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REVIEW ARTICLE

Sustainable Pharma: The Need, Current Status and Mission for the Future

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Abstract

''Good health and well-being" (SDG3) is one of the 17 integrated sustainable development goals (SDG) adopted by the United Nations in 2015. When it comes to health and well-being, pharmaceuticals play a vital role. Pharmaceutical waste and contaminants of emerging concern (CEC) produced during the manufacturing, supply, usage and disposal of drugs, chemicals and personal care products can significantly affect the environment. Some serious global problems have been attributed, at least partly, to the prevalent practices in this sector. With increased awareness, regulations and corporate environmental responsibility, the pharmaceutical industry is making efforts toward sustainability through measures like green production, green technology, improved supply chains, collaborations and strategic partnerships. However, the need is still felt for additional measures to be incorporated into the practice like a circular economy, based on the 4Rs (reduce, recycle, reuse, recover); Artificial Intelligence (AI) can be used to recognise the best way to obtain maximum yield with minimum cost from available resources in an environment-friendly manner for the benefit of society; encouraging the use of renewable energy and promoting research focused on environmental supportive and profitable measures. The journey towards sustainable pharma is complex and requires collaboration across the entire value chain from all the stakeholders, but the benefits to society, the environment and the industry are profound and far-reaching.

Key words: Sustainable development goals; Medical waste disposal; Environment; Microbial drug resistance.

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Introduction

The concept of sustainable development goals (SDGs) was adopted by the United Nations in 2015 to end poverty and inequality, promote global peace and prosperity together with making the environment safer for the present and future generations of all living creatures by the end of 2030.[1] Among the 17 SDGs, also known as global goals, 169 targets were enlisted along with respective indicators (total 247 in number) to measure the progress towards achieving the goal.[1, 2] "Good health and well-being" (SDG3) is one of them to ensure healthy lives and promote well-being for everyone at all ages. However, all goals are integrated like SDG3 is strongly interconnected with goals number 6, 7, 9, 11-15 and 17 (Figure 1).

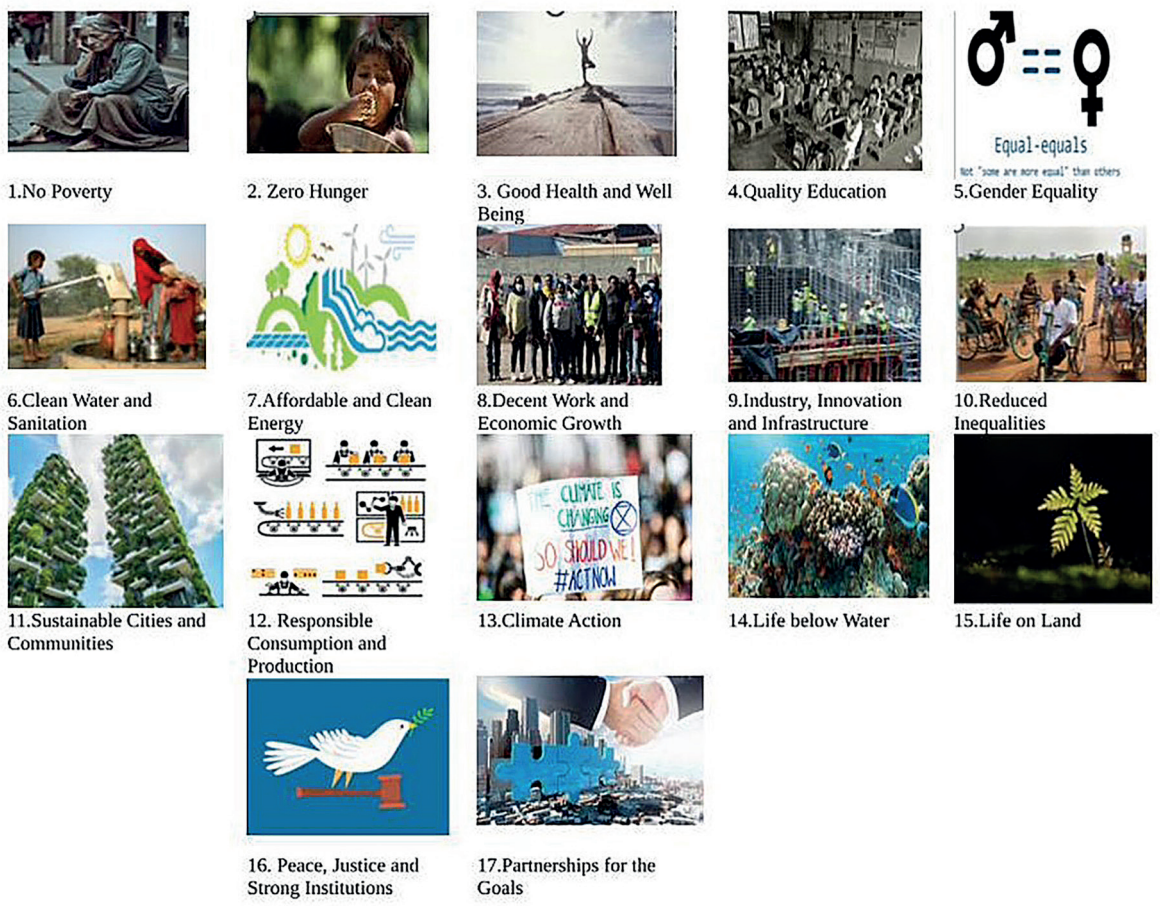

Figure 1: Seventeen sustainable development goals (SDGs)

When it comes to health and well-being, the role of pharmaceuticals plays a key role. Many pharmaceutical companies are driving the sustainability agenda under Corporate Social Responsibility (CSR) and report their sustainability initiatives against the 17 SDGs.[3] In recent years, related branches like eco pharmacovigilance came into existence to study the effect of pharmaceuticals on the environment. The impact of pharmaceuticals on the ecosystem is measured first in an endeavour to safeguard the ecosystem and subsequent data is used to introduce or modify the prevalent practices to further guide SDG3.[4, 5]

This review article discusses the need for sustainable and safe pharma, its current status and a vision with futuristic methods.

Sustainable pharma: the need

Pharmaceutical products, personal care products (PCP) and chemicals are commonly used in healthcare centres, animal husbandry and agriculture.[6, 7] Pharmaceutical waste is any product including biologics and vaccines, materials or substances generated throughout the life cycle of pharmaceutical manufacturing and usage. It also includes discarded, unused and expired pharmaceutical products (Figure 2).[8, 9]

Contaminants of Emerging Concern (CECs) is an important related term. CECs are the chemicals and toxins found in water bodies that may cause ecological or human health impacts but are not currently regulated. The most common types of CECs are pharmaceuticals and personal care products with cyanotoxins, nanoparticles and flame retardants.[10]

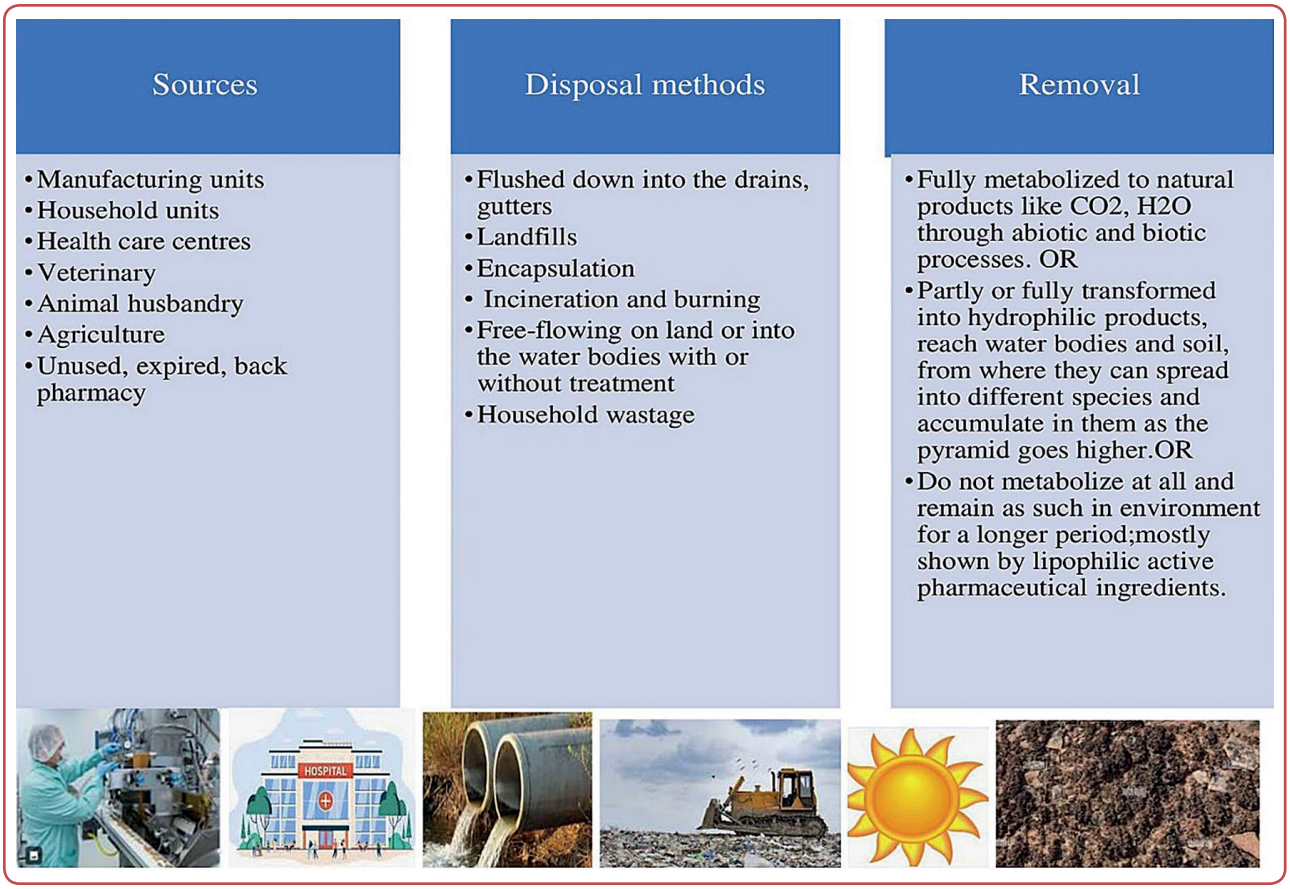

Figure 2: Common sources, disposal methods and fate (removal) of pharmaceutical waste, chemicals and contaminants of emerging concern (CEC)

The pharmaceutical manufacturing processes may generate a variety of waste materials such as solvent residues, chemical intermediates, by-products and contaminated equipment during the processes. Also, waste is generated during the raw material procuration, distribution, administration and disposal.[11]

The pharmaceutical waste generated is usually disposed-off by various methods shown in Figure 2, depending on whether the waste is hazardous or non-hazardous.[12] As can be imagined, pharmaceutical waste disposal methods like flushing into the drain, landfills and free-flowing with or without treatment can cause waste to seep into the environment and pose significant health and safety risks to the general public and other creatures.

Scientists estimated the pharmaceuticals in the environment (PiE) and public supply of surface water, groundwater, drinking/ tap water, food, etc. A study published in the journal "Environmental Science & Technology" estimated that over 631 pharmaceuticals and their metabolites have been detected in aquatic environments worldwide.[13]

Similarly, another global research found that pharmaceutical residues were detected in 258 rivers which reflect the environmental impact on 471.4 million people in 137 different geographic locations. Samples were taken from 1,052 places across 104 nations.[14] Thus, it is not limited to any particular area or country and pharmaceutical compounds have also been detected in the Arctic.[15] On reaching the water bodies, these products affect aquatic systems by their active chemical composition or transformed products or accumulation in the aquatic flora and fauna. Pharmaceutical waste rich in organic matter like acetone and alcohols used as solvents depletes the oxygen and leads to the blooming of algae (eutrophication) posing harmful effects on fishes and other fauna. Similarly, the presence of active pharmaceutical ingredients (API) in the effluent causes hormonal imbalance, immune disruption and even develop resistant bacteria.[15]

Some case studies found serious survival risks

Table 1: Pharmaceuticals in the environment (PiE) accountable for survival risks and other issues in certain species

Product name	Species affected	Consequence	Main affected region
Diclofenac	Vultures	Survival risk	Indian subcontinent
Ethinyl oestradiol	Fish	Male fish showing intersexual features and behavioural changes	Africa
17ß-oestradiol and a mixture of other active endocrine system-related products	Freshwater molluscs	Adult reproduction is interfered and predisposition to parasite infection	UK
Antimicrobials like ciprofloxacin, tetracycline, metronidazole etc.	Human and animals	Morbidity and survival risk due to antimicrobial resistance (AMR)	Asia
Miscellaneous drugs like chemotherapeutics, antidepressants, nonsteroidal anti-inflammatory drugs, lipid-lowering drugs, beta-blockers and antiepileptics	Human and animals	Contribute to increased AMR	Globally

and behavioural changes in certain species due to specific PiE (Table 1). However, not all are as toxic as considered before, one example is propranolol.

Antimicrobial resistance has been recognised by the World Health Organization (WHO) as a serious hazard to global health. The severity of the situation makes sense given that it is anticipated that by 2050, antibiotic-resistant illnesses will be the cause of 10 million annual deaths worldwide. This emphasises how important it is for pharmaceutical companies and related sectors to ascertain that their production and disposal methods of antibiotics are sustainable enough to help reduce this resistance.[16]

Besides the water bodies, industries and modernisation directly or indirectly contribute to atmospheric and climate change through greenhouse gas (GHG) emissions. GHG includes natural and anthropogenic (human-generated) gas namely ozone, carbon dioxide (CO_2), nitrous oxide (N_2O), methane (CH_4), industrial gases like hydrofluorocarbons (HFCs), perfluorocarbons (PFCs), sulphur hexafluoride (SF_6), nitrogen trifluoride (NF_3) along with water vapors.[17,18] Ozone depletion and increased levels of other gases absorb and emit radiations, that are trapped in the atmosphere, raise the temperature and adversely affect the ecosystem.[18]

On average, health systems produce 4–5 % of greenhouse gas emissions in Organisation of Economic Co-operation and Development (OECD) member countries, contributing to climate change and subsequent adverse impacts on human health.[19]

The pharmaceutical industry, like many other sectors, significantly contributes to GHG emissions through its extensive energy consumption, production processes and global supply chains. Manufacturing pharmaceutical products involves energy-intensive chemical reactions, solvents and controlled environments, which generate substantial GHG emissions. Moreover, the logistics of distributing these products globally add to the carbon footprint. In 2019, 20 % of the carbon footprint of the National Health Services (NHS-UK) was ascribed to medicines and chemicals and an additional 5 % was due to anaesthetic gases (2 %) and inhalers (3 %).[20] Likewise, many countries estimated the contribution of pharmaceuticals to health system GHG emissions ranging from 10 % to 55 %.[18]

Several respiratory problems and the spread of vector-borne diseases have been attributed to poor air quality and increased temperature due to GHG. Climate change can disrupt the ecosystems, leading to biodiversity loss and altered ecosystem services, which are crucial for human well-being. One clear example of how increased GHG emissions and rising temperatures adversely affect ecosystems is the phenomenon of coral bleaching in marine environments. Coral reefs are enormously sensitive to changes in water temperature. When water temperatures rise even slightly, corals expel the symbiotic algae (*zooxanthellae*) living in their tissues, causing them to turn white or "bleach." These algae provide corals with essential nutrients through photosynthesis and without them, corals become stressed and, if high temperatures persist, may die. Moreover, human activities produce loads of CO_2, absorbed by the ocean making it acidic and providing unfavourable conditions for corals to survive.[21,22]

Coral reefs are biodiversity hotspots, support-

ing a vast array of aquatic life. Loss of coral reefs due to bleaching events can lead to the collapse of local ecosystems. Species that depend on coral reefs for food, shelter and breeding grounds are directly affected.[22] This disruption can cause declines in fish populations, which are crucial not only to the marine food web but also to human communities that rely on these fish for sustenance and economic activities such as fishing and tourism.

Moreover, the degradation of coral reefs impacts coastal protection. Healthy coral reefs act as natural barriers, absorbing wave energy and reducing the impact of storm surges and coastal erosion. The loss of these protective structures makes coastal areas more vulnerable to rising sea levels and extreme weather events, further exacerbating the negative impacts on ecosystems and human settlements.[23] Thus, sustainable practices in the pharmaceutical industry are vital to mitigate these impacts and promote public health and environmental integrity.

Globally, the risk to the aquatic environment is assessed through a four-tier approach. These are hazard identification, assessment of exposure (predicted environmental concentrations, PEC), hazard characterisation (predicted no effect concentrations, PNEC) and risk characterisation based upon the risk quotient (predicted environmental concentration/predicted no effect concentration, PEC/PNEC for water, sediment and biota).[24]

Attention is required when the PEC/PNEC ratio (environmental risk index) is > 1. Further testing is done, to assess the release and fate of contaminants and environmental concentrations, based on monitoring programs, additional bioassays (bioaccumulation, chronic toxicity), or alternative methodologies (*in silico* and *in vitro* tests). There is no need for risk reduction measures if more data and tests show a decline in the PEC/PNEC ratio in around two weeks considering the worst-case assumptions. However, risk mitigation strategies need to be chosen if the PEC/PNEC ratio stays higher than 1.[24,25] According to a study, the lowest observed effect concentration (LOEC) values of drugs including diclofenac, propranolol and fluoxetine are near the effluent concentration of wastewater treatment plants (WWTPs), suggesting a narrower safety margin.[26] Another study mentions that the degradation efficiency of WWTP also varies from < 10 % to 100 % depending upon the physiochemical characteristics of pharmaceuticals and technology employed. Further, it was found higher in urban areas than rural areas suggesting a possible link to lifestyle.[15]

Likewise, understanding and measuring the carbon footprint is crucial for identifying the major sources of emissions and developing strategies to reduce them. A carbon footprint is the total amount of greenhouse gases (GHGs) emitted directly or indirectly by an individual, organisation, event or product throughout its lifecycle, usually expressed in equivalent tons of carbon dioxide (CO_2e).[27]

Direct emissions are emissions from sources that are owned or controlled by the entity whereas, indirect emissions occur as a consequence of the activities of the entity but happen at sources owned or controlled by another entity. Life cycle emissions for products means the emissions across the entire lifecycle, from raw material extraction, manufacturing, distribution, use and disposal. They are also marked as scope 1,2 and 3 emissions respectively.[18]

By calculating the carbon footprint, individuals and organisations can take informed actions to minimise their environmental impact, such as adopting energy-efficient practices, switching to renewable energy sources, optimising supply chains and promoting sustainable consumption. Thus, there is a need for continuing efforts with multiple approaches that prove themselves worthy on account of Elkington's all three dimensions of sustainability–economic, environmental and social.[28]

Sustainable pharma: current status

Alarmed by the foreseen consequences of potential harmful effects on the environment, aquatic as well as terrestrial, the pharmaceutical industry is increasingly focusing on sustainability, driven by both regulatory requirements and environmental responsibility. Following are some of the practices adopted within the industry:

1. Commitment to net-zero and green technologies

Pharmaceutical companies are determined to

achieve net-zero carbon footprints (defined as, carbon emissions leaving a small number of residual emissions that can be absorbed and handled by nature and other carbon dioxide removal measures, leaving zero in the atmosphere) by adopting sustainable practices throughout drug development and manufacturing. These include investing in green technologies, reducing energy consumption and minimising waste. A study done on 20 leading pharmaceutical companies supports this obligation.[18]

2. Integration of Artificial Intelligence (AI) and advanced technologies

The practice of AI and advanced technologies is helping companies optimise their manufacturing processes, thereby reducing waste and improving energy efficiency. AI is also aiding in better supply chain management and drug shortage mitigation by providing early warnings about potential disruptions.[29, 30]

3. Good manufacturing practice (GMP) in the pharmaceutical sector

GMP ensures the consistency and quality of a product by addressing 5 key components: products, people, processes, procedures and premises. GMP compliance offers numerous advantages of enhanced productivity, profitability and risk mitigation, contributing to sustainability.[31]

4. Collaborations and strategic partnerships

Contract development and manufacturing organisations (CDMOs) play a role in the pharmaceutical supply chain. Collaborating with CDMOs helps integrate green initiatives and sustainable manufacturing processes. This partnership is essential for implementing responsible sourcing and energy-efficient production.[32]

5. Employee-led initiatives and accountability

Employee-led sustainability initiatives and inter-industry collaborations are becoming more prevalent. Some companies have set medium-term priorities to address environmental sustainability.

6. Regulations

Certain guidelines, regulations and programs have been developed and adopted globally by regulatory authorities and other stakeholders from time to time regarding sustainable development.[33, 34] The concept of SDG3 has already been imbibed by European countries as a “Health care without harm” or “Safer pharma campaign” in 2016.[35] Here is a chronological overview of major agreements and milestones related to the health, the environment and its sustainability (Table 2).

Besides the United Nations’ SDGs, which serve

Table 2: Chronological overview of major agreements and milestones related to the environment and its sustainability

Pre-2015: Foundations and precursors
1972 -The United Nations Conference on the Human Environment (Stockholm Conference) The first major worldwide meeting on environmental issues resulted in the foundation of the United Nations Environment Programme (UNEP).
1987 - Brundtland Report (Our Common Future) Introduced the concept of sustainable development and provided the commonly accepted definition: "Development that meets current needs without compromising the ability of future generations to meet their own needs."
1988-The Intergovernmental Panel on Climate Change (IPCC) The United Nations Environment Programme (UNEP) and the World Meteorological Organisation (WMO) formed the Intergovernmental Panel on Climate Change (IPCC) in 1988 to examine climate change science and make recommendations for reducing GHG emissions. The headquarters are in Geneva, Switzerland.
1989-Montreal protocol On January 1, 1989, the United Nations (UN) approved the Montreal Protocol to minimise and eventually eradicate, ozone-depleting pollutants.
1992 - Earth Summit (Rio de Janeiro) Adoption of Agenda 21, a comprehensive plan of action for establishing a worldwide partnership for sustainable development. It also resulted in the formation of the United Nations Framework Convention on Climate Change (UNFCCC), Common but Differentiated Responsibilities (CBDR) and respective capabilities, which means that, while all countries share responsibility for combating climate change, developed countries bear a greater burden due to their historical and current emissions and greater ability to act. The UNFCCC's top decision-making body is the Conference of the Parties (CoP).
1997 - Kyoto Protocol The Kyoto Protocol is a pioneer international pact that established enforceable emission reduction targets for carbon dioxide and five other greenhouse gases for 37 industrialised countries and the European Union. Over the 2008-2012 commitment period, the aims amounted to an average 5 % reduction in 1990 levels. The UNFCCC monitors the reporting procedure.

The Kyoto Protocol's first commitment period expired in 2012. In its stead, the Doha Amendment was agreed upon, which established targets for a second commitment period lasting from 2013 to 2020. However, the modification has not received general approval.
2000 - Millennium Development Goals (MDGs) A series of eight worldwide development goals to be met by 2015, focused on poverty reduction, education, gender equality, child mortality, maternal health, disease, environmental sustainability and global cooperation.
2012-Sustainable Development Solutions Network (SDSN) The UN established the organisation in 2012 to mobilise worldwide scientific and technology expertise to promote practical solutions for sustainable development.
2015: Adoption of the 17 sustainable development goals (SDGs) by the United Nations
The 17 sustainable development goals (SDGs) were adopted at the United Nations Sustainable Development Summit. These objectives cover a wider range of issues, including poverty, inequality, health, climate change, environmental degradation, peace and justice.
2015 - Paris Agreement An international convention under the UN Framework Convention on Climate Change to keep global warming far below 2 °C, with efforts to restrict it to 1.5 °C. This agreement enhances the SDGs, particularly Goal 13 (Climate Action). The Paris Agreement includes obligations from all countries, both developed and developing.
Post-2015: Implementation, integration and monitoring of SDGs
2016 - High-Level Political Forum (HLPF) on Sustainable Development The primary UN platform for reviewing the implementation of the 2030 Agenda and SDGs.
2016 - EU Directive 2016/2341 (IORP II Directive) A European Union directive on the activity and supervision of organisations providing occupational retirement benefits focuses on sustainability.
2017 - Voluntary National Reviews (VNRs) At the HLPF, countries began presenting their progress towards SDGs using VNRs.
2019 - SDG Summit The first SDG Summit to review progress and identify steps to expedite implementation.
2019 - European Green Deal An ambitious roadmap by the European Commission to make Europe climate-neutral by 2050.
2020 -EU Taxonomy Regulation Establishes an EU-wide classification system to identify environmentally sustainable economic activities, guiding for SDG-aligned investment.
2020 - Decade of Action Launch of the Decade of Action to accelerate and deliver the SDGs by 2030.

as a leading guideline related to every aspect of development, ISO 14000 Standards provide practical tools for companies and organisations to manage their environmental responsibilities. Similarly, the GHG Protocol, developed by the World Resources Institute (WRI) and the World Business Council for Sustainable Development (WBCSD) provides comprehensive global standardised frameworks to measure and manage GHG emissions.[33-35]

Under the Paris Agreement, different countries and regions also outlined their plans, as Nationally Determined Contributions (NDCs), to reduce national emissions and support the SDGs. Some examples are India's National Action Plan on Climate Change (NAPCC), The Clean Air Act (USA), the Renewable Energy Directive (EU), The Environment Protection and Biodiversity Conservation Act (Australia), Japan's Basic Environment Law, Climate Change Act in the UK, Germany's Climate Protection Law and California's Clean Energy and Pollution Reduction Act.[33-35]

Finally, to create awareness about the protection of the environment, "Earth Day" and "World Environment Day" are celebrated annually on the 22 April and 5 June, respectively. "Climate Week NYC" is an event in New York City that brings together leaders from the business, government and civil society to showcase climate action and solutions.[34, 35] Thus, these guidelines, programs, awareness campaigns and regulations reflect the diverse approaches and a concerted global effort to achieve sustainable development goals and ensure a healthier planet for future generations.

Challenges

Though the pharmaceutical industry is making strides toward sustainability, there are also significant challenges that require coordinated efforts and substantial investments. Some of them are that there is a scarcity of affordable and sensitive instruments and scales to measure the impact on the environment both short term and long term, shifting towards green technologies is a costlier affair necessitating subsidies and dedicated research, improved and energy efficient supply chain management, etc. All of them demand strong regulatory frameworks and devoted efforts.[36]

Sustainable pharma: a vision and a mission

The concept of sustainable pharma is an ambitious vision where the pharmaceutical industry operates such that it balances economic growth, social responsibility and environmental stewardship. Here's a comprehensive vision for sustainable pharma:

1. Green chemistry and sustainable manufacturing[37]

Green chemistry involves designing chemical products and processes that reduce or eliminate the use and generation of hazardous substances. For the pharmaceutical industry, this means - Eco-friendly processes: develop manufacturing processes that minimise waste, use renewable resources and reduce energy consumption; Solvent reduction: using greener solvents or solvent-free methods to minimise environmental contamination; Efficient synthesis: designing synthetic routes that maximise atom economy and reduce the number of steps, thereby cutting down on raw material use and waste.

2. Circular economy[38]

The 4Rs of circular economy are Reduce, Reuse, Recycle and Recover. It means designing and producing products and processes and consuming them in a way where waste is minimised and materials are reused or recycled. It involves sharing, leasing, reusing, repairing, refurbishing and recycling existing materials and products as long as possible. Closed-loop system: one aspect of circular economy is a closed-loop system where waste from one process serves as input for another, reducing overall waste. However, the circular economy is not always cost-efficient.

3. Energy efficiency and renewable energy[37]

The pharmaceutical industry is energy-intensive. Sustainable pharma envisions - Energy-efficient facilities: constructing and retrofitting buildings to be energy efficient, utilising technologies like light-emitting diode (LED) lighting, high-efficiency HVAC (heating, ventilation and air conditioning) systems and smart energy management systems; Renewable energy: transitioning to renewable energy sources such as solar, wind and geothermal for manufacturing plants and research facilities; Carbon footprint reduction: implementing strategies to reduce greenhouse gas emissions across the entire supply chain temperature to below 2 °C and preferably limited to 1.5 °C.

4. Sustainable supply chain[39]

A sustainable supply chain ensures that every step, from raw material sourcing to product distribution, adheres to sustainability principles - Ethical sourcing: sourcing raw materials from suppliers who adhere to sustainable and ethical practices; Local production: manufacturing products closer to the market to reduce transportation emissions and support local economies; Green logistics: using eco-friendly transportation methods, optimising delivery routes and employing carbon offset programs.

5. Research and development (R&D)[38, 40]

Sustainable R&D focuses on developing drugs that are not only effective but also profitable, practical and have minimal environmental impact:[29] Eco-friendly drug design: designing biodegradable drugs will have minimal impact on ecosystems; Alternatives to animal testing: using advanced technologies like organ-on-chip and computer modelling to reduce reliance on animal testing; Sustainable discovery platforms: leveraging biotechnology and synthetic biology to discover new drugs using more sustainable methods.

6. Social responsibility and community engagement[38-40]

Sustainable pharma extends beyond environmental considerations to include social responsibility - Access to medicines: ensuring affordable access to essential medicines for all, particularly in low

and middle-income countries; Community health initiatives: investing, engaging and volunteering in community health programs and education to improve public health outcomes; Fair labour practices: upholding fair labour practices and ensuring safe working conditions across the supply chain; Educating the masses for appropriate use and proper disposal.

7. Policy and regulatory compliance[40, 41]

Regulatory collaboration: a study has shown that controls, legitimacy and deterrence have significant effects rather than social norms and values especially in small and medium entrepreneurial ventures while addressing sustainability during manufacturing, thereby, supporting the need to collaborate with regulatory bodies to develop and implement sustainability standards and guidelines; Transparency and reporting: maintaining transparency in sustainability practices and regularly reporting on progress towards sustainability goals; Advocacy: advocating for policies that support environmental protection, public health and social equity in the pharmaceutical sector; Incentives: to embrace sustainable technologies.

8. Innovation and continuous improvement

Sustainability is an ongoing process that requires continuous innovation and improvement - Sustainable innovation: encouraging innovation in sustainable practices through R&D investments, partnerships with academic institutions and open innovation platforms; Monitoring and evaluation: regularly monitoring sustainability performance and using data-driven approaches to make continuous improvements; Stakeholder engagement: engaging with stakeholders, including employees, patients, regulators and the community, to align on sustainability goals and collaborate on initiatives.

9. Miscellaneous

Besides those discussed above, ways like e-packaging and the consumption of wise list products have been suggested. The term 'wise list products' here refers to the products that serve the same purpose and have the same ingredients as others but are sustainable in their manufacturing and subsequent processes.[42, 43] The necessity of agricultural vigilance to assess soil and water contamination and bioaccumulation in animals and crops was also put forth.[44]

Conclusion

The need for sustainable pharma is genuine, the current approach is commendable and a holistic vision integrating environmental, social and economic dimensions is essentially required to create a resilient, ethical and environmentally conscious pharmaceutical industry. By adopting sustainable practices, the industry can not only mitigate its environmental impact but also contribute to global health and social equity. The journey towards sustainable pharma is complex and requires collaboration across the entire value chain, but the benefits to society, the environment and the industry are profound and far-reaching.

Ethics

This study was a secondary analysis based on the currently existing data and not directly involve with human participants or experimental animals. Therefore, the ethics approval was not required in this paper.

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Conflicts of interest

The authors declare that there is no conflict of interest.

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Data access

The data that support the findings of this study are available from the corresponding author upon reasonable individual request.

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