



Life Science Perspectives on ESG

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Executive summary

All Life Science companies seek to improve health outcomes for patients and access to medicines utilizing scientific and technological innovation. The guiding principles that lay the foundation for the ethical standards and core values of the life science sector began with the Declaration of Helsinki (1964); which established that the rights and interests of individual research subjects should always take precedence over innovation, which was developed from the principles of the Nuremberg code (1947). Today the life science sector seeks to align global ESG standards and reporting requirements to these guiding principles; protecting public health as we now, not only seek to understand the aetiology of disease and develop treatments, but also make a conscious and sustainable effort to reduce the burden advancements in clinical development have on vulnerable groups, individuals and our environment. It is anticipated that the advancement of ESG reporting requirements globally will ensure that the life science sector is able to prioritize its resources to achieve success in this important area, ensuring the best possible outcome for all.



What is ESG?

The collective terms: environmental; social; and governance reporting are commonly abbreviated to “ESG”, there are accepted criteria associated with these broad categories that form a set of standards that socially conscious investors, and other important stakeholders, use to screen potential investments and the perceived ethics of an organisation. Investors are increasingly applying these non-financial factors as part of their analysis process to identify material risks and growth opportunities. As a result of the concerning global environmental situation; climate change; social inequality; lack of diversity in critical arenas; and the perceived lack of governance and corporate accountability commercial and governmental stakeholders are looking beyond the financial performance of organisations.

The core tenets of ESG are important for companies to embrace and incorporate into their corporate culture, and organisations are now actively reporting on their vision and progress in the areas of ESG. This article will discuss various ESG trends in Life Science companies and the initiatives that regulators and other critical stakeholders are taking to demand ESG reporting, and why corporate players in all sectors, must now address their core ESG metrics and sustainability performance, to the same degree as financial performance.



Environmental

Life Science companies face the challenge of accelerating innovation in asset development within the rigorous standards set by global regulators. There are notable advancements being made to challenge regulatory data norms for example:

1. Increased investment and activity in the 3Rs (Replacement, Reduction, Refinement) in the preclinical development of medicines - delivering new research models, tools, and approaches with reduced reliance on animal testing; improved animal welfare; and improved scientific and predictive value¹.
2. The use of technology, facilitating monitoring of several types of data input remotely to support decentralized trials allowing trial participation from one's own home. The use of these technologies is subject to ensuring patient safety without compromising data integrity and clinical trial endpoints.

Alongside such paradigm shifts in drug development, life science companies have a major role to play in supporting global initiatives to fight climate change. The EU Green Deal outlines the framework for a sustainable transition to net carbon neutrality “net zero” for the continent by 2050. This includes policies to reduce net greenhouse gas emissions by 55% by 2030. Following the 2021 United Nations Climate Change Conference (COP26) there is an expectation that Life Science companies create a reporting roadmap: starting with identification of relevant key performance indicators (KPIs) through to a scale up of commitments to achieve carbon neutrality: whilst avoiding “greenwashing” which is merely the facade of sustainability to mislead stakeholders.

The development of recycling initiatives in the manufacture of products, and accurately monitoring carbon footprint during the product lifecycle, are critical areas in which Life Science companies may demonstrate their achievements versus their environmental aspirations. Companies will increasingly be called upon to demonstrate that their initiatives are fit for purpose: of high quality and in line with globally recognised sustainability standards e.g., the International Sustainability Standard Board (ISSB); a standard-setting body established in 2021-2022 whose mandate is the creation and development of “sustainability-related financial reporting standards” to meet investors’ needs for sustainability reporting.



Social

The Social domain of ESG reporting is complex and perhaps the most difficult to quantify for commercial organisations. For example how a company manages its relationships with “Human Capital” both internally and externally, is key to a successful ESG strategy. Employees are important advocates and enablers of ESG strategies. Research has shown that 35% of an employee’s emotional investment in their work, and

20% of their desire to stay within a company is attributable to how “included” they feel in their workplace². One approach to strengthen this area could be via investment in diversity and inclusion training, this may lead to a reduction in employee attrition rates due to an increased perception of “well-being”, and skilled and dedicated employees are increasingly supportive and loyal to their employers. Many organisations are seeking to ensure that they have a more diverse pool of employees with the awareness to tackle environmental issues that affect different areas of business and communities; developing strategies that reflect both local, national, and global needs³.

Climate change is undermining many of the social determinants for good health, such as livelihoods, equality and access to health care and social support structures. These climate-sensitive health risks are disproportionately felt by the most vulnerable and disadvantaged: including women; children; ethnic minorities; poor communities; migrants or displaced persons; older populations; and those with underlying health conditions⁴. Developing a robust model to achieve a positive impact on society is underpinned by achieving equitable access to healthcare and ensuring that clinical research includes a diverse range of trial participants that reflect the “real-world effectiveness” of medicines. Life science companies should seek to collaborate and set up healthcare initiatives that ensure an uninterrupted supply of medicines to vulnerable groups in the face of climate-related pressures.



¹Graham ML, Prescott MJ. The multifactorial role of the 3Rs in shifting the harm-benefit analysis in animal models of disease. Eur J Pharmacol. 2015 Jul 15;759:19-29.

²Dnika J. Travis, Emily Shaffer, and Jennifer Thorpe-Moscon, Getting Real About Inclusive Leadership: Why Change Starts With You (Catalyst, 2019).

³<https://globaldiversitypractice.com/diversity-and-inclusion-are-more-than-the-s-in-esg/>

⁴<https://www.who.int/news-room/fact-sheets/detail/climate-change-and-health>



Governance

Increasingly stakeholders, including investors, policymakers, consumers, and employees, are demanding change. More than eight out of 10 global consumers expect CEOs to lead on societal issues.



ESG scoring is becoming weighted now for supply chain tenders (i.e., modern slavery act annual statement) – stakeholder should plan to develop a greater capacity to assess an activities impact on local communities i.e., minimising water footprint during product manufacture in water stressed areas.

These stakeholders are also demanding accountability and transparency on financial exposure to risk, opportunities, governance, and fiduciary duty related to human capital.

Aligned with the World Economic Forum and the UN Sustainable development Goals (SDG's), the development of a framework to help the Life Science sector respond to ESG challenges should be at the forefront of executive decision-making and leadership strategy. It is expected that factors such as ethical leadership behaviour; equal pay; equal opportunities; and eradication of corrupt practice are prioritised, as businesses evolve and develop opportunities for long term sustainable growth, whilst identifying ESG metrics that support ESG reporting

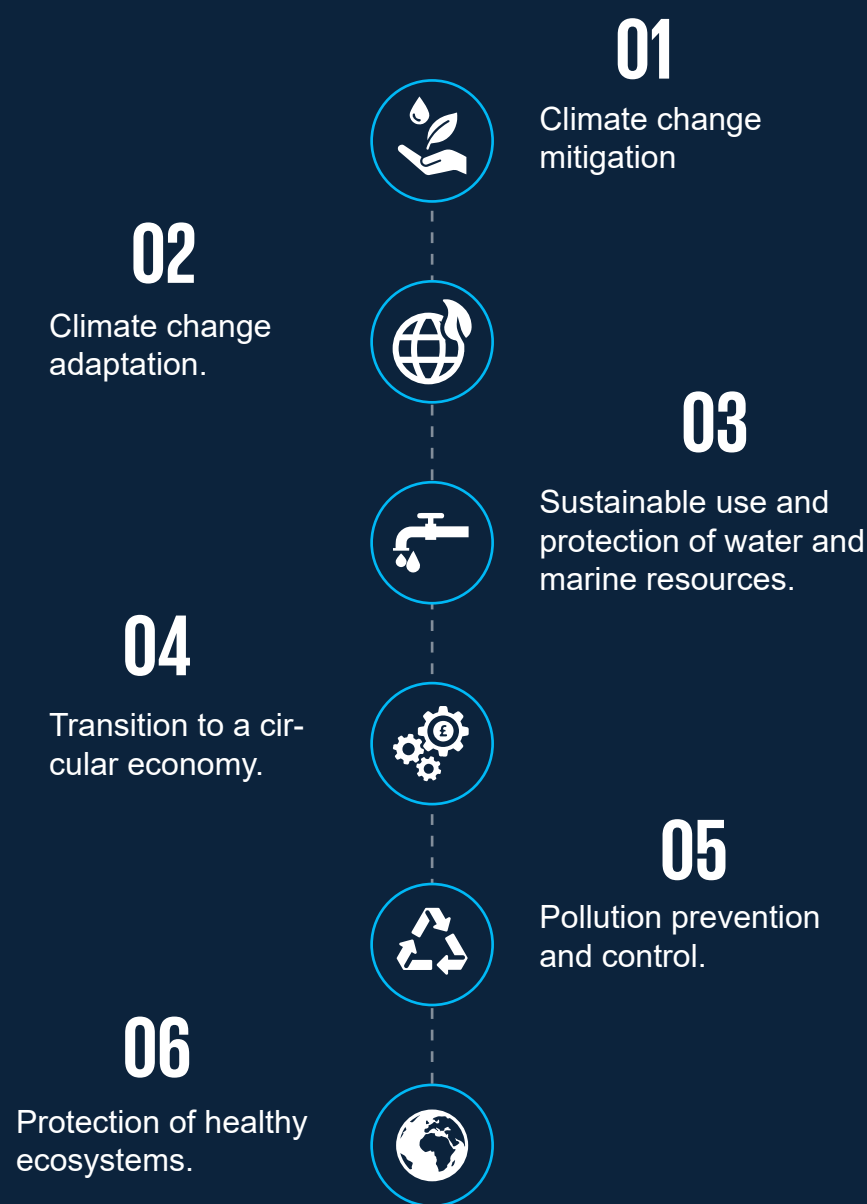


Gender disparities in governance: Repeated research has shown that gender-diverse boards are linked to improved investment efficiency, better engagement between board members as well as less fraud cases and operations-based lawsuits. The inclusion of women on corporate boards also increases the likelihoods of discussion on social issues, climate change and work/life balance.

ESG EU Taxonomy

In July 2020, the EU introduced the “ESG Taxonomy”, this offers a classification system for companies and investors to determine whether an economic activity is defined as “green” or not, which will help the EU curb greenwashing.

The Taxonomy will provide the basis for the EU to label businesses ‘green friendly’ or ‘green hostile’. The EU Taxonomy is a classification system, establishing a list of environmentally sustainable economic activities which provide companies, investors, and policymakers with appropriate definitions for which economic activities can be considered environmentally sustainable. It is hoped that the taxonomy will create security for investors; protect private investors from greenwashing; help companies to become more climate-friendly; mitigate market fragmentation; and help shift investments where they are most needed⁵. The taxonomy objectives are listed below:



For objectives (1) and (2), disclosure requirements apply from 1 January 2022 and from 1 January 2023 for the remaining objectives.

⁵https://ec.europa.eu/info/business-economy-euro/banking-and-finance/sustainable-finance/eu-taxonomy-sustainable-activities_en

Current ESG initiatives within the Life Science Industry

In September 2020, a pharma company became the first to issue a sustainability-linked bond (SLB), valued at €1.85 billion, through which bondholders will receive higher interest if the company fails to meet its social target of increasing access to specific drugs in developing countries. The targets are a part of the company's 2025 Patient Access program, include increasing patient outreach in low- and middle-income countries (LMICs) by at least 200% for specific drugs, and by at least 50% for programs in leprosy, malaria, Chagas disease and sickle cell disease.

Sustainability-linked bonds (SLBs)⁶:

There is a rapidly evolving ESG-themed bond market which provides a tool for public debt investors to achieve a positive contribution to environmental or social challenges. Some pharmaceutical companies are recognizing that there is an opportunity to attract significant investment through the issuance of green bonds. In September 2020, the European Central Bank⁷ announced that bonds with coupon structures linked to certain sustainability performance targets will become eligible for collateral from the 1st January 2021, provided it meets at least one of the six environmental objectives put forth by the EU ESG Taxonomy, this is a clear indicator that the taxonomy is to be recognized as the industry wide reference point for sustainability KPIs going forward.

Sustainable Supply Chain

The roadmap for supply chain sustainability in the life science sector stretches from the sourcing of raw materials to the final packaging and transport of a finished product.

There is increasing pressure on companies to reduce the carbon footprint of drug development – in fact it was recently reported that the manufacture of drugs contributes to more greenhouse gas emissions than the automotive industry⁸. Some of the key focus areas to revolutionize this challenge include:

- Replacing reliance on finite and polluting energy resources to manufacture active pharmaceutical ingredients (APIs)
- Transitioning from batch manufacturing to single, continuous manufacturing (separate production stages lead to significantly higher carbon emissions)
- Transitioning from fossil-fuel reliant, cold chain shipping to greener alternatives
- Reduction in single-use plastics for packaging



Cold chain shipping: A cold chain is a temperature-controlled supply chain allowing for an uninterrupted series of refrigerated production, storage and distribution activities and associated equipment which maintain a given low-temperature range essential for the storage and hence preservation of many pharmaceutical drugs and other medical and biological agents. If you can keep medicines and vaccines at the right temperature up to the moment they are delivered, you can improve health. Heavily dependent on fossil fuels to power associated vehicles and refrigerants, the real challenge is how companies will be able to ensure cold chain resilience while meeting their net-zero targets on carbon emissions? Clearly there isn't a single solution in this complex area rather a portfolio of solutions which require exploration.

Taxation

ESG represents a real opportunity to make a difference for future generations. Tax plays a key role in this journey by encouraging behavioural change and by funding operational changes to the business. Tax transparency, while not a measure of sustainability in and of itself, is a useful tool to hold businesses to account and to build trust with stakeholders (as well as being critical for good governance). The focus on tax transparency for Life Sciences companies is increasing, driven by pressure from Regulators, Investors and the public. "Owning the narrative" is key; in terms of how much and where tax is paid and the group's approach to tax (strategy and governance) and paying its fair share. There is a trend towards increasingly more transparent, comprehensive disclosure with more focus on how tax risk is managed. The introduction by the EU of mandatory public country by country, alongside the increased pressure (driven by stakeholders) for organisations to comply with voluntary frameworks such as GRI: 207 (tax), will further drive the tax transparency bar.

⁶European pharma..., 27 November 2020, UniCredit

⁷ ECB to accept..., 22 September 2020, ECB Europa

⁸Lotfi Belkhir, Ahmed Elmelig, Carbon footprint of the global pharmaceutical industry and relative impact of its major players, Journal of Cleaner Production, Volume 214, 2019, Pages 185-194,

Environmental and social pressures are forcing many businesses to shift their strategic focus, even as far as divesting from certain commodities or activities or reinventing themselves as zero carbon, or zero harm enterprises. The tax implications of supply chain changes, such as shortening of routes and changes in transport modes, relocation of manufacturing, storage and other physical assets, need to be carefully examined. Such fundamental shifts are an opportunity to reconsider a group's entire value chain, IP and TP model and footprint, especially in tandem with BEPS as the international tax environment rapidly changes and responsible tax awareness grows.

Governments across the world are introducing new taxes - "carrots and sticks" - to change behaviour and drive decarbonisation. Some of the proposed policies that are interesting for Life Science companies from a tax perspective are plastic packaging taxes, revision to the EU's emissions trading system and energy taxation directive and developments relating to carbon pricing and border adjustment taxes along with other environmental taxes anticipated over the medium and long term. It can be challenging for organisations to keep up to date with the continually evolving tax landscape, but it is important to do so given the role tax reliefs etc "the carrots" can play in funding an organisations net zero journey and the impact of environmental taxes "the sticks" on pricing.

Continuous manufacturing in the Biotech industry



By switching from batch to continuous manufacturing, companies can achieve an economic and sustainable advantage as it allows them to rapidly adapt to changing market demand whilst reducing pressure on capital and footprint manufacturing plants and contributing to the overall corporate ESG strategy.

For certain classes of biopharmaceutical products upstream continuous manufacturing has always been applied: for example, unstable proteins that rapidly degrade in a culture broth. There is potential for this universal production platform to be extended to other classes of product, such as antibodies,

What Are Industry Expert's saying?

"We are glad to see the Parliament could raise the ambition on the content of the reporting requirements, as quality and comparability are currently missing around sustainability information" and it is hoped that more sustainability information will be included in the future."

"There's an expectation that companies operating in the European Union will come under a lot more pressure to source this data, largely,



Recently, a Global Pharma company commissioned its first-ever electric powered delivery van equipped with a refrigeration unit for cold storage, enabling the company to save at least eight metric tons of CO2 annually.

which are relatively stable molecules. Moreover, Regulatory authorities in the three ICH regions and beyond are encouraging industry to adopt new technology as supported by ICH Q8(R2), Q9, Q10 and Q11 bringing innovation to the forefront.

Continuous manufacturing in the pharma industry



In 2019 a European pharma company, announced plans to open a new continuous manufacturing plant in the US, resulting in an 80% reduction in carbon emissions compared to its traditional manufacturing facility and reducing water and chemical usage by 91% and 94% respectively.

Renewable energy across value chain

Notable advancements in the use of renewable energy have been made in the Life Science sector. Schneider Electric launched its "Energize Programme" to address the need to increase utilization of renewable energy sources across the pharma value chain in 2021, a collaboration between 10 global pharmaceutical companies to engage hundreds of suppliers in bold climate action and decarbonization of the pharmaceutical value chain. In this case study, stakeholders encouraged suppliers to "decarbonize" their operations, leveraging renewable energy adoption.

Many big pharma companies have set targets to generate electricity solely from renewable sources within the next five years, including ambitious plans to become 100% solar powered within 10 years.

Reducing plastic usage

As part of the ESG strategy, companies are running tests to measure the relative footprint of different drugs and take steps to improve the highest pollution. If you can reduce packaging and switch to biodegradable material, not only do you reduce shipping footprint, lowering carbon emissions across the supply chain; you also reduce the environmental impact of plastic waste.

Life Science companies can turn to a growing number of "sustainability partners", such as the European Federation of Pharmaceutical Industries and Associations (EFPIA). EFPIA has stated that most of its members have set sustainability goals for themselves, "EFPIA member companies strive to invent, produce and distribute new medicines and vaccines in a safe and environmentally responsible manner. Furthermore, we are actively providing a safe and healthy workplace while reducing the environmental impact in our operations and those of our supply partners around the world."

⁹Environment, Health, Safety and Sustainability (efpia.eu), 2022



What are the key trends in Life Science Companies?

European Life Science companies are performing well when it comes to the scale and creativity of net-zero goals .

One example is the EU's launch of financial penalties for emissions as early as 2025, making EU (incl. the UK) the first international market to set such regulations, gave the sector an incentive versus their US peers. Some of the initiatives within the Life Science Industry include:

1

Looking beyond Scope 1 and 2 emissions into Scope 3 to monitor the carbon footprint of suppliers' operations across the value chain

2

Launching comprehensive sustainability programs

3

Developing sustainable fuels

4

Ramping up product innovation

Reducing Wastage¹¹

Efforts to minimize the environmental impact of chemistry is a prominent area specific to the life science sector. "Green Chemistry" focuses on the design of products and processes that minimize or eliminate the use and generation of hazardous substances in the design of medicinal products and manufacturing processes.

A Japanese Life Science company was able to develop processes that reportedly resulted in

78%

less waste

93%

less organic solvent used

46%

less water

whilst still being able to increase yield of their investigational drug.

¹⁰Path to net..., 17 December 2021, S&P Capital IQ

¹¹What is Big Pharma..., 3 November 2021, The CSR Journal

What about the Biotech and Medtech sector?

[...]

Developing Sustainable Fuel

In the UK a biotech¹ manufacturer utilizes hydrocarbon fuels from industrial, marine, and agricultural wastes including CO₂. This company has developed techniques that allow it to leverage carbon capture and storage technologies to recycle its carbon source to produce biofuels for aviation, domestic and transportation sectors.

One Dutch-based Medtech manufacturer¹ achieved carbon neutral status (Scope 1 and 2) in 2020, hence ramped up its supplier sustainability program with a goal of at least 50% of its suppliers (based on spend) committing to science-based targets for CO₂ emissions reduction by 2025.

To curb misleading greenwashing and bring in more transparency, the European Commission has put forth the Corporate Sustainability Reporting Directive (CSRD)¹²: EU legislation requiring all large companies to publish regular reports on their environmental and social impact activities.

The CSRD was put forth following the criticism that the existing Non-Financial Reporting Directive lacked consistency and quality:

- Companies will now have to include CSRD in their main annual report for better investor visibility, rather than publishing a separate report.
- All large companies to comply as of 2024, with reports published from 2025.
- For listed small- to medium-sized enterprises (SMEs) the application of standards will be delayed and proportionately, while unlisted SMEs can use them voluntarily

¹²The EU Corporate..., 19 May 2021, Covington





Access to Medicine and Drug Pricing

Although the Life Science industry is working towards driving access to medicines, inflationary pressures and currency instability are acting as headwinds. Investor pressures in the US are expected to align drug pricing with Institute for Clinical and Economic Review's guidance (ICER) guidance

Access to medicines and Affordability

The Life Science industry is working towards ensuring adequate community health protection and pricing their drugs to increase affordability.

- According to the WHO, around 2 billion people lack access to basic/essential medicines across the globe¹³. Additionally, US SDGs also emphasize the growing need for access to affordable essential drugs in developing nations in co-operation with pharmaceutical companies
- Inflationary pressures on the cost of raw materials, active ingredients, and currency instability are both impacting drug affordability. There is a possibility that, in the US, the ICER¹⁴ (advocating for cost effectiveness) may in the future form a component of a pharma company's evaluation against ESG targets, with investors potentially putting pressure on companies to align prices with ICER guidance

Case studies

Pharmaceutical and Biotech company

Swiss-based Novartis has put forth steep targets to increase patients reached with strategic innovative medicines in low- and middle-income countries by at least 200% by 2025¹.

Germany-based Bayer is supporting 100 million smallholder farmers in LMI countries and 100 million people in underserved communities with self-care. The Group is also providing 100 million women in LMICs with modern contraception¹.

Recently, French-multinational healthcare company Sanofi outlined that as part of its Corporate Social Responsibility strategy it created a not-for-profit Global Healthcare organization enabling the world's poorest 40 countries to access and continuously supply 30 essential medicines. The organization donates 100,000 ampoules (small-sealed vials) annually to treat patients with rare disease¹. This is a clear example of the sectors paradigm shift towards ESG values to positively influence the ethical development of their business

¹³Stop ignoring..., 17 January 2020, Pharmaceutical Technology

¹⁴Pricing and..., 9 February 2022, Pharmaceutical Technology

The world is progressing ...



... towards responsible business

Final Thoughts

Over the last five years global public discourse has progressed to position Environmental, Social and Governance (ESG) issues at the forefront of our collective consciousness. Commercial organisations in every sector now recognise that they are accountable to shareholders, customers and all stakeholders within their sphere of operation across these areas. ESG reporting is at the forefront of discussion and Life Science organisations are adapting to this new challenge. The pharmaceutical, medical device and diagnostic regulatory landscape is changing, and it is expected that in the immediate future regulators and payers will expect organisations to demonstrate a meaningful focus on ESG considerations throughout asset development, launch and commercialization.

Environmental and social pressures are forcing many businesses to shift their strategic focus, even as far as divesting from certain commodities or activities or reinventing themselves as zero carbon, or zero harm enterprises. The tax implications of supply chain changes, such as shortening of routes and changes in transport modes, relocation of manufacturing, storage and other physical assets, need to be carefully examined. Such fundamental shifts are an opportunity to reconsider a group's entire value chain, IP and TP model and footprint, especially in tandem with BEPS as the international tax environment rapidly changes and responsible tax awareness grows.

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The KPMG Life Science Regulatory Solutions Practice is keen to support companies who strive to identify, scale up and report their ESG objectives, firmly placing ESG at the heart of their culture and agenda and embedding it within working practices and future state plans. The future goal is to address the challenges in this article and beyond; working with our stakeholders to deliver strategic ESG outcomes whilst keeping abreast of applicable regulations within this rapidly changing landscape.

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