages. In this regard, the United Nations have set a few meaningful goals by 2030 such as the reduction of the global maternal mortality ratio to less than 70 per 100,000 live births, the end preventable deaths of newborns and children under 5 years of age, the end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases etc. Reaching these objectives will undeniably be enabled by a strong public-private relationship, to ensure medical innovations (medicines, vaccines, diagnostics etc), which mainly designed in private laboratories, are made available to all human beings.

Sustainability Opportunities

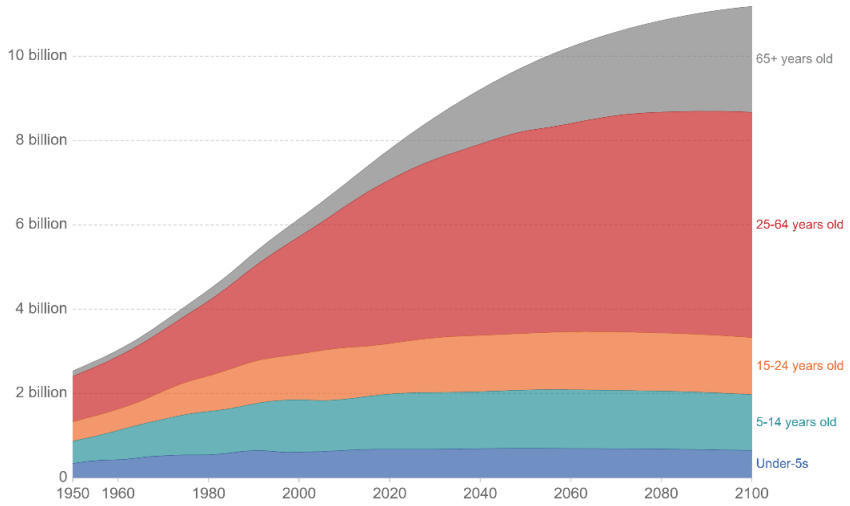
Impactful Innovation

Many technological innovations apply to the medical sector and have the potential to disrupt the industry in the next few years. Technical innovations are identifiable at different stages of the supply chain. Hospitals, nursing home or healthcare infrastructures are increasingly relying on new technologies to conduct day to day operations (administrative, scheduling, patient follow-up and monitoring, etc.) and to deliver care (medtech products, surgery robotics, treatments etc.). Overall, this innovation trend can have tremendous positive impacts, providing patients with a better experience, less invasive treatments, and an improved follow-up.

Improving standard of care

New technologies applied to the medical sector have the potential to improve current standard of care. Medical devices companies are more and more investing in nanotechnologies, wearables, robotics, and artificial intelligence to develop products that will positively contribute to global health. For example, in the last decades, robotics in the medical field have already transformed how surgeries are performed, providing better experience for patients, less invasive treatment and easier recovery.
Moreover, in a context of an increasingly aging population and thus a higher share of people receiving long-term care (Figure 3), existing healthcare services are posed to be increasingly under strain. Common conditions in older age include hearing loss, cataracts, pain and osteoarthritis, chronic obstructive pulmonary disease, diabetes, etc. Furthermore, as people age, they are more likely to experience several conditions at the same time and geriatric syndromes (including frailty, urinary incontinence, falls, delirium and pressure ulcers). Yet expect for countries that have developed geriatric medicine as a specialty, they are often integrated in traditional health systems. In this context, medical devices and services companies have a clear role to play to ensure healthy aging by developing products to address the evolution of needs and provide healthcare services aligned with the care expectations of the patients.

Figure 3: Population by broad age group projected to 2100, World, 1950 to 2100



Source: Mirova/ (UN World Population prospects, Our World in Data, 2017)

Improving healthcare related processes

Alongside, innovation enables actors in the industry to overcome long-time challenges related to organizational or information sharing obstacles. For example, electronic health records (the

digital version of a patient's paper chart), enable information on a patient to be instantly and securely available to with patients, their caregivers and healthcare teams. As illustrated during the COVID19 crisis, technologies have been key to enabling the scale up remote care models, which are expected to be extremely benefiting for chronic disease and for health maintenance. For example, the emergence of telemedicine during the pandemic was enabled by the ability to leverage on all the data generated by the new devices.

From a sustainable investment perspective, we favor the uptake of new technologies applied to the medical services sector that have a demonstrated potential to deliver positive impact, either by addressing unmet medical needs and thus improving quality of care, or in order to streamline costs and reducing inefficiencies within the broader sector. Among the technologies that we look positively, there are for example wearable patches to diagnose heart conditions, sensors to monitor asthma medication intake, telehealth, and platforms allowing behavior modification such as smoking cessation.

KEY INDICATORS

- Indicators of revenue from technologies applied to the medical sector that bring positive impact such as telehealth and behavior modification technologies.
- Reported indicators/research into proven positive impact of the technology.

Access to care

Despite an improving global trend in life expectancy, low- and middle- income countries still struggle to improve overall health conditions due to lack of infrastructure and poor access to healthcare services. Some diseases such as malaria, HIV or lower respiratory infections that are predominant in developing countries, have shrunk on a global basis, but they continue to heavily affect some of the most vulnerable populations worldwide.

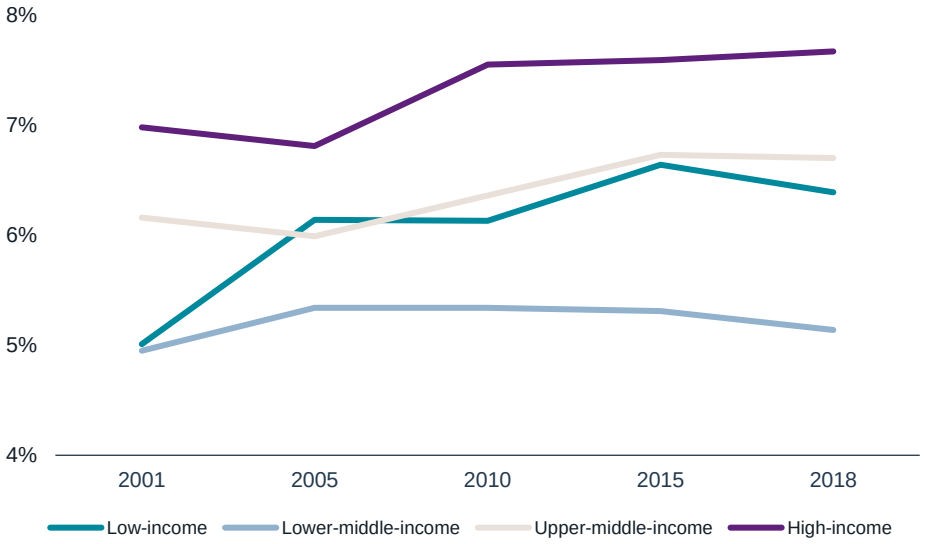
While access to medical treatment tends to focus on medical products, affordable access to medical devices and medical equipment remain extremely important to address the Sustainable Development Goal 3. Indeed, global health is largely supported by early and relevant prevention, healthcare facilities and infrastructures as well as relevant and modern equipment.

Prevention is particularly relevant to address access to medicine. Indeed, preventive and screening services have been proved to be effective to detect the early onset of diseases to patients. The lack of access to diagnostic tools may lead to the prevalence of some medical conditions among specific underserved populations. In developing countries, such conditions concern viral diseases transmitted by vectors such as malaria, chikungunya, Zika virus fever, dengue etc. Diagnostics and testing tools have been crucial to overcome the COVID19 pandemic and some epidemic such as Ebola. Alongside, early diagnostics are also a major challenge in oncology where early cancer screening is decisive to overcome the disease. According to a study published in the Lancet, patients diagnosed with cancer at an early stage have the best chance of curative treatment and long-term survival; for example, 57% of people with lung cancer survive their disease for 5 years or more when diagnosed at stage I compared with only 3% of those diagnosed at stage IV. In parallel, according to the OECD, lower-income people consistently have a lower utilization of preventive services. For example, for cervical, breast and colorectal cancers, low-income will have a lower probability of 17, 13 and 6 percentage points respectively to undergo screening in the recommended period in comparison with the high-income people. To overcome these inequalities, and the failure in the system to provide equitable access to prevention, the OECD recommends a reconfiguration of the system towards a primary health care delivery towards more patient-centered models.

While, across OECD countries, quality of care has generally improved thanks to earlier detection, as well as through improved awareness around disease prevention, these improvements happened at a cost. According to the OECD databases, in 2019, prior to the

COVID19 pandemic, average health spending as a share of GDP across the OECD was around 8.8%. This figure has remained largely stable since 2009 as growth in health spending remained in line with overall economic growth since the last economic crisis. With a growing share of population aged over 65 years (Figure 3), this may thus increase demand for long-term care services and thus put further strain on government budgets for healthcare, which compete with other budget expenses such as education, security, and employment, among others.

Figure 4: Current Health Expenditure (CHE) as percentage of GDP (%)



Source: Mirova/ (WHO, 2021)

In this context, private companies in the sector have a crucial role to play. Considering that innovation can theoretically contribute to the decrease in prices, private companies in the sector could be expected to leverage innovation to ensure larger access. Nevertheless, the relationship between innovation and decreased pricing may not be straightforward, and innovation has historically contributed to the development of very high-performing products, at a very high cost. Indeed, innovations frequently create incremental outcome gains in diagnostic or in therapeutic characteristics which often lead to higher prices compared to existing alternatives. Alongside, companies can focus on reducing costs through innovations targeted to improve the efficiency of existing alternatives. In other industries, such as the computing industry, innovation has focused on the ability to reduce costs while retaining performance. Regarding medical services, innovation can also ensure the automation of administrative tasks for more efficient use of physicians' time, ensuring lower costs and potentially better access.

Finally, medical conditions necessitating prosthesis and hospitalization are also affected by service supply and access to hospitalization. While the public sector has an important role to play in order to increase access to care and favor early diagnosis and treatment, the private sector can also foster services and tools supply that increase access to care in countries with low-income populations.

Access to care should be embedded into the strategy of companies operating within the broader medical services sector. Companies providing essential medical equipment in low-income countries at reasonable costs, as well as those adopting strategies to expand access to care among low-income patients are encouraged.

Initiatives aiming at increasing research collaboration in developing countries, allowing early diagnosis of infants in low-income countries, and helping build local infrastructure for treatment are also valued.

KEY INDICATORS

- Indicators of revenue (either forecasted or realized) from low-income countries and/or low-income populations and existing affordability strategies.
- Quantitative indicators related to the number of people covered by a company's access to healthcare strategy.
- Investment (both CapEx and R&D budget) dedicated to improving medical access and development of an inclusive business model.

Exposure to Opportunities

	Indicators considered : % of revenue dedicated to providing effective access to treatment, including those dedicated to tackling diagnosis and treatment of endemic and tropical diseases % revenue dedicated to the development of personalised % of expenditure (both CapEx and R&D) dedicated to the above-mentioned opportunities Number of patients and corporate spending dedicated to increasing treatment access in low-income countries and populations.	
High exposure	Proven, significant involvement in any of the following areas, on the basis of the above-listed indicators, without threshold: • Access to care • Impactful innovation	The analysis of CapEx and R&D budget devoted to activities at high opportunity as well as the revenues generated by these activities will also be supported by qualitative indicators such as the presence of a clear strategy toward the development of such solutions.
Significant exposure	All companies within the medical services sector that are involved in providing medical services intended for humans with the aim of improving overall health conditions.	
Low or no exposure	• Healthcare ancillary services (e.g. distribution, marketing, database management) despite having a degree of specialisation for the health sector • Medical services and tools dedicated to aesthetic treatments	
Negative exposure	n/a	

Environmental and Social Risk

Safety Standards

Products and patients' safety remain the most important risk to be managed by medical services providers and devices producers. While care providers (including nursing homes and hospital clinics) need to abide by high-quality safety procedures and standards of care, equipment manufacturers must follow strict safety standards within their manufacturing operations.

Safety incidents primarily occur due to inadequate safety procedures and testing from the manufacturers. Therefore, this is an area where stakeholders and regulators display a high level of vigilance. In the US, the FDA has the authority to obtain assurance of safety before products are marketed. In the EU, the CE mark status certifies a product's compliance with the European safety standards. For the rest of the world, the WHO (World Health Organization) has developed a version of Good Manufacturing Practice (GMP) indicators that are less stringent than the European and US ones. However, as with many issues related to the healthcare sector, regulation around medical devices' safety differs significantly across countries. As of May 2021, the latest Directive of the European Union (EU MDR 2017/745) became fully applicable. The directive has set more stringent requirements than previous ones, typically increasing the emphasis on a life-cycle approach to safety, backed up by clinical data and post-market monitoring.

Nevertheless, even the most stringent safety requirements currently fail to demand publicly available scientific evidence on the devices' safety and effectiveness. Safety incidents may lead to product or device recalls by the competent authorities. In the US the FDA classifies recalls into three categories, from class I - the most severe type of incident, to class III - the less severe. Several companies have been mired in controversy for having to withdraw defective products from the market, especially class I recalls, such as implantable cardiac devices and protheses. Given the potential severity of medical device recalls on public health, the FDA outlined a plan for improving device safety scrutiny based on sharing best practices. However, facility inspections from the competent authorities and publication of device recalls are currently limited to the US. In Europe, the European Medicines Agency issues recommendations but does not publish aggregate data on device recalls.

Companies managing healthcare facilities are less directly exposed to product safety issues, are responsible for providing high standards of care to their patients and customers. As such, they are also required to put in place strict safety measures including facilities inspections and, when possible, pursue external quality certifications such as the ISO 9001 and ISO 13485, or the Joint Certification Model (JCM) in the hospital area.

Finally, safety issues increasingly include company's ability to protect its computers systems from cyberattacks and security breaches. Indeed, in 2020, during the COVID19 crisis, the occurrence of cyberattacks in hospitals have received higher scrutiny as health care systems were already facing unprecedented pressure. Moreover, several medical devices embedding computer systems have been recalled in the last few years due their vulnerability against security breaches. For example, vulnerabilities in several implantable cardiac devices linked to wireless communication protocol have affect defibrillators or therapy hardware in 2019. Concretely, such vulnerabilities in computer systems enables hackers to access to the devices, connected monitors or clinical programming devices, blocking the activities, and demanding for a ransom. Alongside, hackers can also steal personal sensitive data, blackmailing patients or selling them. Thus, companies and infrastructures operators are expected to rapidly invest in cybersecurity, train employees and ensure devices are protected against any security breaches to protect patients against dysfunctions and induced hazards.

We expect companies within the sector to demonstrate effective quality management systems that encompass regular audits of their own facilities and those of partner manufacturers, and we encourage transparent reporting around the identified causes of product recalls. Additionally, we expect companies to show back-up plans for product recalls and device manufacturing plants suspension. Companies are also expected to have strong post-sale customer services to assist those affected by safety issues related to their products.

KEY INDICATORS

- Results and follow-up of safety audits.
- Presence and robustness of quality management system (including cybersecurity).
- Presence of quality certifications at manufacturing plants/care facilities.
- Track record of product recall and, when available, classification of seriousness (class I, II and III of FDA)
- Occurrence of repeated severe controversies

Ethical R&D Practices

Medical devices that are applied in human bodies have a broad field of application, some of which are used to bridge, and substitute disturbed or lost structures or functions in human bodies. Of prominence, neuro-protheses use electrical stimuli to control and stimulate tissue. Among these feature cardiac pacemakers and cochlear implants for deaf patients, which have widespread use. Thus, research and development operations to develop medical devices can be associated with a variety of ethical issues, including animal experiments, human clinical trials, and scope of use. The difficulty in assessing ethical issues arises as benefits for patients need to be weighed against the potential implications these medical devices may have.

At early stage of development, after in-vitro testing (i.e. non-animal alternatives), medical devices need to be tested on animals to determine the suitability and safety for continued testing on humans. During this phase, animals with lower taxonomical classifications are usually used, most frequently guinea pigs, squirrel, and rhesus monkeys. Upon successful completion of animal testing, the final step is the development of clinical trials on a selected sample of patients. However, patients must give their informed consent before testing a new development in a clinical trial. To ensure informed consent, researchers (i.e. those who carry the experiments) are expected to carefully clarify all possible consequences of the test to the patients to minimize confusion and concerns.

Companies in the medical services industry that conduct R&D into medical devices should commit to the three Rs (reduction, refinement, replacement) which entail the minimization of experiments on animals whenever substitute tests are possible, the avoidance of animal suffering and a commitment towards finding alternatives to animal testing. In addition, they should abide by the WHO's Good Clinical Research Practice (GCP) guidelines for clinical trials. Selection of trial sites and experienced and qualified investigators is also of utmost importance, alongside the review of all studies by an independent ethics committee. Clinical trials should also be conducted according to basic ethical principles, which have their origin in the Declaration of Helsinki, and impact the responsibility of each party in the process. When third parties are used in the development of pre-clinical and clinical trials, companies are expected to carry out assessments and continuous monitoring of contractor's practices and

We encourage companies to display high standards when conducting studies and tests, both on animals and on individuals. While acknowledging that the medical service industry today still relies heavily on pre-clinical trials on animals, we value companies developing alternative tests that do not rely on animals. We also expect companies to abide by the WHO's GCP guidelines and the Helsinki Declaration and to be particularly demanding and vigilant toward their contract manufacturing organizations (CMOs) when externalizing pre-clinical and clinical studies.

KEY INDICATORS

- Use of written protocol for conducting clinical studies according to the Helsinki Declaration as well as the GCP guidelines.
- Externalized studies: audit and monitoring of the contracted external third parties (i.e. the CMOs).
- Commitment to 3 Rs and development of animal testing alternatives.

Supply Chain Risk Management

Companies in the medical services industry involved in the production and marketing of diagnostics and medical equipment often rely on contractors to provide key materials and components of their products, which are then assembled in-house. Based on the risk associated, the FDA classifies medical devices into Class I, Class II, and Class III, with the latter bearing the highest risk and thus requiring more stringent regulatory control before being marketed (e.g. heart valves). Among these, Class II devices hold the biggest market share in outsourced products due to limited regulatory requirements and moderate related risks. From a product development perspective, the market is further segmented, including regulatory consulting services, product design and development services, as well as product testing and maintenance services. Due to complex manufacturing and technical cost containment, product design services constitute the biggest market segment amongst all outsourced services (Transparency Market Research, 2012).

Companies may rely on a multitude of key suppliers, often located in developing countries. Sometimes environmental and social standards of contractors may fall behind best practices: as medical products may involve the use of hazardous substances, environmental pollution risks are particularly high in the sector, according to the type of products manufactured. Similarly, supply-chain risks associated with safe manufacturing and management of the labor force are an issue to which companies need to pay attention.

We expect companies to extend their code of conduct to contractors and carry out audits of facilities of key contractors to ensure these abide by the company's quality standards, including labor and environmental standards. Transparency over suppliers' performance is also encouraged.

KEY INDICATORS

- Supplier screening encompassing labor and environmental standards.
- Code of conduct encompassing labor and environmental standards applicable to key suppliers.
- Regular auditing and monitoring mechanisms for key suppliers and transparency on results, corrective measures and trainings.

Human Resources

Healthcare services play a fundamental role in society and the economy, to such an extent that the International Labor Organization (ILO) promotes dedicated labor standards in the sector. Decent working conditions for healthcare professionals are essential to ensure good quality of care for patients. Therefore, companies involved in providing private healthcare services such as nursing homes and private clinics need to pay particular attention to several factors. On the one hand, selection and training of the workforce – including contractors - is essential to foster ethical conduct and improve safety outcomes for patients. On the other hand, personnel retention is particularly valuable in this space: although staff pay varies widely across geographies, nursing personnel sometimes receive a salary close to the national minimum, which can adversely impact motivation and quality of care. In addition, due to the close contact with patients affected by a variety of medical conditions, it is important that nursing staff, including contractors, can operate in safe conditions and receive adequate

training to avoid contracting transmissible diseases. Furthermore, psychological preparation and mentoring for staff is also desirable, especially when interacting with patients affected by severe pathologies. Within this context, the use of reporting channels such as speak-up lines allowing employees to voice their difficulties and seek help is recommended.

We encourage companies within the healthcare services sector to pay special attention to the selection and training of their personnel and adopt a code of conduct including integrity and quality of care applicable to all employees and contractors. In addition, we expect companies involved in providing private healthcare services to monitor the quality of service of their employees as well as their motivation and quality of work-life balance through dedicated reporting channels and mentoring.

KEY INDICATORS

- Use of and training around a code of conduct for all employees and contractors
- Quality monitoring mechanisms and continuous professional training of personnel
- Reporting channels for employees and contractors (e.g. anonymous speak-up lines)
- Relevant pay practices and reduced inequalities among workforce.

Environmental Impact of Products

The medical services sector generally has moderate environmental impacts associated to the manufacturing processes, as these are generally associated with so-called “light” industry. Although medical devices and tools generate waste, including hazardous medical waste and polluting substances that require appropriate treatment, medical waste disposal is generally highly regulated in the industry.

The medical services sector spans private healthcare facilities and equipment manufacturers, both of which have environmental impacts primarily related to waste disposal and energy efficiency. Healthcare services providers such as private clinics, nursing homes and laboratories are required to abide by stringent standards in relation to disposal of hazardous medical waste, including infectious, pharmaceutical as well as pathological and radioactive waste. They can reduce energy consumption of their operations, which are relatively limited in the sector, primarily through energy-efficient building design.

Alongside, despite the limited energy consumption of their processes, medical device manufacturers have a high environmental footprint related to both non-hazardous and hazardous waste. While regulation around medical waste disposal in the sector is generally high, companies can still adopt enhanced closed-loop systems to reduce pollution and energy consumption of production processes. Overall, companies are encouraged to implement take-back initiatives and to initiate research to potentially recycle parts of their products, especially considering the increasing share of technology implemented into medical devices, which more resources intensive than previously. Moreover, companies can easily improve the environmental impact of their products through more responsible packaging practices (mainly secondary that are less regulated).

As most companies buy parts from third-party suppliers which then are assembled in-house, we expect them to put in place systems to screen and audit suppliers’ manufacturing practices to also monitor environmental impacts of operations.

We expect companies to follow best practices that go beyond local regulatory requirements when it comes to hazardous waste management. We also encourage the adoption of energy-efficient and closed-loop manufacturing practices, whenever possible, and engagement with suppliers on environmental issues. Finally, companies are expected to develop programs to increase the share of sustainable packaging in their products as well as initiate take-back programs to start recycle at least parts of their devices.

KEY INDICATORS

- Environmental policy encompassing energy efficiency and waste reduction
- Use of best-practice standards around medical waste disposal
- Policies and audit for environmental risk management at own and supplier facilities.

Business Ethics

Companies within the medical services industry need to abide by high levels of ethical standards, from product development and manufacturing to marketing. For healthcare service providers, the key ethical challenge is to maintain high standards of care while containing costs. Although risks are differentiated among product manufacturers and service providers, business ethics remains a high risk in the sector as it can influence a company's ability to preserve business relationships with partner organizations in the sector as well as customers.

While perhaps a more prevalent area of potential concern in pharmaceuticals, ethical marketing, we believe, is also an issue that poses risks for medical device companies. Sales practices such as marketing products for indications that have not been approved (off-label marketing) can lead to sizeable settlements and/or fines under the False Claims Act.

Incentive structures in many medical device sales models raise the risks of corruption and bribery, given the high cost per device, the typical commission-based payment framework for sales reps, and the large influence of doctors in product choice.

Although these companies are less exposed to the ethical risks incurred in the pharmaceutical sector, we expect them to abide by high-level standards about the development and marketing of their products. Besides adhering to high operational standards containing safety risks, companies need to engage the entire supply chain to deliver high quality medical tools and implants. We also expect companies to train personnel to minimize risk of corruption and abide by high levels of transparency regarding the potential health risks connected to the products provided, including informing medical personnel to which products are delivered.

In the healthcare services sector, which includes private clinics and nursing homes, we expect companies to pursue high standards of care and weigh the benefits of cost containment against patient's benefits. We also expect the adoption of a group-wide code of ethics applicable to all employees and contractors and regular training on the code, as well as internal audits of facilities and use of anonymous patient and employee hotlines to signal potential misconduct. Finally, we encourage periodical reports of quality controls and internal whistleblowing to the Board.

An emerging topic in the industry is data privacy and ethics when treating data gathered from patients. As explained in the opportunity review, companies can leverage their impact in ensuring better management of patients' data, providing better follow up for patients such as those suffering from diabetes conditions. Yet, companies should also start committing in not merchandizing this sensitive data

We expect companies to adopt strict codes of business ethics publicly available and applicable to all employees as well as contractors. For medical devices companies, we also expect them to monitor suppliers' adherence to high levels of social and environmental practices related to product manufacturing, including through regular audits. In addition, we value the presence of a whistleblowing mechanism applicable to all employees as well as third parties, supported by the presence of a third-party ombudsman. Transparency and quantitative KPIs on such measures are valued.

KEY INDICATORS

- Code of business ethics applicable to employees, management, and contractors, translated in local languages.
- Audit and monitoring systems for suppliers' manufacturing facilities.
- Whistleblowing mechanisms applicable to employees and third parties, and presence of a third-party ombudsman

Sustainable Development Governance

Companies within the medical service sector should integrate the management of social, environmental and ethical business issues at the board-level so as to bring them into the heart of their business strategies: access to care, anti-corruption, ethics in research and marketing standards for medical device manufacturers and standards of care for healthcare service providers are issues that require concerted effort for companies with a global reach and a multitude of stakeholders, such as medical product companies. To this regard, we expect companies to integrate key corporate social responsibility (CSR) criteria into the remuneration of their employees with managerial responsibilities as well as top management and Board executives. In particular, we expect variable compensation of sales-based representatives to be based less on purely quantitative criteria and increasingly more on qualitative criteria so as to encourage the use of ethical business practices in marketing to healthcare professionals worldwide.

Due to the importance of such issues, companies should also have board representatives with extensive experience in key sustainability issues for the sector, and also when necessary set up a sustainability committee to the board with oversight of environmental and social risks, including business ethics, so as to inform the board of its decision-making.

In addition, business ethics plays a pivotal role in the medical services sector; key business ethics challenges include transparency and ethics in pre-clinical and clinical trials, transparent marketing practices, and anti-corruption mechanisms.

We encourage companies to set up stretching sustainability targets and reflect these in the variable remuneration of top management and employees with managerial responsibilities to incorporate sustainability into business performance. We also look for proactive participation of the Board in such matters via ad hoc sustainability committees that provide periodical oversight to the Board and the appointment of Directors with expertise in sustainability, including anti-corruption.

We also pay close attention to companies' approaches to value distribution, which should be carried out in a way that is fair to all the company's stakeholders.

KEY INDICATORS

- Quality of the sustainable development approach
- A director or board committee specifically responsible for CSR matters.
- Incorporation of non-financial criteria into the variable compensation of executives
- Use of qualitative criteria within the remuneration of sales representatives aimed at reducing kickback practices
- Equity in value distribution

Risk Assessment

	Criteria
Positive	Not fulfilling the criteria that move the opinion to « risk » AND - Absence of severe and recurrent controversies AND appropriate management of operational H&S topics AND appropriate management of human right issues and human resources issues AND appropriate environmental risk-management
Neutral	- Presence of severe BUT not recurrent controversies AND appropriate management of operational H&S topics AND appropriate management of human right issues AND human resources issues AND appropriate environmental risk-management
Risk	- Response of the company to repeated ethical controversies deemed inadequate or inappropriate OR - inappropriate management of operational H&S topics OR - inappropriate management of human right issues AND human resources issues OR - inappropriate environmental risk-management

Conclusion

The medical services sector provides sustainability value-added through its involvement in providing healthcare services and medical products that may improve quality of life. However, only companies that demonstrate a clear involvement in fostering access to care and fostering impactful innovation are identified as delivering highly on sustainability. In addition, companies will have to demonstrate superior management of the sustainability and business ethics risks that characterize the sector: product safety, management of supply-chain social and environmental issues where relevant and adoption of high standards of care for healthcare service providers are particularly important to determine the suitability of companies for investment.

In 2020, during the COVID19 crisis, companies in the sector have demonstrated their ability to play a crucial role to ensure global health which should not be undermined. Indeed, companies in the medical devices sector are clearly enablers for global health and hospital facilities are a necessary pillar for development and well-being. The crisis also revealed their weaknesses, rapid overcharge of hospital and that global health also was supported by human, who needs adequate pay and rest, highlighting the need for a greater transparency in the sector overall.

However well-positioned from a sustainability opportunity standpoint, companies recurrently involved in malpractice allegations and controversies and with poor risk management systems will be downgraded, without a concerted effort to improve business practices and transparency. We will continuously engage with companies to ensure adoption of best-practices and periodically evaluate our opinion.

Our Approach to sustainability assessment

Acting as a responsible investor requires interpreting the economic world within its social and environmental context. This approach calls for understanding the interactions between different private-public players, small-medium-large companies, developed and developing economies to ensure that each player's growth is consistent with the balance of the rest of the system. It is a long-term approach that guarantees that today's choices will not lead to negative consequences for future generations. Understanding these complex relationships demands:

- Clear understanding of sustainable development issues facing our societies,
- Assessing the possible interactions between the assets of our investment strategies and these sustainability issues.

The SDGs as a Guide

Following the Millennium Development Goals created in 2000, the United Nations set out a new framework for sustainable development in 2015. It contains 17 Sustainable Development Goals (SDGs), broken down into 169 specific targets designed to address the main social and environmental issues between 2015 and 2030. In addition to having been adopted by all members of the United Nations, the SGDs offer several advantages.

First, they establish a comprehensive framework concerning environmental and social issues, applicable to all economies regardless of their level of development. Thus, while some issues such as ending hunger or ensuring access to water for all are often more relevant for low- and middle-income countries, other objectives such as fighting climate change or making cities safe, resilient and sustainable, are applicable at all levels of development.

Moreover, the SDGs can be considered as a frame of reference for sustainable development issues for a variety of actors, from governments to companies and investors. The private sphere is increasingly considering environmental and social issues, illustrating new forms of governance where subjects of general interest are no longer solely the prerogative of the public sphere. Considering the SDGs can help companies to think on how they create environmental, economic, and social value.

Finally, the SDGs help investors to question the long-term resilience of their assets and portfolios to the ongoing transformations. Then, investors can go even further by looking at their exposure to new solutions and economic models that will respond to long-term economic transformations. For example, the targets associated with the SDGs to significantly increase the share of renewable energy and to double energy efficiency by 2030 imply a profound transformation within the energy sector.

We consider the SDGs squarely in line with our mission. As a result, in 2016, Mirova decided to use this framework to define its responsible investment approach.

Figure 5: The UN 17 Sustainable Development Goals

	End poverty in all its forms everywhere		Reduce inequalities within and among countries
	End hunger, achieve food security and improved nutrition and promote sustainable agriculture		Make cities and human settlements inclusive, safe, resilient and sustainable
	Ensure healthy lives and promote well-being for all at all ages		Ensure sustainable consumption and production patterns
	Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all		Take urgent measures to combat climate change and its impacts
	Achieve gender equality and empower all women and girls		Conserve and sustainably use the oceans, seas and marine resources for sustainable development
	Ensure availability and sustainable management of water and sanitation for all		Protect, restore and promote sustainable use of territorial ecosystems, sustainably manage forests, combat desertification, and halt and reverse land degradation and halt biodiversity loss
	Ensure access to affordable, reliable, sustainable and modern energy for all		Promote peaceful and inclusive societies for sustainable development, provide access to justice for all and build effective, accountable and inclusive institutions at all levels
	Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all		Strengthen the means of implementation and revitalize the global partnership for sustainable development
	Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation		

Source: United Nations

Assessing Environmental and Social Quality by the SDGs

We believe that the SDGs will transform the economy as we know it. Acting as a responsible investor starts with taking a broader view of the way investors think about the environmental and social profile of the assets they finance. These interactions can be grouped into two categories:

- **Materiality**: how the current transitions are likely to affect the economic models of the assets financed either positively or negatively.
- **Impact:** how investors can play a role in the emergence of a more sustainable economy

We believe that these two approaches are closely linked. Our evaluation methodology thus seeks to capture the extent to which each asset contributes to the SDGs. From our perspective, this approach provides a relevant vision on both the “Materiality” and “Impact” aspects.

A Five-level Qualitative Analysis

Mirova has based its environmental and social evaluation method on four principles:

A RISK/OPPORTUNITY APPROACH

Achieving the SDGs requires taking two different dimensions into account that often go together.

- Capturing opportunities: when companies center their strategies on innovative business models and technologies focused on technological and societal transformation, they can often capture opportunities related to the SDGs.
- Managing risks: by proactively managing risks related to these transitions, companies can reduce and re-internalize their social and environmental externalities, which often takes the form of general management of sustainability issues.

This analysis structure gives equal importance to opportunities and risks. It is the first prism through which we analyze sustainable development issues.

A LIFE-CYCLE VISION

To identify the issues that could impact an asset, the analysis of environmental and social issues must consider the entire life cycle of products and services, from raw material extraction to end-of-life phase.

TARGETED AND DIFFERENTIATED ISSUES

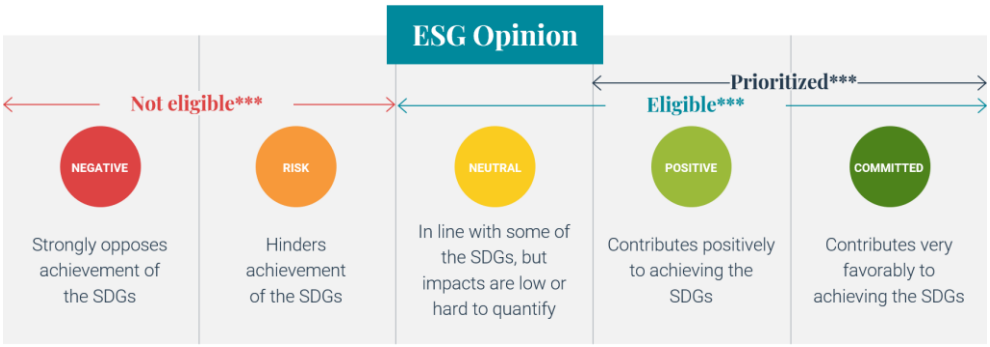
Our risk/opportunity analysis focuses on the elements most likely to have a real impact on the assets studied and on society in general. Additionally, the issues that economic players face

are very different depending on the sector and can even vary within the same sector[1]. For example, it is important for us to focus on work conditions for suppliers in the textile industry, while for automobile manufacturers, the focus will be more on energy consumption during product use.

So, our analysis focuses on a limited number of issues adapted to the specificities of each asset.

A QUALITATIVE RATING SCALE

Our analyses are summarized through an overall qualitative opinion on five levels. This opinion assesses to what extent an asset contributes to the SDGs.



***[2]

This rating scale is based on the SDGs and their achievement. As a result, opinions are not assigned based on a distribution set in advance: we are not grading on a curve overall or by sector. Mirova does not exclude any industry on principle, and carries out a thorough analysis of the environmental and social impacts of any asset. For some sectors, this analysis may lead to the exclusion of all or some of its actors. For example, companies involved in fossil fuel extraction are considered “Risk” at best, while renewable energy companies are generally well rated.

An indicative grid provides some overall guidelines regarding the links between opportunities, risks and the overall sustainability opinion.

Sustainability Risks Review					
	Positive	Risk	Positive	Positive / Committed	Committed
	Neutral	Negative / Risk	Neutral	Neutral / Positive	Positive / Committed
	Risk	Negative	Negative / Risk	Risk	Risk
		Negative	Low or no	Significant	High
		Sustainability Opportunities Exposure			

1 For every sector, defining key issues is the subject of a specific study. This document is available on Mirova *website.* https://www.mirova.com/fr/recherche/comprendre#vision
2 *** For Mirova’s investments

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