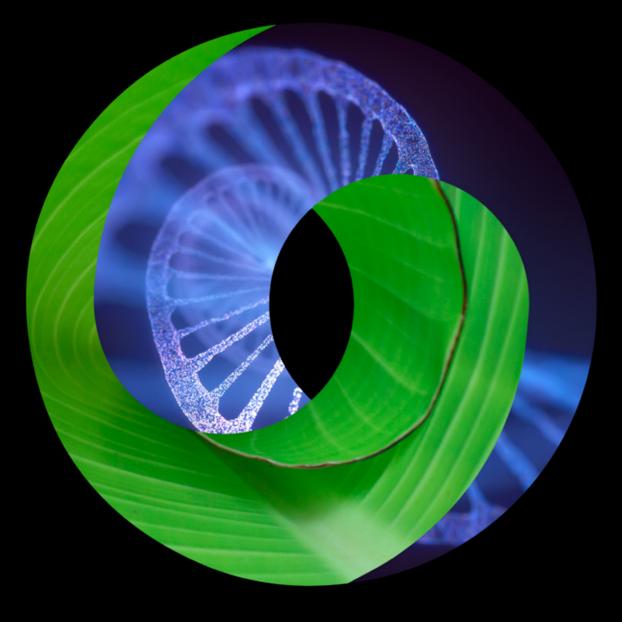
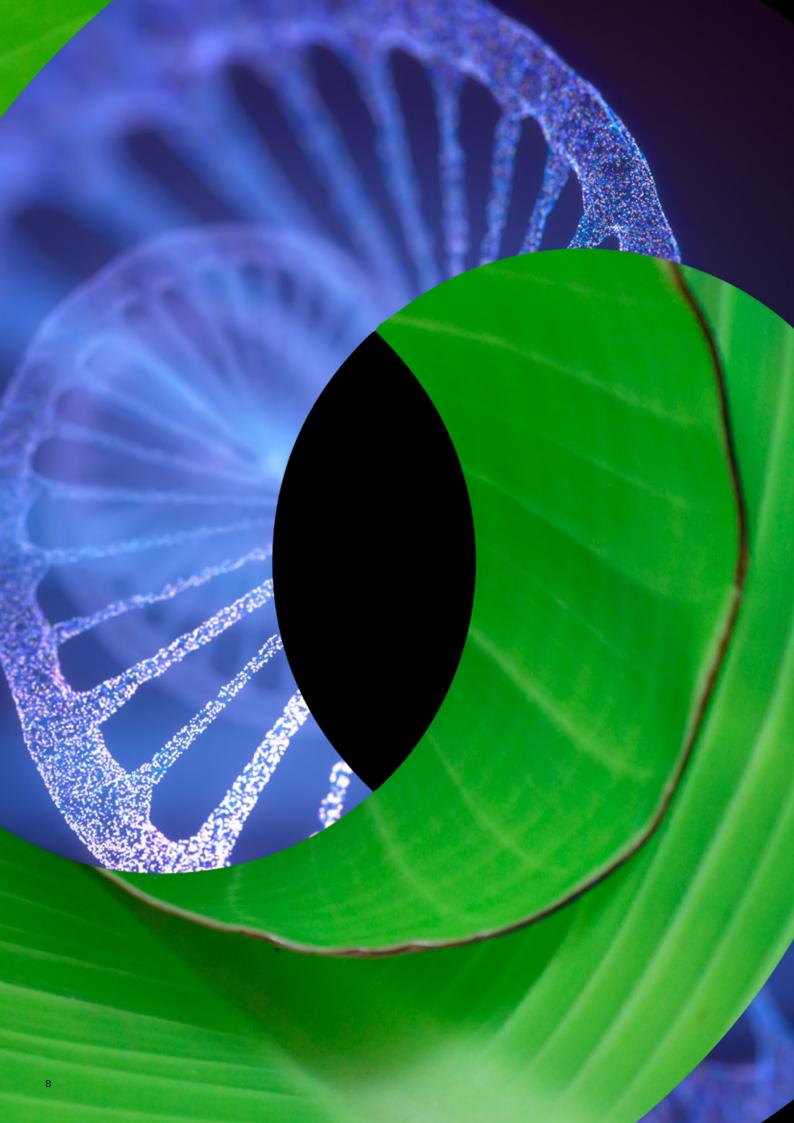
Deloitte.



Embedding environmental sustainability into pharma's DNA

> Deloitte Centre for Health Solutions

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Contents

The importance of climate change and the sustainability agenda	04
Reinforcing the need for change	06
Influencing the pace and scale of change	08
Tackling today's net zero challenges	11
Realising a net zero future, ensuring progress and embedding change	17
Endnotes	19

The research evidence is unequivocal: public health and the health of the economy and the planet are inextricably linked, and no continent, country or community is immune from the impact of climate change. The race to net zero is a race to a healthier, cleaner and more resilient future.

As the climate crisis escalates, so too does scrutiny of how companies are addressing environmental sustainability challenges. The pharmaceutical (pharma) industry's involvement in environmental issues is multifaceted, with implications for the entire product value chain. Although there are complex challenges to overcome, there are also many opportunities to accelerate the pace of change and unlock new business prospects. To achieve their sustainability ambitions, pharma companies need to undergo a fundamental transformation spearheaded by strong leadership, enhanced collaboration and a willingness to innovate with evidence-based improvement initiatives embedded across the industry.

The importance of climate change and the sustainability agenda

"We are moving too slowly as an industry towards a sustainable future. Instead of having a lukewarm commitment we need to ensure we match our stated promises and goals."

Chief Procurement Officer, large pharma company, Germany, Deloitte led-interview Concerns about climate change and environmental, social and governance (ESG) issues affect all stakeholders in pharma – governments and health organisations, companies, employees, investors, suppliers, patients and the public. Embedding an ESG culture including science-based targets (SBTs) and a net zero mind-set within a company can improve awareness of risks and opportunities, maintain regulatory compliance, gain the trust of stakeholders, obtain finance for investment, and attract and retain talent.

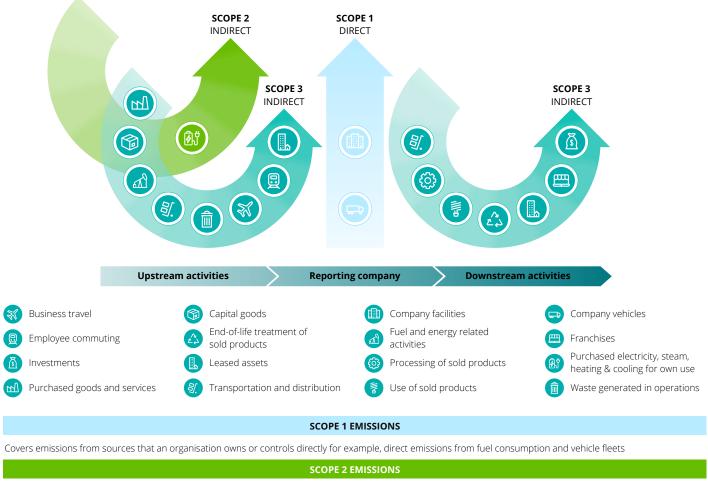
The pharma industry develops life-saving medicines which puts companies in a unique position to address aspects of social sustainability through improving public health, however stakeholders increasingly expect more direct interventions on equity of access and affordability. At the same time, pharma companies face growing pressures to reduce their environmental footprint across the product lifecycle from their research and development (R&D) methods and production processes, optimising supply chains and logistics, and engaging more closely with patients and healthcare professionals (HCPs) about product use and disposal.

Although pharma companies are adopting ambitious and measurable goals and setting out a plan of action, the choice of targets, measurement of achievements and the pace of progress is variable and there is often a critical gap between aspiration and action. To achieve their targets, companies need to take proactive steps to increase transparency and collaboration, establish and analyse extensive data sets to generate actionable insights and consider a radical reform of existing processes to deliver a bold, lasting transformation. The pharma industry will need to fundamentally reimagine existing drug development and manufacturing processes, business models, supply chains and digital infrastructure to collectively reach their commitments, and they need to do this now given the long development cycles. While pharma's products in development are not for today's market, but for the next decade and beyond, detailed consideration will also need to be given to the environmental footprint of products already in the market.

This overview report focuses mainly on the environmental aspects of ESG, including managing the use of the planet's finite resources more effectively and the industry's approaches to reducing Scope 1, 2 and 3 greenhouse gas (GHG) emissions (see Figure 1). It explores the pressing challenges facing pharma in achieving ambitious environmental sustainability targets and what an environmentallysustainable pharma company and its supply chain might look like. The report also evaluates ways of making progress towards environmental sustainability, through easy wins across the value chain, culture changes and new investment. These quick wins can provide the license to make transformative, more fundamental changes that are necessary to achieve pharma's targets. The report also considers the social implications of the actions to reduce the environmental footprint.

Figure 1. Overview of emissions across the value chain

The complexity of decarbonisation comes from needing to not only understand but transform the emissions of your supply chain and upstream use



Are emissions that a company causes indirectly when the energy it purchases and uses is produced. For example, energy-related indirect emissions, including emissions from purchased electricity, heating and cooling.

SCOPE 3 EMISSIONS

Encompasses emissions that are not produced by the company itself, and not the result of activities from assets owned or controlled by them, but by those that it's indirectly responsible for, up and down its value chain. For example when we buy, use and dispose of products from suppliers; business travel; employee commuting; recruitment agencies; and IT providers. Indirect emissions from their supply chain often represent the largest proportion of an organisation's greenhouse gas emissions.

Source GHG protocol, Corporate Value Chain Reporting Standard.

"ESG is an important part of how the company looks at itself and frankly how it is judged by the outside world."

VP Corporate Brand Equity, large pharma company, USA

Reinforcing the need for change

While there is now a global consensus on the case for change, there has never been a more important time to understand and assess corporate responses to the climate crisis. Actions taken this decade will determine the level of warming over the course of this century, and the severity of the subsequent impacts around the world. The healthcare industry contributes 4.4 per cent of all GHG emissions meaning if it were a country, it would be the fifth largest emitter on the planet.¹ The UK's NHS is responsible for 5.4 per cent of the UK's total carbon emissions and estimates that 25 per cent of their emissions are due to medicines.2,3

Historically, the spotlight on emissions reduction has focused mostly on industrial sectors, such as mining, energy and automotive industries, with the carbon footprint of the pharmaceutical sector, receiving minimal attention in peerreviewed literature. Despite lagging behind these industries, the pharma industry is increasingly aware that it needs to take action for environmental sustainability. Moreover, pharma can also learn from the bold actions being taken in these industries. While several leading pharma companies are already making notable progress, others are still at the early stages of identifying actions to take. The pharma industry has a notable lack of low-carbon products or services compared to other industries.⁴ Nevertheless, most companies likely underestimate the size of the challenge, given the inherent complexities of the industry.

We commissioned a series of semistructured interviews of 25 sustainability leaders. Fifty-six per cent (14/25) of respondents 'strongly agreed' and 24 per cent (6/25) 'agreed' that their organisation was extremely concerned about the impact of climate change on their business.

Interestingly 12 per cent (3/25) strongly disagreed with the statement, with one stating they were giving more focus to social initiatives and difficulties harmonising change across tens of thousands of suppliers. There was a similar pattern for respondents concern about their organisations impact on the environment, half of respondents 'strongly agreed' (12/24) and 42 per cent (10/24) 'agreed'. However, there was a more mixed response with regard to translating concerns into strategies and wide variations in their approach to prioritisation of issues (see Figure 2). Pharma companies acknowledge the benefits of action on climate change and are making bold statements with some publishing ambitious targets, but most still struggle with the disconnect between ambition and action.

Our literature review shows that most companies are focused mainly on Scope 1 and 2 including a number who have set SBTs to reduce the impact of their activities and products on the environment. However, progress against these targets is variable and there is a critical gap between aspiration and action. Seven of the top 20 pharma companies by R&D spend have not set verified SBTs. Importantly, of the 13 companies who have and the two who have committed to, only one has verified longterm targets which satisfy SBTi's Corporate Net-Zero Standard criteria.⁵ Most organisations will need to reduce emissions by 90 per cent to reach net zero, requiring bold but credible plans which extend across each company's extensive Scope 3 emissions. In the future, validation of longterm SBTs will be increasingly important as it demonstrates credibility in the reporting of emissions targets and data.

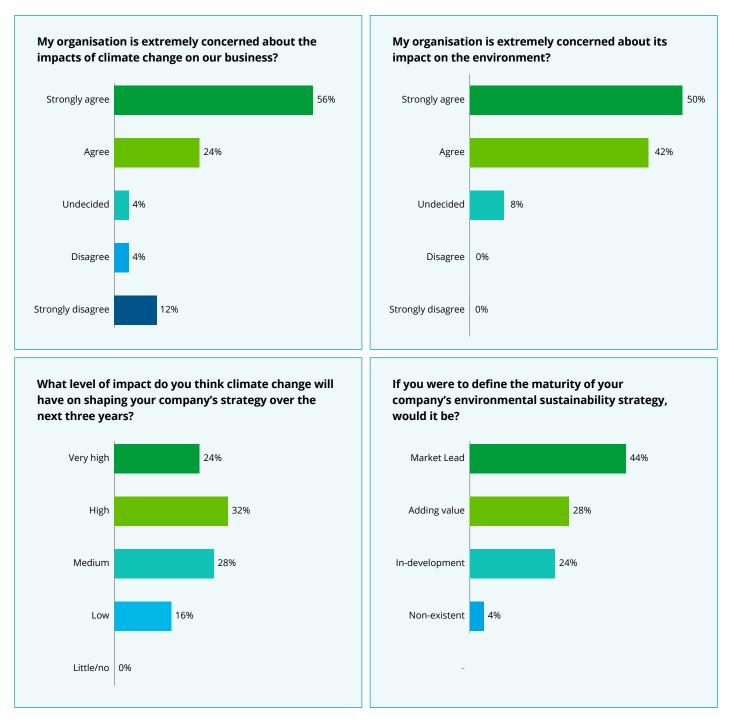


Figure 2. Sustainability Leaders concern about climate change and implications for their strategy

Source: Deloitte analysis of Global data commissioned interviews of 25 sustainability leaders in global pharma industry

Note: Question: To what extent do you agree with the following statements?. Q2: 'My organisation is extremely concerned about the impacts of climate change on our business? Q3 'My organisation is extremely concerned about it's impact on the environment?. Q4:What level of impact do you think climate change will have on shaping your company's strategy over the next three years? Q5: If you were to define the maturity of your company's environmental sustainability strategy, would it be?

Influencing the pace and scale of change

For the pharma industry to reach their net-zero targets, limit their use of natural resources and reduce waste, an overhaul of processes is needed across the entire product life cycle and value chain. Momentum across the multiyear business cycles needs to be maintained as new, transformative approaches are adopted. In parallel companies need to question the existing manufacturing processes and products. Figure 3 shows six cross cutting themes that will impact the extent and pace with which pharma can achieve measurable progress towards their sustainability targets.

Figure 3. Critical themes that cut across the pharma 'product' value chain which will influence the pace and scale of achieving environmental and social sustainability targets



Source: Deloitte analysis.

"I think digitisation will be an enabler in terms of progress. There are lots of solutions on the market which do similar things and can capture multimodal data. To date we've yet to see an off-the-shelf solution which can integrate this data and add value for us in quantifying progress, but undoubtedly these will come"

Head of Operations Sustainability, large pharma company, UK, Deloitte-led interview

Digitalisation and role of data analytics in improving end-to-end visibility

The exponential growth in data across the value chain and the capacity to use artificial intelligence (AI) to derive insights opens up an opportunity to identify critical environmental challenges and to target activities for improving sustainability. These include improving the speed and efficiency of drug discovery, providing realworld evidence in clinical trials, providing end-to-end visibility of supply chain, monitoring cold chain transportation, and improving engagement with patients on adherence to medication and the disposal thereof. Drawing on multiple data sets in an integrated, common insight platform can inform, forewarn and measure environmental action across the value chain. However, there were significant challenges reported among sustainability leaders around the capacity, ability and opportunity to integrate complex multimodal datasets, limiting progress and impact. It is also crucial to recognise that data collection, storage and analytics add to carbon emissions and have high energy needs.

Leadership and behaviour change to drive achievement of net-zero targets

Pharma's net zero targets cannot be achieved without the active support of motivated, educated and committed employees who are incentivised to change habits and patterns of consumption. To make meaningful progress there needs to be a sustainability culture throughout the organisation and across all roles. Achieving such a culture requires leaders across the organisation that see the risks of inaction and make bold decisions to embrace the opportunities for environmental sustainability. Those that embed climate change initiatives directly into their strategic operations are more likely to obtain buy-in from managers and employees and influence third parties' behaviours, as well as helping to recruit and retain talent. Investors can be incentivised to provide finance through issues of green bonds or sustainabilitylinked bonds. Beyond providing funds for sustainability initiatives, green bonds can enhance a company's reputation and confirm its sustainability commitments by communicating key goals and objectives and increasing transparency through third party evaluation of performance.

Measuring and reporting performance to increase transparency, confidence and trust

One of the most important challenges for a pharma company is to quantify and assess its environmental impact. A comprehensive, consistent strategy across the ecosystem is needed to identify what and how to measure. Accurate measurements of the environmental footprint of products and processes will enable companies to employ this knowledge to identify hotspots and target interventions where they are most needed.

However, there is a lack of consistency in how companies are measuring and reporting, other than what is required by regulators and published in annual reports. These measures are too important, and progress too vital to wait for annual disclosures. The use of different metrics and heterogeneity across ranking systems makes benchmarking against other companies difficult. Ultimately, companies need to be transparent about how they are measuring performance and the progress achieved to help improve the confidence and trust of both internal and external stakeholders. We are witnessing ESG reporting transitioning from sustainability to finance teams, to increase the cadence and apply the same rigour to ESG as exists in financial reporting. The natural evolution will be from compliance-based reporting to corporate key performance indicators (KPIs) and ultimately towards site and product based reporting where each product produced carries an ESG rating.

The role of standards and regulations

The pharma industry is one of the most highly regulated industries, which is crucial for maintaining patient safety, public confidence and ensuring the intended outcomes of treatments. A challenge for pharma is that any measures to reduce carbon emissions need to maintain high standards of quality assurance and compliance.

"For employee engagement, it helps us live our values if a directive to really embed ESG and environmental principles into our strategy and operations is coming from our top leadership."

Global director ESG communications, large pharma company, US, commissioned interview by GlobalData

Setting stretching sustainability goals and targets may be achievable for new drugs in development but tackling the carbon footprint of drugs already commercialised is a much more daunting task. Reviewing and improving the sustainability of products already in the market will require support and flexibility from regulators. Potential solutions include rolling reviews of data, open collaboration with regulators, prioritisation of substantial reductions in carbon footprints and a consistent voice from the industry. The pharma leaders we interviewed thought that the number and enforcement of regulations will likely increase, but the majority felt the need for a balance, so that regulations enable and support change, rather than enforce change. Pharma approaches the challenge to reach net zero in the context of the highly regulatory environment but cannot allow the complexities to be a reason not to drive change.

"Consistent messages from the pharma industry will enable a regulatory sector shift rather than company by company movement, but it's difficult as we aren't always talking about same thing, and we are usually comparing apples to pears."

Global sustainability leader, large pharma company, UK, Deloitte-led interview

"We need to move from an ego-system to an eco-system approach."

Chief Procurement Officer, large pharma company, Germany, Deloitte-led interview

"We either all win or all lose. The competitive mindset doesn't work in sustainability."

C-suite executive, large pharma company, US, Deloitte-led interview

A circular economy and life cycle management

A circular economy, in contrast to the 'takemake-waste' linear economic model, aims to decouple growth from the consumption of finite resources.⁶ If pharma companies embrace a more circular economy, this could help achieve their environmental and carbon reduction targets, increasing efficiency and lowering costs due to reductions in waste and usage of fresh water and energy. Principles for a circular economy include designing out waste and pollution from products and processes, reusing and recycling products and materials, and regenerating rather than degrading natural systems. A lifecycle assessment (LCA) quantifies the environmental impact of a product, technology or process throughout its entire lifecycle from raw material extraction, through manufacture, use and disposal. Consistency in approach between pharma companies is essential to allow sensible comparisons to be made between different products. Also, by looking at the sustainable impact of a product or process in conjunction with the economic implications over its entire life cycle, pharma companies can balance initial monetary investment with potential long-term savings. Adopting this approach for environmentally friendly solutions will enable companies to obtain a better understanding of the return on investment.

The power of collaboration

Within highly regulated and commercialised consumer-centric markets such as pharma, which are characterised by patent security and long and expensive development cycles, collaboration between companies is generally regarded as something that undermines competitive advantage. However, pharma is increasingly embracing more collaborative ways of working to tackle climate change, recognising that no company can achieve net zero on its own. Twenty-four out of 25 of our interviewees considered the need for collaboration on climate change to be critical. By sharing solutions, companies can save time, effort and costs, increase the pace of change, and in doing so improve the industry's reputation. Moreover, measures taken by the industry as a whole are more likely to be successful than initiatives that are taken company by company. For example, the Energize initiative involves ten big pharma companies using power purchase agreements (PPAs) to benefit from economies of scale when purchasing renewable energy.⁷ Pharma companies can also expect their main suppliers to meet similar environmental standards, and to measure and report the same metrics, increasing likelihood of compliance.

Tackling today's net zero challenges

For pharma companies to achieve their net zero ambitions, and optimise their use of natural resources, the entire product value chain needs to be overhauled, from drug discovery and procuring consumables and operating the R&D lab, through to the disposal of medicines. Quick wins across the product lifecycle can provide the license to make transformative, more fundamental changes that are necessary to achieve pharma's targets. Longer-term investments, alongside the quick wins, can help pharma move more quickly along the path to carbon neutrality and adopt crucial reframing approaches, see Figure 4.

Figure 4. Initiatives and quick wins to reduce the environmental footprint of a medicine's lifecycle

DRUG DISCOVERY, DEVELOPMENT AND SCALING	MANUFACTURING AND SUPPLY CHAIN	PACKAGING, TRANSPORT AND COLD CHAIN LOGISTICS	PATIENT ENGAGEMENT, MEDICINES OPTIMISATION AND DISPOSAL
Infrastructure and equipment • Optimise heating ventilation air cooling (HVAC) systems • Low-energy lighting strategies • Utilise lab and building layout • Freezer management • Efficient fumehood use • Minimise autoclave runs	Supply chain • End-to-end visibility • Intelligent automation • Demand forecasting • Inventory management • Consolidate suppliers • Leverage collective buying power	 Packaging Recover and reuse offcuts Recyclable-by-design Utilise chemically recycled plastic Development of bioplastics 	 Product redesign Evaluate mode of delivery (injectables, inhalers, vaccines) Recyclable-by-design packaging Digitise patient information leaflets Product redesign: Design products in parallel with business model
 Research design Smarter purchasing decisions Minimise single use plastic Clarify recycling procedures Considerate solvent and reagent selection Recycle personal protective equipment Al-supported discovery Minimise wet-lab experimental steps 	Manufacturing • Automated quality testing • Optimise inventory levels • Flexible scaling of production • Utilise continuous manufacturing • Predictive maintenance • Manufacturing: Embed circular economy principles	 Transport Optimise mode of transport Manage temperature sensitivity Select bio-fuels Increase fuel efficiency 	 Transparency about emissions Standardise format of environmental impact data Extensive stability studies to extend shelf life
Clinical trials • Adaptive and innovative trial design • Remote data collection • Minimise travel requirements • Utilise hybrid trials • Reduce trial failures • Review method of medicine delivery	 Water management Comprehensive water management plan Emphasise recycle, reuse, and reduce Selective sorting of water waste High quality monitoring systems Zero liquid discharge 	 Cold-chain Prioritise reusable, active systems Rigorous end-to-end temperature control Al to identify risks in real time Analytics to optimise shipping duration and packing procedures 	Reducing medicine waste Image: Constraint of the second secon
Scaling • Embed green chemistry principles • Considerate solvent selection • Minimise hazardous substance use Streamline chemical synthesis process • Utilise organic catalysts • Minimise waste	Waste management • Waste minimisation plan • Hazardous waste regulatory compliance • Segregation of waste • Flexible storage of waste • Single use plastic disposal and medical waste disposal	Logistics • Al-enabled predictions of weather patterns, energy waste and water use • Forecast demand • Optimise transport routes with advanced analytics	 Disposal of medication Reverse logistics to divert medicine from household waste streams Education and awareness programmes Collection schemes for unused medicine

Improving the sustainability of drug discovery, development and scaling

Pharma companies hope that an asset being screened in an R&D lab in 2022 will become a future medicine and meet the regulatory requirements and expectations of society for the future of health. An innovative and economically effective sustainability approach is needed to create a future where pharma is 'sustainable-by-design' across all steps of the product development process. This transformational change needs to be underpinned by evidence-based insights and an enhanced awareness, including educating scientists to innovate, develop and adopt novel 'green' technological and scientific advances.

Pharma labs use energy-intensive equipment to run operations aroundthe-clock and maintain a constant environment. The energy used by equipment such as freezers, autoclaves and centrifuges constitutes up to 50 per cent of the total energy used in a lab.8 Simple steps can be taken to reduce the environmental impact of equipment already in the lab include: adjusting the temperature of cold storage; lowering the fume-hood sash when not in use; using low water autoclaves which only run when full; and turning off equipment when not in use. When purchasing new equipment, energy efficiency and minimising lab waste should be criteria in procurement decisions to support processes designed to minimise wate, energy and material use. To lower the carbon footprint of their labs, pharma companies can use renewable energy to power low energy use equipment and conduct waste audits to identify more effective recycling and waste reduction processes.

Automating drug discovery

Pharma companies should take an endto-end view of the clinical development process, including waste generation, pollutants, energy use and renewable materials, to identify opportunities for reducing emissions and waste. There is potential for greater efficiency from informed choices in drug discovery, by applying the concept of 'sustainability-bydesign'. As identified in our report Intelligent *drug discovery: Powered by AI*, the discovery of a new drug is a long, expensive and often unsuccessful process. Al-powered screening can improve the accuracy, predictability and speed of discovery.9 It could also reduce drastically the consumption of natural resources and energy associated with wet chemistry. Moreover, adopting green chemistry principles can also improve environmental sustainability. These processes in drug discovery can then transition to the scaling and manufacturing stages, bringing substantial economic benefits. In designing synthesis to optimise the use of materials, fewer by-products and less waste will be generated, minimising storage, synthesis steps and disposal costs.

Increasing the productivity of clinical trials

The outsourcing of clinical trials by pharma companies to clinical research organisations (CROs) has increased steadily over the past decade as more third party vendors have entered the market. By 2020 some 75 per cent of clinical trials were outsourced.¹⁰ Clinical trials are increasingly using real world evidence (RWE), observational studies and AI-enabled technologies to capture more real-time data, resulting in a transformation of trial designs. Indeed, the adoption of AI technologies is helping to energise all trial design and gain environmental sustainability benefits through: optimising data collection; improving patient and trial site selection reducing delays and abandonment; monitoring and managing patients remotely; reducing the need for travel while improving adherence and reducing attrition; and consolidating all data on to a shared cloud-based analytics platform.¹¹

Scaling production

When registering an API manufacturing process with the regulators, a pharma company must commit to a specific solvent, catalyst and manufacturing process. Although in theory this commitment can be amended later, doing so is costly, complex and time-consuming. Green chemistry decisions should therefore begin at the R&D stage so that they can be adopted and improved throughout the scaling and manufacturing processes. Scientists need to consider the efficiency and cost benefits, energy consumption and water use of solvents, materials and catalysts to make the most suitable choices. An efficient synthesis should reduce the number of steps needed, and minimise hazardous intermediates and waste production, while maximising economy. Case study 1 demonstrates how My Green Lab can help companies obtain additive contributions by realising quick wins across the R&D lab process to improve the environmental footprint of drug development.

Case study 1. AstraZeneca and My Green Lab: Creating a culture of sustainability in labs

Situation

AstraZeneca recognised the need to reduce the environmental footprint of their global laboratory network and in 2021 partnered with the non-profit organisation, My Green Lab, in a programme to reduce the environmental impact of their lab practices. My Green Lab certification is considered the gold standard for laboratory sustainability best practices around the world and has been recognised by the pharmaceutical sector as part of the UN Framework Convention on Climate Change (UNFCC) Race to Zero.

Solution

My Green Lab certification provides scientists and the teams that support laboratories with actionable ways to make meaningful change. The programme covers 14 topics including energy, water, waste, chemistry/materials and engagement, with a forensic focus on behaviour change and tasks that scientists can do themselves. It also provides recommendations for more extensive changes to the layout of the lab and preventative maintenance of equipment that can substantially impact sustainability parameters in the longer term.

Outcomes

Engagement: In 2021 a total of 36 laboratory functions across 31 sites were involved in the programme. Twelve were certified across 11 sites: four achieved the highest green certification level, one achieved Platinum, six Gold and one Silver. Overall, the programme contributed to a significant change and widespread engagement across the company.

Savings and return on investment (ROI): AstraZeneca has credited My Green Lab with helping it reach a 97 per cent rate for recycling biological waste at a facility in Gaithersburg, Maryland, and prompting the recycling of tens of thousands of plastic centrifuge tubes and serological pipets in Cambridge, UK. In 2021, for the second consecutive year, AstraZeneca won the Biotech/Biopharma organisation category in the International Freezer Challenge, saving 1,858 kWh/day across the participating sites.^{12,13,14} "R&D has lots of existing ingrained processes. Let's say we have an existing laboratory, maybe its many years old, it would require large capital investment to make changes. However, there are a lot of breakthrough discoveries happening and new sustainable ways of doing research. While changing existing activities presents large difficulties, newer developments, new laboratories, new R&D spaces, they present little or no difficulties."

Principal Project Engineer, large pharma, US, commissioned interview by GlobalData

"It's a big challenge because you have vendors that are very small, that might provide you with a very critical material for your product or an ancillary material that helps make your product, and you have one source. You have to figure out how to work with that person or that group."

Vice President of Environmental Health and Safety, mid pharma, US, commissioned interview by GlobalData

Reducing the environmental footprint of manufacturing and supply chain

Manufacturing was identified by the majority of our interviewees as the most difficult area in which to bring about environmental change. Pharma supply chains are global, complex and interconnected across the industry. They involve multiple suppliers of APIs, numerous distribution centres and manufacturing sites, and multi-modal forms of 'cold chain' transport. The COVID pandemic highlighted the need for greater agility and resilience across the supply chain to respond to market disruptions. Our interviewees commented that reducing Scope 3 emissions was an extremely difficult challenge due to the need to influence numerous participants across a highly complex supply chain and their huge reliance on third party suppliers. While quality of the product is paramount, procurement decisions should include consideration of the carbon footprint, waste, water requirements and energy usage of suppliers and logistic companies.

End-to-end digital visibility across the supply chain can be used to identify hotspots, support real-time decision making and improve demand forecasting. Pharma companies, acting in collaboration, can incentivise third party organisations to set their own targets for improving their environmental footprint, both upstream and downstream from their own operations. For example:

 Batch manufacturing involves pharma products being made in multiple steps with production stopping while the material moves to the next step. These may span several manufacturing sites which are often spread across the globe. Continuous manufacturing (CM) methods can provide technical improvements such as increased yields, less waste, lower water usage and much shorter manufacturing times. However, moving from batch manufacturing to continuous manufacturing requires significant validation effort and attracts strict regulatory scrutiny so can be expensive to introduce for products already on the market.

- A comprehensive water programme that emphasises the 4Rs of the circular economy (reduce, reuse, recycle and recover) and reduces pollution is essential if the industry is to tackle growing shortages of fresh water and threats to the planet's other finite resources. With 'traditional' wastewater management very different effluents may be mixed, making it difficult to treat or recycle in selective waste collection systems. Water reuse is an ideal aim but it needs careful implementation and high-quality monitoring systems so that water quality is not affected, and contaminants can be identified at very low concentrations.
- Pharma manufacturers need to comply with changing regulations for hazardous waste disposal. An expensive but commonly used fix-all is for waste to be treated as hazardous when there is uncertainty about its correct classification. Waste disposal procedures need to be optimised to minimise contamination of the environment and reduce energy usage in the disposal methods used. If incineration is the only option, the energy generated can be used for heat and power production. Flexible hazardous waste storage can allow capacity to fluctuate between materials without breaching site regulations or causing unnecessary collections. Segregation of different manufacturing wastes can improve compliance and safety, while enabling efficient reuse and recycling, and making cost savings.

Optimising size of and material used for packaging, mode of transport and logistics

Many medicines are temperature-sensitive and require cold chain storage and distribution to maintain the integrity of drug substances and products. Sustainability-bydesign in the R&D lab can help minimise cold chain requirements, and the localised nature of continuous manufacturing reduces transportation requirements. To improve the environmental footprint of cold chain logistics, greener and bio-based fuels can be used, and for longer distance modes of transport, trains and barges can be an alternative to 'aviation by default'. Reusable packaging instead of traditional polystyrene is environmentally superior over the life-time of use. End-to-end transparency of logistics activities can identify risks in real time, minimise losses and inform future decisions about packing procedures and shipping duration.

Packaging protects medicines from physical and chemical damage during transportation, storage and use, with a focus on safety and sterility. The highly regulated environment means that adopting recycling or reuse practices that are common in other industries are difficult for pharma due to the risk of leaching impurities into the medicine. Collaboration between clinical and commercial teams during early phases of development to find sustainable solutions can help realise the benefits of cost and process efficiency while maintaining regulatory compliance.

Pioneering new technology can break down plastics back to base molecule level and then convert them into virgin-grade quality material, enabling full recycling of plastic that in the past could not be decomposed.¹⁵ Chemically recycled plastic can be used in the highly regulated pharma industry as it is indistinguishable from the new product. As demand and supply is increased, the scale and cost of these techniques can be optimised. Bioplastics made from renewable biomaterials are being developed for use in pharmaceuticals, but more stringent and longitudinal testing is still required due to their unpredictable rates of decay in varying climates and potentially reduced capacity for preserving medicines.

Improving patient engagement, medicine optimisation and product disposal

Billions of dollars of medicines are lost each year, many due to avoidable errors, often in logistics, which adversely affect quality and lead to premature waste or disposal.^{16,17} However, even if medicines are delivered on time and to a high quality, there are still problems with waste due to reliance on estimated expiry dates at the time of production. Indeed, 90 per cent of medicines are safe and effective for five years or longer after their 'expiry' date, but currently they are destroyed by default.18 Extensive stability studies conducted during development, before regulatory approval, can result in a more ambitious shelf-life potential being agreed.

Decisions such as limiting the use of colours, multiple materials and label sizes can all increase the possibility for outer packaging to be recyclable-by-design. Mono-material packaging, or packaging that can follow the same recycling stream, can help to ease the complications of recycling: this can then encourage more patients to recycle their secondary and tertiary medicine packaging materials. Digitising leaflets (e-leaflets) reduce paper waste and the amount of secondary packaging required. Education campaigns can also raise awareness of recycling secondary and tertiary packaging among HCPs and patients.

Healthcare leaders have called on the pharma industry to make information about the environmental impact of medicines readily available in a standardised data format.¹⁹ This will enable prescribers to keep informed about environmental sustainability and consider it as a factor in decision-making, if safety and expected outcome for the patient is not compromised. Several healthcare systems are using their procurement power to influence pharma to reduce their emissions.

Once a patient is supplied with medicine or therapeutics, there is a significant challenge to ensure that the correct dosage is taken and that medicines are not wasted through lack of education or poor adherence. Pharma can improve adherence to medication through patient support programmes and rolling out smart packaging, alongside agile delivery solutions and continuous manufacturing to support a no-dose-wasted programme.²⁰

Education programmes and awareness campaigns inform patients about how to dispose of unused medicines and the risks from pharmaceuticals in the environment. Pharma can also include waste disposal procedures or takeback programmes in their product leaflets or on packaging, to emphasise that disposal of medicines must not follow the standard household waste streams. Pharma companies can use reverse logistic schemes to divert unused medicines from standard household waste streams to those specifically designed for pharmaceutical products. However these would need to be supported by collection schemes for unused medication on a regional or national level, which pharma can advocate. Case study 2 demonstrates the power of collaborative organisations to improve accessibility and the environmental sustainability of the pharma ecosystem.

Case study 2: The Sustainable Medicines Partnership (SMP): Making medicines more accessible and more sustainable.

Situation

The SMP is a not-for-profit, private-public multi-stakeholder global collaboration focused on raising awareness and implementing evidence-based solutions to modern medicine. The initiative is led by YewMaker, an action lab that builds, tests and scales sustainable healthcare solutions. It aims to help build a collaborative ecosystem for reducing medicine wastage, making a positive impact on the environment and also making the availability of medicines more equitable.

The Problem

- Billions of medicines are discarded unused every year.²¹
- Two billion people do not have access to basic medicines.²²
- Poor visibility through the medicines supply chain causes avoidable losses.
- Reliance on paper medicines information that wastes resources and is rarely read.
- Reliance on single use plastics in medicine packaging.

Solutions & Outcomes

The four-year SMP programme targets six pillars of sustainable medicines aiming to deliver data driven solutions, sector wide frameworks, standards, and implementation toolkits.

SMP Projects include building tools such as Medicine Carbon Footprint (MCF) classifier, to better measure and compare the carbon footprint of medicines.²³ Digitising medicines information to provide patient-centred, standardised, multimedia, inclusive medicines information.²⁴ And piloting circular solutions to reduce single-use plastics in packaging without compromising function.²⁵

Implications of changes made across the product lifecycle for social sustainability

Virtual trials can deliver benefits for both environmental and social sustainability. By enabling wider participation across geographies, they can tackle health inequalities by ensuring that the research is more equitable and representative of the population that it is intended to serve. Improved efficiency in R&D means that new medicines will get to market more quickly. While patient safety remains of paramount importance, a more agile and adaptable approach to regulation and shorter drug development cycle times can reduce the costs of development and consequently the launch price needed to achieve a return on investment.

Embedding green chemistry principles across R&D and manufacturing alongside reviewing waste and water policies will reduce the risk of pollution entering the water system. Adopting continuous manufacturing (CM) methods can mean safer working conditions due to the limited manual handling. CM also enables production to happen at a faster pace and with in-line automated quality testing, ultimately enabling the medicines to reach the market faster to meet the area of unmet need for patients sooner.

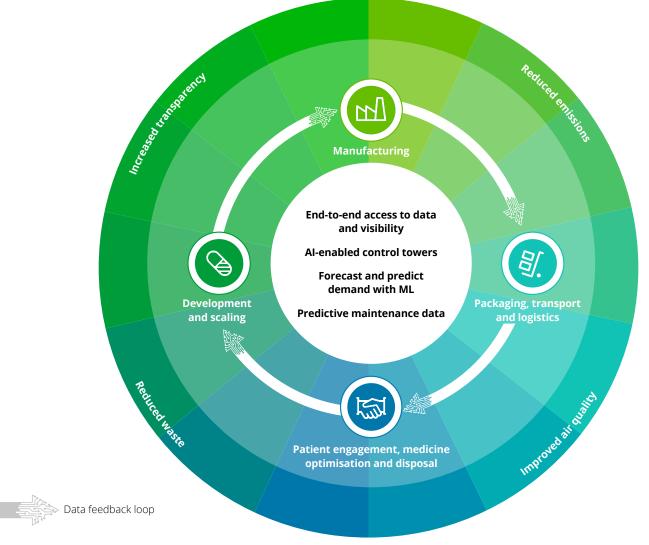
Advocating for the digital first approach to replacing paper information leaflets hopes to provide more tailored information, improved readability and searchability, faster sharing of new information, but the accessibility to digital infrastructure must be considered. When adopting innovative recyclable packaging, the interaction and possible leaching into medicines needs to be closely monitored to ensure medication remains stable and impacts the patient as intended.

Realising a net zero future, ensuring progress and embedding change

Many pharma companies have begun to make significant commitments and take action to achieve a net zero ecosystem that consumes minimal natural resources. However, many of the decisions are being taken on the basis of inadequate data and insights. While radical and rapid decarbonisation is needed for ambitious targets to be reached on time, internal initiatives and quick wins across the life cycle of a medicine can improve environmental credentials. There is a need to improve data management, share effective initiatives, champion successes across the industry and embrace cross-sector collaboration to achieve the common goal of reducing the environmental footprint of the pharma sector.

Our vision for a net zero medicine of the future (see Figure 5) involves a high level of collaboration and sharing of data throughout the industry, supported by interconnected data systems, powered by AI algorithms and underpinned by the principles of a circular economy. Sustainability-by-design should be at the forefront of thinking by all stakeholders, from the R&D scientist and manufacturing scaling lead to the packaging designer and logistics manager. These should work collaboratively to ensure that green measures are firmly embedded across the product value chain.

Figure 5. Improving environmental sustainability of medicines through end-to-end visibility of the supply chain



Digitally enabled end-to-end visibility allows energy and waste hotspots to be flagged and actively targeted in a continually evolving and improving sustainable environment. Transparent, actionable data insights inform bold and decisive action by leaders across the industry. Existing processes have been reimagined, with full engagement of HCPs, patients and, importantly, regulators. Companies have also undertaken a systematic review of all medicines in the market, to identify how best to reduce their carbon footprints.

We have identified several quick wins across a medicine's life cycle and value chain to help progress towards end-to-end sustainability. As these quick wins become the gold standard, company-wide, environmentally sustainable, cultural behaviour changes will be normalised. The additive impact of small changes and positive actions today will become the big impact of tomorrow. Integrating these considerations throughout the organisation will have implications across procurement, talent, supply chain, product development and more, heralding a shift in mindset across all stakeholders.

However, beyond the quick wins, fundamental changes to ways of working with significant reimagination of business processes, digital infrastructure and the wider network is needed. Substantial overhaul of regulated products and processes will still be necessary to enable the pharma industry to achieve its ambitious goals and will require the support and flexibility from engaged regulators. Significant alterations across waste and water management, energy use and supplier policies can be made without affecting regulatory processes. A transformation across the industry will occur as pharma redesigns its products, business models, supply chains and digital ecosystem over the coming decade to meet its goals.

By following recognised frameworks to influence the setting of appropriate goals and assess progress, pharma can continue to drive transformation which is measurable, industry-wide and incentivises ecosystem change.

Transparent measuring and analysis of qualitative and quantitative environmental metrics helps to understand and communicate the company's performance, risks, and opportunities. Long-term transformative goals across the industry need near-term accountability through a plan which includes tangible, measurable targets and incentives in the short term. The quick wins showcased can kick-start progress, but further step wise change is required.

While, traditionally, businesses are conditioned to protect intellectual property, the journey to net zero and minimised use of natural resources necessitates an ecosystem wide collaborative approach to magnify impact beyond a company's own operations and address climate change at a systems level. This includes working with suppliers, peers, governments, regulators, and HCPs to share leading practices, inspire greater commitments and incentivise progress.

Embedding environmental sustainability into pharma's DNA is a momentous challenge. We are in a decisive decade to act against climate change, and bold actions resulting in measurable impact shared across the industry are needed to accelerate the pace of change. The environment, investors, employees and, of course, patients will benefit from those companies that move effectively from ambition to measurable action. This in turn will increase trust and overall perception of the company, attracting investment and helping the company win the race for, and retaining, talent. For pharma companies and their stakeholders, achieving net zero and minimising use of finite natural resources brings many pressing challenges, but also many opportunities to positively realign their mission and purpose to serve patients and contribute to global society while enhancing profitability, reputation and resilience.

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