CHAPTER: 2

REGULATORY, ETHICAL, AND ENVIRONMENTAL PERSPECTIVE IN SUSTAINABLE PHARMA

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Abstract

Sustainable pharmaceuticals need a compromise in system where regulatory requirements, ethical requirements and environmental requirements intersect each other to ensure that the drug lifecycle causes minimum ecological damage. This chapter examines major regulatory initiatives such as the Corporate Sustainability Reporting Directive (CSRD) of the European Union (EU) and the WHO project, the regulatory highway of greener pharmaceuticals, as well as EMA guidelines of environmental risk assessment (ERA). The ethical issues, such as fair-distributed access, the privacy of data collected through AI designing, and animal testing options are examined through the concept of green chemistry. The environmental standpoints include manufacturing wastewater pollution, carbon footprint and approaches such as biodegradable formulation lifecycle assessments (LCAs). Case studies emphasize reaction by the industries, including CO 2 reduction goals and recycled packages as part of the European Green Deal. Issues such as lapses in the enforcement and harmonization of policies globally are discussed and the policy incentives, collaboration between the stakeholders, and innovation in the production of green products are suggested. The purpose of these views is to harmonize the pharmaceutical development with the UN Sustainable Development Goals to a sustainable, responsible future.

Keywords: *Pharmaceutical Regulations, Drug Approval Processes, Environmental Risk Assessment (ERA), Sustainable Regulatory Frameworks.*

2.1 Introduction

There are three spheres of sustainability; environmental, social, and economic. The UN has identified these as the 17 SDGs that will help facilitate the sustainability agenda at the international, national and local levels [1]. Sustainability in pharmaceuticals includes health benefits,

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addressing environmental impacts, and having equitable access to the drug over the entire course of its lifecycle shown in Fig 2.1.

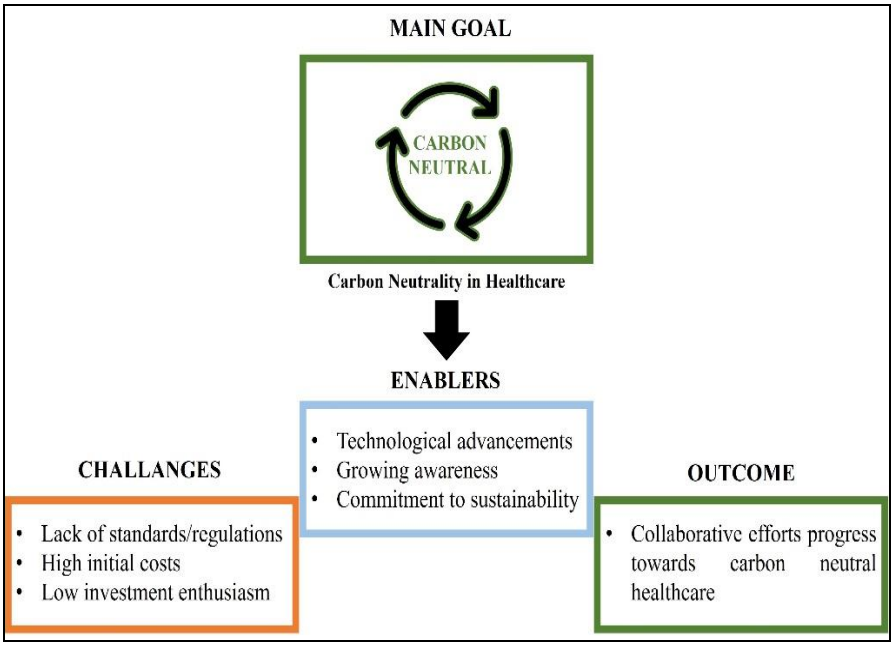

Fig 2.1: - Healthcare sustainability via innovation

2.1.1 Core Principles of Environmental, Social, and Governance (ESG) Factors

With mounting anxiety regarding sustainable practices, ESG offers an internationally accepted standard for examining sustainability in the areas of environment, social issues, and governance [2]. ESG integration evaluates environmental, social, and governance performance, shaping business risks, opportunities, legislation, and societal values. Environmental sustainability involves many different areas, including climate change action, ecosystem health, human health and social well-being, and sustainable development, with a wide range of stakeholder interests [3]

2.1.2 Lifecycle Impacts from Discovery to Disposal

A pharmaceutical company's entire value chain affects the environment throughout the lifecycle of a drug beginning with discovery and ending when the drug is disposed of. Many of these activities to develop and produce drugs are resource and energy intensive, so any initiative to address sustainability must take a holistic view of the entire lifecycle [4].

2.1.3 Interplay of Regulations, Ethics, and Ecology

Cost-effective and practical ecological measures need to be developed in order for traditional ecology to be able to adapt to those landscapes that are dominated by humans.

2.2 Regulatory Frameworks Worldwide

Global regulatory agencies are incorporating sustainability into the pharmaceutical industry by establishing requirements regarding safety/quality/environmental protection standards. As ESG-related legislation progresses, there is an increasing demand for companies to provide more transparency and accountability at every stage of the product's lifecycle [5].

2.2.1 EU CSRD, Green Deal, and ESPR (with pharma exemptions)

CSRD (Corporate Level Reporting Directive), as well as the European Green Deal and ESPR (Environmental Packaging Regulation), all promote transparency and reduction of emissions, the use of clean energy, and reducing waste from the pharmaceuticals industry, but there are many exemptions and special considerations that are available for medicines that could be deemed critical to patient safety [6].

2.2.2. WHO and EMA guidelines for ERAs and green manufacturing

The WHO and the EMA promote sustainable pharmaceuticals with guidance to perform environmental risk assessments and better waste management procedures. Furthermore, WHO and EMA are working together to promote GREEN Manufacturing (less use of solvents) and improve the energy efficiency of drug manufacturing while ensuring drug quality and the safety of patients [7].

2.2.3. US FDA trends in sustainability reporting for 2026

Trends in sustainability reporting by the U.S. FDA for 2026 are particularly pertinent for sectors such as pharmaceuticals (it’s important to note that the FDA currently lacks a specific sustainability reporting requirement like those for financial regulators, yet wider regulatory and reporting expectations shape how companies handle ESG disclosures) [8]

1. Increasing Sustainability Disclosure Expectations

By 2026, sustainability reporting in the U.S. is shifting from voluntary narrative disclosures to more structured, mandatory reporting shaped by a combination of regulatory, investor, and market pressures. Although the FDA has not established detailed sustainability reporting rules, public

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companies and regulated organizations are progressively anticipated to align their disclosures with global frameworks (such as ISSB, TCFD, GRI) that address environmental effects, climate risks, and governance metrics relevant to regulatory adherence and risk management [9].

2. Regulatory and Market Pressure for Transparent ESG Data

SB 253/261 of California: U.S. pharmaceutical companies will need to report on climate change and emissions-verified data. While this is separate from the FDA, their regulations will impact regulatory strategies, the sustainability of their supply chains, and any decisions that would be made related to submissions made to the FDA [10].

3. Shift from Voluntary Frameworks to Standardized Reporting

U.S. companies are shifting from unstructured sustainability disclosures to standardized ESG reporting that combines various frameworks (GRI for impact, SASB for industry relevance, and ISSB as a global standard). This reflects worldwide trends where sustainability outcomes must be accurate, comparable, and verifiable to meet the needs of regulators, investors, and stakeholders—enhancing credibility when dealing with health regulators on environmental risk matters within the scope of wider corporate governance [11].

4. Specialize in ESG Data Quality, Materiality and Assurance

Corporations are putting more emphasis on the accuracy of the data, dual materiality assessment (encompassing both financial and environmental/social impacts), and external verification which is becoming an increasingly common routine in 2026 reports. Even though the regulatory guidance documents of the FDA do not mandate disclosures of sustainability, the broader reporting trend influences corporate regulatory strategy and compliance, risk management, and disclosures of trust to the public [12].

2.3 Ethical Dimensions

The main elements of ethical sustainable practices in the pharmaceutical industry are the protection of the patient, the equitable access to medication, and defense of the members of the population (as well as the ecological systems). It is the responsibility of the industry to ensure clear communication of information and curb the current damage to the environment so that the future generations are sustained and not lost.

2.3.1. Equity in access to sustainable medicines

The manufacturing techniques of sustainable pharmaceuticals must reduce the negative impact on the environment, and, in the same breath, ensure that these medicines are available to the poor and other disadvantaged populations across the globe [13].

2.3.2. AI ethics, data biases, and transparency in R&D

Artificial Intelligence in Pharmaceutical Research and Development Is Ethically Problematic due to Data Prejudice, Transparency, and Accountability. The combination of various datasets, explainable models, and continuous bias monitoring make the environment balanced in terms of innovation, patient safety, equity, and scientific integrity.

2.3.3. Alternatives to informed consent and animal testing

Pharmaceutical research is shifting to the more extensive use of non-animal substitutes (i.e. in vitro models and simulations) through the application of the 3Rs principles to present pertinent information, where feasible, to humans. Informed consent to clinical studies ensures that possible dangers and the possible advantages are well-explained to the participants and so, such studies can be carried out in an ethical and sustainable manner [14].

2.4 Environmental Challenges and Solutions

Areas of concern to the pharmaceutical industry include excessive energy usage within the industry, unsafe disposal of chemical wastes, contamination of water by active pharmaceuticals, and self-defeating supply chains. Green chemistry, better wastewater treatment, greater energy efficiency, and the application of the concepts of a circular economy in the packaging and waste management are sustainable approaches.

2.4.1. Wastewater pollution, emissions, and microplastic risks

The wastewater chemicals, emissions, and microplastics are pharmaceutical pollutants that affect ecosystems and also, the formation of antimicrobial resistance that has impacts on human and animal health. Reduction of these effects involves both sophisticated techniques of wastewater and emissions treatment, and the creation and consumption of recyclable and green products [15].

2.4.2. Green chemistry, waste reduction, and renewable energy adoption

Green chemistry is applied in the production of pharmaceuticals that are produced in a sustainable manner, waste is minimized, and renewable energy

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used to reduce impact on the environment. These approaches are usually used to improve operational effectiveness, to satisfy regulatory standards, and to guarantee that the drugs will be effective and safe to patients and will be manufactured to quality standards.

2.4.3. Tools like LCAs and carbon footprint audits

Pharmaceutical firms employ Life Cycle Assessments (LCAs) and carbon footprint assessments to determine the environmental impacts of a product during its entire lifecycle and through its supply chain. These methods help to determine how to approach sustainability through information-based strategies, comply with regulations, and reduce total carbon emissions [16].

2.5 Case Studies and Industry Practices

Case studies and industry practices illustrate how pharmaceutical companies are turning sustainability commitments into concrete actions. Many organizations have implemented green chemistry, energy-efficient manufacturing methods, and improved wastewater management to reduce environmental impact.

2.5.1. Pharma leaders in ESG compliance and CO_2 targets

Novartis, GSK, Roche, and AstraZeneca are among the leaders in Environmental, Social, and Governance (ESG) because they have established CO_2 reduction goals, use renewable energy sources, are working on improving efficiency, and have set a strong standard for transparency of their sustainable practices through reporting.

2.5.2. CDMO trends for 2026 sustainable supply chains

Here are some CDMO trends for 2026 focused on sustainable supply chains in the pharmaceutical industry:

1. Sustainability Integration into Core Operations

Pharmaceuticals combine sustainable practices into their operations by using eco-friendly chemistry techniques when developing products and streamlining processes with more efficient production methods throughout their entire supply chain network; keeping track of these activities via digital tracking systems helps ensure that the company meets regulatory requirements while improving its overall environmental impact [17].

2. Decarbonized Facilities and Resource Stewardship

Pharmaceutical manufacturers are utilizing modernized production processes, alternative power sources, increased efficiency in resource

utilization, improved sanitation units for removing contaminants from used equipment and materials, increased recycling into the circular economy, and continuing to produce high quality products to help achieve their environmental sustainability initiatives.

3. Digital and Data Driven Efficiency

Pharmaceuticals use digital technology solutions like AI, analytics, and predictive modeling to improve their manufacturing and supply chain processes. Digital technologies allow real-time monitoring of all operations, which can create less waste, use less energy, release less CO_2 into the atmosphere, improve sustainability, increase operational efficiency, increase the quality of products, and meet regulatory requirements.

2.5.3. Packaging regulations under EU 2025/40

Pharmaceutical businesses utilize renewable energy and utilize resources efficiently to lower their carbon footprint through facility upgrades, alternative energy sources, efficient resource usage, new wastewater technologies, recycling, and circular economy methods—all while producing superior-quality products [18].

2.6 Challenges and Future Directions

To create equilibrium among patient safety, environmental objectives, and regulatory compliance, pharmaceutical businesses must employ circular economy implementation, ESG compliance with their business practices, and monitoring of the footprint of their establishment, in addition to collaborative innovation Shown in Fig 2.2.

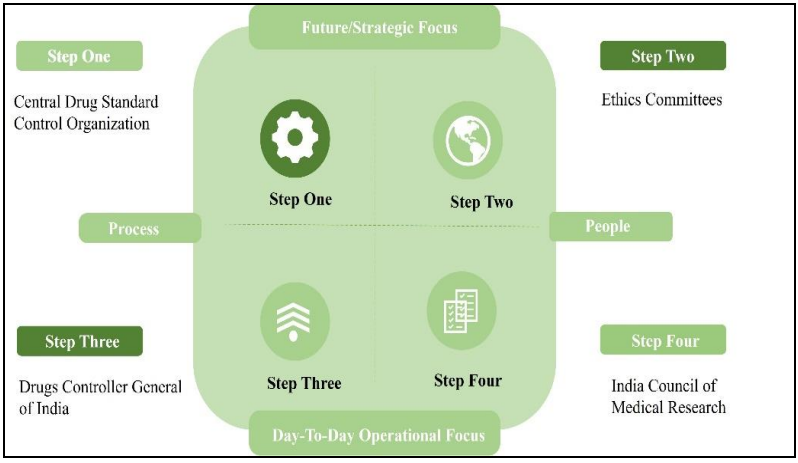

Fig 2.2: - Healthcare governance framework with four steps.

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2.6.1. Gaps in enforcement, funding, and global alignment

Weak regulations, lack of funding, and absence of global standards hinder pharmaceutical sustainability. Greater enforcement of regulations, better allocation of resources, and improved international collaboration are all necessary to improve pharmaceutical sustainability [19].

2.6.2. Policy incentives like tax breaks for green tech

Governmental programs such as tax incentives, grants, and subsidies promote the use of renewable energy, energy-efficient equipment, and new methods of waste management in the pharmaceutical industry. These financial incentives will help to enhance sustainability, stimulate innovation, and ultimately help meet Environmental Social Governance (ESG) goals for these companies [20].

2.6.3. Prospects for integrated frameworks and innovation

Sustainable development of pharmaceuticals includes global regulations, ESG (environmental, social, and governance), operational best practices, innovative green chemistry technologies & renewable energy technologies, and/or digital optimization methodologies that reduce environmental footprint, as well as improving operational performance, ensuring compliance, and providing equitable access to safe/effective medications[21].

2.7 Conclusion

The sustainable pharmaceutical model will include compliance with regulations; ethical conduct; protecting the environment; using green chemistry; utilizing renewable energy sources; utilizing sustainable packaging formats; providing equal access; and utilizing AI technologies responsibly. While there are challenges to enforcing compliance and consistent standards worldwide, the use of data-driven tools and innovations, new policies to support these innovations, and collaboration among the various stakeholders will lead to a more responsible and efficient pharmaceutical sector.

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