CPHI Online

The CPHI Sustainability Report 2023

Towards a Greener Future

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Scope 3 emissions

This report identifies scope 3 emissions as the most problematic for the pharmaceutical industry. Scope 3 emissions occur throughout the supply chain and are particularly difficult to quantify due to challenges in identifying indirect emissions from 3rd party contributors. Scope 3 emissions account for the majority of a company's carbon footprint, but they have less control on mitigating the impacts from this. The industry needs to improve their monitoring of scope 3 emissions and reduce them dramatically to limit global warming by 1.5°C as laid out in the Paris Agreement.

2

Collaboration

Collaboration is widely considered vital in reducing emissions from the industry and meeting net zero targets. Government bodies, regulators, companies, and consortiums are coming together with initiatives to make environmentally friendly processes more accessible, encourage innovation, and ultimately meet sustainability targets.

Key Findings

3 Regulations

Environment-based regulations are globally disparate, making it more complex for companies to meet the different regulations in different areas. There is also a distinct lack of regulation and legislature around sustainability in the pharma industry, leading to reduced reporting and accountability. Companies are working together to lobby for better, more consistent regulation in the industry, to ensure more companies have more sustainable commitments.

4 Sharing best practice

Working so interconnectedly through each stage of the supply chain means companies with differing expertise can share knowledge and examine the best ways of working to become more efficient, more environmentally friendly, and build a more stable supply chain. By using wider forums more established companies and smaller, innovative start-up companies can share their knowledge and individual expertise to accelerate progress and have a greater chance of meeting reduction targets within the next few years.

Pharma’s Green Revolution:

Transforming the Supply Chain

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Transforming the Supply Chain

Sustainability within the pharmaceutical supply chain has been of growing consideration within the industry. The pharma industry acknowledges the role it plays in contributing to climate change, (accounting for (4.4%) of greenhouse gas emissions globally)[1], with contributions from drug manufacturing accounting for 25-33% of all healthcare emissions, and consequently its responsibility to minimise that impact [2].

The growth of the pharmaceutical industry is projected to continue at a rate of 15.9% from now until 2030, which would imply a parallel increase in the amount of emissions, so addressing this issue and mitigating the effects on the

planet as quickly as possible is essential [1].

As climate change has largely undisputed repercussions for global public health through droughts, flooding, and heatwaves as well as contributing to air pollution, reduction in water quality and reduction in biodiversity all contributing to human mortality, poverty, and disease [3], companies are viewing planet health as intrinsically connected to human health, and therefore a priority for ensuring the best care for people all over the world.

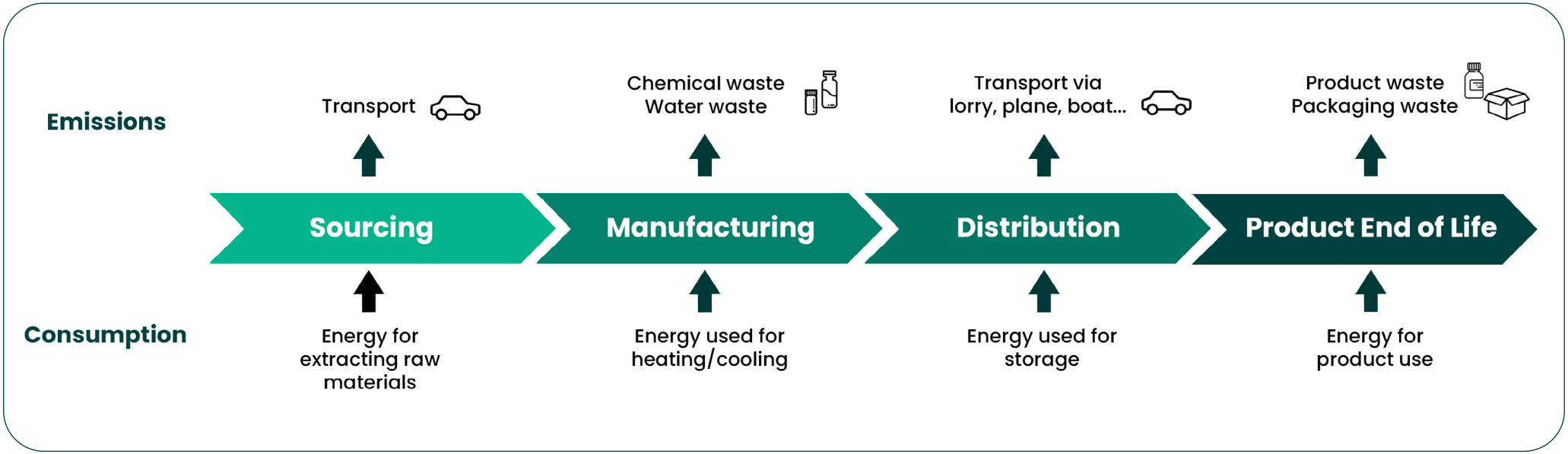
As one of the largest industries contributing to climate change and the effects of global warming, pharma is in a unique position to spearhead a shift in culture towards sustainability and ESG practices, something that may inspire other industries to follow suit.

As urgency from within the sector to address these issues increases, so does pressure from the outside, including from other industries, governments, and the public [4].

While the pharma industry has been lauded for its innovation, especially during the pandemic, this momentum must be continued, and innovators are now proposing to tackle issues in climate change with a comparable level of vigour [5]. As one of the largest industries contributing to climate change and the effects of global warming [4], pharma is in a unique position to spearhead a shift in culture towards sustainability and ESG practices, something that may inspire other industries to follow suit.

Every part of the supply chain contributes to the use of energy and the subsequent effusion of energy. Aspects of the pharmaceutical supply chain have been set in stone for a long time, with these methods accounting for 90% of the energy consumption of a company, but the industry will have to review these long-standing methods to upgrade the infrastructure and support more eco-friendly practices [6].

Figure 1



While many large companies have already begun implementing these changes, with the development of new plants and manufacturing sites, these are in the minority due to the costly nature of such an endeavour.

This highlights another issue; smaller companies – as sustainability has to become a core value for everyone to have the greatest impact – may struggle to make major changes to their existing systems without extensive support.

Figure 2: Biggest challenges facing pharma companies in becoming more sustainable

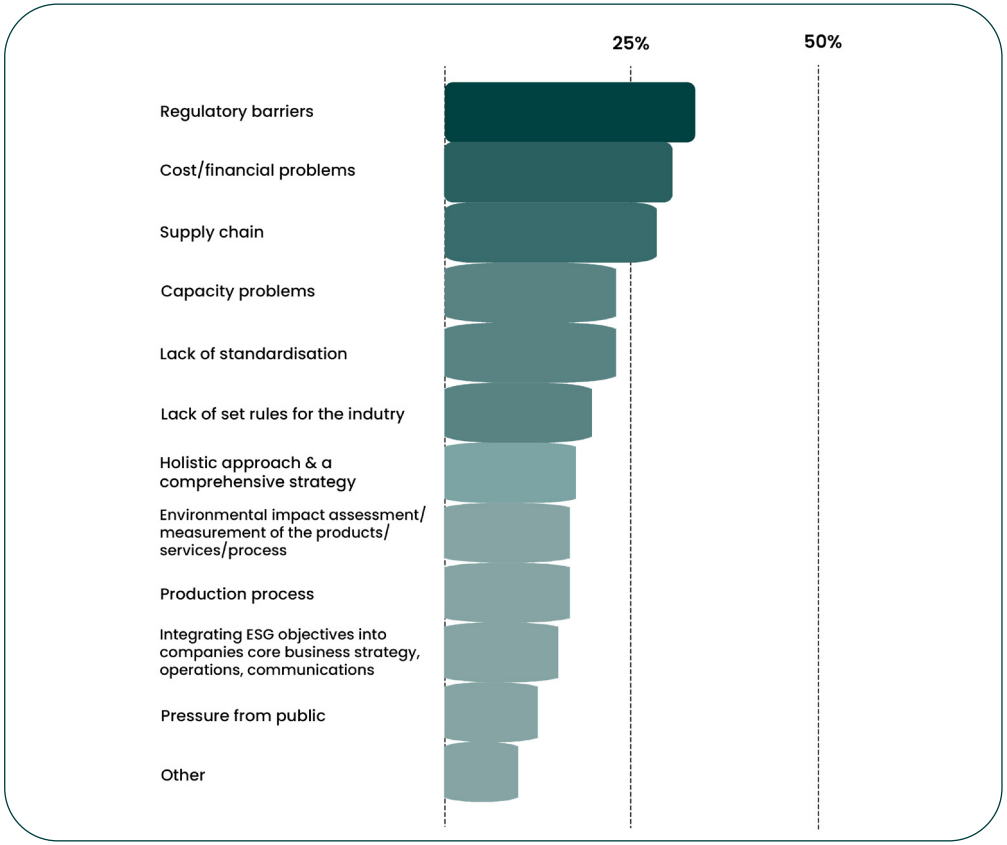


Figure 2 shows the results from a recent survey from CPHI from a range of pharmaceutical companies, the survey looked to identify some of the biggest challenges the industry is facing in working towards becoming more sustainable. The supply chain is a vital part of the industry and is severely inhibited by regulatory issues and financial pressure, making it all the more difficult to successfully implement solutions.

Aurelio Arias, Director of Thought Leadership at IQVIA comments on the industry players' responsibilities:

"Pharma companies have typically had a long-standing focus on social responsibility, typically centred on increasing access to medicines and more recently on diversity and inclusion. They have also needed to be responsible for environmental health and safety for obvious reasons. However over the past few years, the attention on reducing the impact on climate change has increased and this is noticed across the industry through increases membership to rating agencies, hiring of ESG officers, disclosure statements and goal-setting across major

public companies. We hope that the momentum continues through to smaller, private companies in all continents."

Emissions from the industry can be broken down into 3 categories: scope 1, scope 2, and scope 3 emissions. Scope 1 emissions are generally the first that come to mind being the most direct, but these are not as big a contributor to overall emissions. Scope 2 emissions account for a large proportion of energy usage within the supply chain, namely in the manufacturing process. Scope 3 emissions are the emissions that are less obvious, and therefore their impact goes unchecked. We need to develop new goals that address these areas, and focus on reducing the pharmaceutical carbon footprint, limiting the repercussions for our planet.

The industry is working symbiotically with governmental bodies, consortiums, and health services where it is able to make a difference [4]. Leaders are starting to recognise that they can't wait for governments to inform on when to take action with catch-all solutions, but rather they have to act more immediately to address the most ruinous aspects of the pharmaceutical supply chain for the environment; and they can do this on an individual, targeted level, and by working together with other companies and initiatives to make the most significant difference.

This report covers all key aspects of the pharmaceutical supply chain, how each link in the chain has contributed to climate change, and what has been done and can be done to improve how the industry progresses to ensure we can keep supplying medicines to improve population health by protecting the planet at the same time.

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>
> **Aurelio Arias,** Director of Thought Leadership at IQVA

Pharma's Climate Footprint:

Quantifying the Impact

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Climate change has a significant impact on human health all over the world. Global warming leads to natural disasters such as flooding, decreased water quality, heat waves, air pollution and a decrease in biodiversity [4]. These all have a knock-on effect on people, increasing chronic illnesses, allergies, mental health difficulties, and malnutrition [4,7].

When talking about the impact the pharmaceutical industry has on the environment, it is vital to consider the emissions produced. Scope 1 emissions include the direct and measurable greenhouse gas emissions a pharmaceutical company makes, such as from fuel

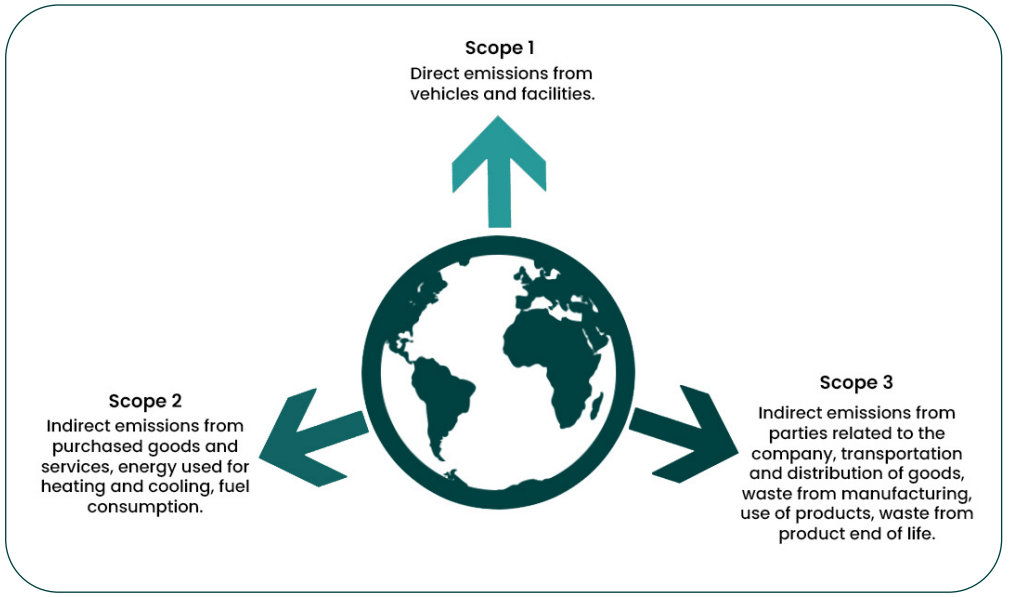
combustion from vehicles in transporting of goods and materials. Scope 2 emissions are more indirect, such as from using energy to heat/cool in the development stages of the value chain [8].

Finally, scope 3 emissions take into account the other emissions associated with the pharmaceutical company. This can include all emissions the company may be indirectly responsible for, for example, those produced by the suppliers at the start of the supply chain, to those produced by customers at the other end of the chain.

> **"Studies from publicly available corporate scope 3 reports suggest that manufacturing is the largest component of emissions attributable to a pharmaceutical company, contributing to around 80% of indirect emissions."**
>
> **Aurelio Arias,** Director of Thought Leadership at IQVA

Scope 1 and 2 emissions are more visible and more easily addressable, but scope 3 emissions are where the real difficulties lie, and unfortunately, is the greatest source of emissions [9]. Scope 3 emissions are also more likely to be out of a company's direct control, meaning they are harder to address in the first place, let alone manage effectively.

Figure 3

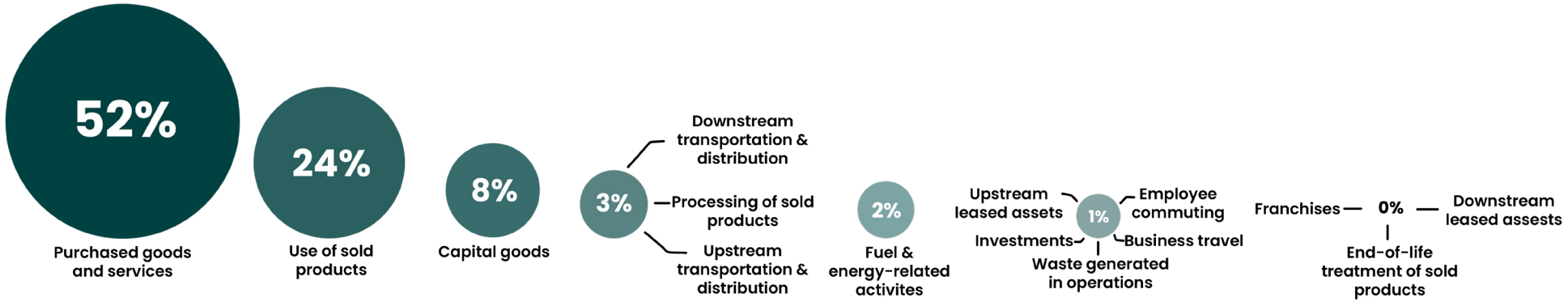


Arias, added:

"Studies from publicly available corporate scope 3 reports suggest that manufacturing is the largest component of emissions attributable to a pharmaceutical company, contributing to around 80% of indirect emissions."

Since 2016, it appears that scope 3 emissions from pharmaceutical companies have increased, however, this is most likely due to an increase in accurate reporting of this data. Currently, there are few guidelines in place to encourage the reporting of a company's emissions, so much of this data is missing [1]. As the industry works towards sustainability goals, reporting data will become more prominent, and it could appear that emissions are increasing [1]. As time goes on however, with more

Figure 4



comprehensive tracking of data, there will hopefully be a decrease in emissions in time to meet targets in the Paris Agreement [10]. To reach these goals, and those such as the UN's **Race to Zero Campaign**, scope 3 emissions need to be urgently and proactively addressed.

Figure 4 shows the breakdown of scope 3 emissions according to companies who have reported the data, showing which categories are the main contributors.

The geographical spread of the greatest emissions across the pharma industry is as much as one would expect. In areas where the majority of sourcing and manufacturing occurs, there is a high intensity of emissions, which can be split down into scope 1 and 2 emissions. The highest levels seen more recently have been in the Asia Pacific region. Scope 3 emissions are not yet broken down by region, but remain relatively consistent from 2015 until recently when they started to increase, with a sharp peak in 2022 [1]. The data for scope 3 is mostly projected figures as this is not readily or easily reported as yet, with data only coming from the largest European and US-based companies and even within that there is still much debate over what exactly to include in reporting.

As nearshoring becomes more frequent, with companies opening plants closer to home and *in situ* to countries that will need the medicines – a feature that became shockingly necessary in the COVID-19 pandemic – the geographical distribution of emissions will change [11].

How this impact has been perceived by those on the inside has been slowly transforming over the past few decades, with sustainability concerns throughout the supply chain steadily climbing up the list of priorities and some of the biggest pharmaceutical companies in the world urging action [1].

Ingrid Vande Velde from the **PSCI** highlights some of the key changes they've noted in this respect:

"We have seen a move towards responsible procurement practices, which seek to tackle sustainability issues from the operational side rather than the high-level strategic. Responsible procurement offers a more hands-on

approach, anchored in the procurement or sourcing teams. The goal of responsible procurement is to improve the ethical, environmental, and social performance of suppliers and ultimately mitigate any negative impacts found within the supply chain. Not only have we seen responsible procurement teams and practices grow in recent years, but also the maturity of the approach companies take to evaluating their suppliers using responsible procurement criteria."

Nicola Coles from BioPhorum is keen to emphasise the influence of those on the outside of the supply chain, talking about public perception, feedback from healthcare systems across the world. This feedback has driven change from the top down to encourage companies and stakeholders to push for more innovation in sustainability to enable more tangible reductions in emissions, across all scopes.

"The customer voice is becoming a lot louder, and a lot clearer which is great to see. The customer voice in this instance is the wider healthcare system, the healthcare providers and the patients they serve. In the UK, the NHS is really leading the way in terms of setting out its own green policies with respect to aggressive decarbonisation ambitions and working with other global health economies to develop similar policies. I also see a shift from sustainability being seen as an area of competitive advantage to the recognition that we need to work collaboratively to create the infrastructure and marketplace for the industry to succeed. Through extended producer responsibility and the focus on scope 3 emissions, organisations are now actively engaging with their ecosystem through industry collaborations like BioPhorum. The reality is if one part of the system fails, we all fail."

> **"The goal of responsible procurement is to improve the ethical, environmental, and social performance of suppliers and ultimately mitigate any negative impacts found within the supply chain. "**
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> **Ingrid Vande Velde,** PCSI


Collaboration:
The Catalyst
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An overwhelming impression from the industry when faced with tackling these environmental issues is that we need to work together to make the biggest changes. Climate change isn't a responsibility to be shouldered by one party.

As many contributors share a common supply chain, the scope 3 emissions are shared across the board and therefore so is the struggle to identify and keep these emissions in check. The shared responsibility leads to the logical next step – to work together to rein in the emissions from the supply chain. Not only does this should how important it is to the industry to enact change but also it's the best way to be truly effective. Many companies and bodies are now joining initiatives, consortiums, and

coalitions all with significant goals they can work towards together.

One of the largest coalitions is the UN's Race to Zero campaign, which includes 11,309 non-State actors including 8,307 companies, 595 financial institutions, 1,136 cities, 52 states and regions, 1,125 educational institutions and 65 healthcare institutions (as of September 2022), with a commitment to reach Net Zero by 2050 [12].

A more supply chain-specific initiative is the **Sustainable Markets Initiative** from the Health Systems Task Force, which has helpfully developed a set of targets for suppliers, specifically designed to be tackled in a cooperative way [13].

The targets easily set out the minimum requirements for climate stability needed from suppliers, reducing complexity for the supply chain players, so they aren't quite so intimidating to take on [13].

One thing we know is that it's often the smaller pharmaceutical companies that struggle most to change their processes and implement more environmentally friendly ways of working. For such companies cost margins can be slim, leaving little room to overhaul processes or be flexible according to customer needs. This is where we need larger pharmaceutical companies to support them and raise them up so that they can continue to contribute to the industry, whilst ensuring the smaller companies can do this in a sustainable way.

Vande Velde from the PSCI commented:

"There is so much valuable knowledge to building a sustainable supply chain that larger pharma companies can share with smaller ones. Many of the approaches, tools, and resources have already been developed and are easily transferrable to smaller companies at the start of their journey. We believe that collaboration is key. At the PSCI, we bring together experts from pharma companies of all sizes to share knowledge, develop industry-wide tools, and enable peer learning. This is particularly important for industry-wide issues like decarbonisation which will require companies of all sizes to work together to reduce supply chain emissions."

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The PSCI is one of the initiatives that is helping to shape this journey by setting out guidance for pharmaceutical companies and, importantly, keeping the industry informed. Coles from BioPhorum also weighed in:

"I think about the supply chain rather than small vs big. A need for those across the supply chain, to clearly understand the intent of licence holders and healthcare providers; the direction the sector is going in, the timetable for action, and how we might track performance. This will help everyone be able to align their innovation efforts. That is why clear roadmaps like the BioPhorum Environmental Sustainability Roadmap are so critical. Then, there is the need to align strategic intent to broader operational engagement – to what extent can procurement teams articulate an organisation's direction and has this been embedded in procurement practices? It seems that organisations are getting better at signalling intent around decarbonisation but are less clear on how to practically embed circularity. In a highly regulated sector where change is slow – the signals for this innovation need to come now if we are to adapt.

There is also a responsibility from those further up the supply chain to listen intently downstream, to understand how some players may be using their smaller size to be more agile and to consider how this could be scaled up, and to identify opportunities for collaboration around keytopics that may require innovation. It is important that all companies celebrate and share success so that they can be widely adopted. It is equally important to share lessons learnt so that others can achieve the same improvements without making the same mistakes along the way. In this way spare sustainability capacity can be invested widely assuring the industries transition swiftly."

As Coles suggests, the increase in communication and understanding between companies and assets along the supply chain will give rise to solutions for the areas that tend to go under the radar, which will be particularly key in addressing scope 3 emissions.

Further to how companies can help each other end-to-end in the supply chain itself, sustainability in this industry is also an immovable object from the point of view of government bodies. Legislature around sustainable practices is undergoing a massive overhaul and coming under much scrutiny. There has been much progress here too, with several accords – such as the Paris Agreement – regarding reductions in emissions, but there are still several gaps when considering the different stages of the pharma supply chain. What pharmaceutical companies have to balance is whether to wait for further guidance and regulations to come into force from governmental bodies around the world, or whether to act pre-emptively in cases.

Coles from BioPhorum comments on the organisations supporting industry stakeholders in complying with regulations around sustainability:

"There are many collaborations looking at different aspects of the challenge. Organisations such as the SMI are focusing on the relationship between the pharma industry and the healthcare provision sector to improve sustainability performance transparency and improve decision-making. The Energize programme, delivered by Schneider Electric, supports access to renewable energy for pharmaceutical supply chains. Regulatory organisations like EFPIA are playing their part to look at the local regulatory environment to support change."

Aurelio Arias, Director of Thought Leadership at IQVIA described some of the considerations companies are committing to in this area already:

"Legislation has been introduced to encourage greater disclosure if companies grow to a certain size, for example, the EU's significant CSRD standard. Moreover, in COP26 in 2021, 63 countries committed to sustainable health systems from diverse geographical regions. One of the leading

health systems is the NHS in England, having committed to Net Zero by 2040, stipulating that all suppliers to the NHS, including pharmaceutical companies, will need to adhere to ESG published progress reports from 2030 onwards."

This was further supported by Vande Velde from the PSCI:

"Over the past few years, we've seen a huge surge of activity in the legislative space from the Taskforce for Climate-related Financial Disclosures (TCFD) requirements to the Modern Slavery Act, as well as the incoming SEC Guidelines on Climate Risk Disclosures in the United States. In the supply chain space, the incoming German Supply Chain Act has significantly accelerated companies' attention and work in this space and will have significant impacts going forward around data collection, due diligence, and risk. These pieces of legislation are influencing where we buy and how we buy, by demanding more transparency from the supply chains of global brands."

> **"One of the key challenges that remains is the disconnect between the global intent of many players and the local reality of regional regulation and legislation. Initiatives to improve the industry's water and waste performance are often beset with a complex web of local regulation that hampers roll out."**
>
> **Nicola Coles,** Phorum Director, BioPhorum Sustainability

BioPhorum supports the continued efforts to work together across bodies, but Coles acknowledges that several challenges remain and that some initiatives may just be helping to shift the problem further down the line:

"In a highly regulated environment, we must strive to build in sustainability right from the beginning to avoid a future refile of products given the length of time and number of resources a refile may take. But this may not be possible. Not all the solutions we need in terms of innovative materials exist. So, we need to think about how we design

in flexibility to allow a shift to a more sustainable level of performance at some point in the future. The products we file today will undoubtedly have a higher carbon load than products designed in the future with new materials and processes.

Regulatory agencies are providing the tools for this flexibility through more efficient post approval change management and BioPhorum is supporting the industries adoption of this approach via work on QbD.

One of the key challenges that remains is the disconnect between the global intent of many players and the local reality of regional regulation and legislation. Initiatives to improve the industry's water and waste performance are often beset with a complex web of local regulation that hampers roll out."

William Cashin, Chief Quality & Compliance Officer from CordenPharma asserts that collaboration needs to come from all stakeholders throughout the chain, including suppliers, customers, and government authorities.

"CordenPharma is focused on becoming more strategic about the energy and electricity we consume to produce our customers' medicines that transform the lives of their patients. To that end, we encourage our suppliers and customers to engage with us for increased science investment in order to produce more efficient processing steps that allow us to reduce/reuse the waste generated from these steps.

Global regulators can also play their part with supporting adoption ICH Q12 allowing lifecycle production process changes with low to moderate risk more easily than was the case in the past.

There are often good ideas at CDMO manufacturing sites on how to make the medicine more efficiently – after regulatory approval – which is stifled by customers unable or unwilling to face costly and time-consuming regulatory changes all over the world."

This point highlights an important roadblock in the road to Net Zero – the cost associated with changing these highly energy-intensive processes to more greener methods. With regulations coming into play, pharmaceutical companies dealing in each aspect of the supply chain must amend their business practices to comply, which can incur a cost or, if not met, a fine for the offending party [14].

Coles points out how industry-wide collaborations can help to make these costs more manageable, by addressing certain aspects of the implementation process of sustainable initiatives:

"BioPhorum can help harmonise the strategic intent. This might lead to a reduction in your consultancy spend, because instead of paying somebody to write a strategy for you, BioPhorum members write strategy collectively and you can be confident that it's got both your fellow traveller and your customer's support."

"Collaboration can reduce aborted efforts because with a harmonised approach we can fail fast and move on. We do not have time for everybody to 'have a go' and decide what does or doesn't work but instead, we learn from each other. If we know ten companies are doing something well, then we should do it too. This should improve the speed at which best practise and adoption is rolled out."

By learning from each other, companies can save time and money, which is imperative to meeting reduction targets by 2030 and a reflection of the effort as a whole to reduce carbon emissions, illustrating just how important it is to work together.

Making Sourcing Sustainable from the Start

Making Sourcing Sustainable from the Start

The environmental impact of the pharmaceutical supply chain starts right at the beginning, with sourcing the raw materials used to produce medicines and materials.

The raw materials themselves are often non-renewable; carbon-based products used to make drugs and plastics for packaging, among others. However, some raw materials of natural origin can be sourced more sustainably. For use in products, materials such as palm oil, cellulose, sugar, tin, gold and other minerals can be extracted under responsible initiatives such as the Forest Stewardship Council Certification, the Roundtable on Sustainable Palm Oil, and the Minerals Traceability Programme to name a few [15].

Materials for packaging can also be sourced more sustainably; examples include paper from timber managed under various certifications and sustainable forestry initiatives, natural rubber harvested under the Forest Stewardship Council Certification, and aluminium via the Aluminium Stewardship Initiative [15].

Creating a circular economy in packaging materials is a key approach towards reducing emissions associated with procuring the components for drug packaging in the supply chain. The use of recycled plastic, renewable materials, and glass is becoming more common, and companies are doing well in this aspect, but still faces a few challenges here.

Bormioli Pharma adopted a 50-in-5 programme to push towards using at least 50% of recycled materials in their products in the next 5 years [16].

"The 50-in-5 programme that we are deploying right now is offering a solid sustainable solution to the pharmaceutical industry, well in advance compared with the limit stipulated by the European Union's single plastic use directive that is requiring by 2035 a minimum of 30% of recycled materials. We want to be able to offer to the pharma industry sustainable packaging solutions in almost any kind of packaging form they need. Supporting a sustainable growth business model, caring for the patient and for the planet," stated Andrea Sentimenti, the Marketing & Innovation Director from Bormioli Pharma.

Raw materials themselves are often non-renewable; carbon-based products used to make drugs and plastics for packaging, among others.

Bormioli is also leading the way in the use of bio-based renewable materials for a range of uses, but notes that this is limited to legislative restrictions.

"We have bio-based solutions, in the form of products obtained from renewable materials such as sugar cane.

We have PLA-based products of polylactic acid coming from waste of corn. We have recycled polypropylene; we have recycled HDPE; we are offering the possibility for a pharmaceutical company to get a package that is fully or partially sustainable. So using a limited amount of non-renewable sources goes a long way towards meeting the directives that the European Union is trying to implement right now."

In addition to their recycled and bio-based products, Bormioli Pharma has created materials that actively reduce emissions via carbon capture, as explained by Sentimenti:

"We have in our product range also a 'carbon capture PET solution'. This is a polymer generated by using as a primary component the carbon dioxide captured from the environment, whereby the product is not generating any kind of CO2 but through a very innovative process contributes to reducing the amount of this global warming gas. CO2 collected is then transformed through fermentation into materials (MEG) used for production of PET."

One aspect of sourcing that contributes to emissions is of course the energy used in the synthesis of raw materials, and to transport the materials to manufacturing facilities ready for the next step. The elements used in the chemical synthesis of materials for components including APIs and small-molecule drugs include those derived from carbon-based fossil fuels such as petroleum [17]. Unfortunately, figures on how much carbon is used in these processes are not available, something that will need to change as the industry strives to quantify their impact and reduce it.

"We are offering the possibility for a pharmaceutical company to get a package that is fully or partially sustainable. So using a limited amount of non-renewable sources goes a long way towards meeting the directives that the European Union is trying to implement right now."

Andrea Sentimenti, Marketing & Innovation Director, Bormioli Pharma

Prescription Pollution:

The Environmental Impact of Pharma Manufacturing

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The Environmental Impact of Pharma Manufacturing

In the supply chain, one of the most obvious areas where the contribution to greenhouse gas emissions is high is in the manufacturing sector [18]. This mostly includes scope 1 emissions and scope 2 emissions through energy use.

In the manufacturing of both small and large molecule drugs, very precise processes occur, which leaves little room for manoeuvrability in reducing energy consumption.

William Cashin from CordenPharma explains how energy is used in their production line: "For aseptic manufacturing, the key energy demand is the GMP need to protect

the medicine from (particulate) contamination. Our cleanrooms (HVAC) as well as autoclaves (sterilisation) and depyrogenation tunnels on the fill and finish production lines use a lot of energy. For our peptide and oligonucleotide API production, plant synthesis equipment and specialised equipment such as lyophilisers at commercial scale would be the most energy-intensive operations."

However, many companies are using ingenious techniques to cut down on this aspect or compensate as best they can, as Cashin states:

"At CordenPharma we are investing in new technologies. One example is our green purification Supercritical Fluid Chromatography (SFC) at Chenôve, France. This investment is intended for lipids (mRNA) and cell and gene therapies – a growing target focus area for our customers. Our SFC uses reclaimed CO2 coupled with online carbon dioxide recycling to virtually eliminate emissions."

Coles notes that collaborations can help to make the application of new technologies more accessible throughout sourcing and manufacturing:

"BioPhorum is supporting the interface between raw material and consumable suppliers in the biomanufacturing industry, by seeking to improve sustainability performance transparency and improve decision making for biomanufacturing. We are also looking at the operational efficiency of the biomanufacturing process. The industry is making a shift to renewable energy and pursuing a program of electrification. Alongside this we will need to reduce our demand for energy which is where collaborations like BioPhorum can play a critical role.

In time we may find that we need to convene the conveners and build a clearer understanding of the important roles we each play – to avoid duplication or contradiction that will deplete scarce sustainability resources and create inertia through confusion."

The **ACS Green Chemistry Institute Pharmaceutical Roundtable** is an organisation striving to integrate green processes into the pharmaceutical supply chain to ensure environmental sustainability and a more secure business model [19]. The Roundtable acts as a resource for its

members, with a plethora of green chemistry tools and educational materials.

Internally, pharmaceutical companies, such as Bristol-Myers Squibb, are engaging more with the use of green chemistry by using alternative solvents that are safer and lead to a reduced carbon footprint [20].

Arias furthers this, suggesting that companies can lobby for even wider-reaching changes:

"Companies can form supplier networks and reform procurement to incentivise greener technologies. For example, a large component of manufacturing emissions comes from the use of electricity. If the national grid allows, switching to a renewable energy source can reduce emissions in a meaningful way."

Many companies are building more environmentally friendly manufacturing plants in the form of biomanufacturing plants. By using the latest technology and equipment they have the capacity for higher cellular productivity and cell densities, leading to smaller bioreactors and even single-use bioreactors made from a sustainable disposable plastic; this allows companies to build smaller, more efficient plants [21].

Governments are stepping up to encourage these sorts of developments, with the USA increasing investment in biotechnology and biomanufacturing initiatives, under the guidance of President Biden. The National Biotechnology and Biomanufacturing Initiative aims to strengthen supply chains through the use of biotechnology and expansion of domestic biomanufacturing, furthering innovation and growing the number of bioproducts they are bringing to the market [22].

These changes in processes, flexibility, technological advances, and subsequent increase in efficiency will also help to make the supply chain more resilient, and therefore more stable in the face of future disruptions such as those seen during the COVID-19 pandemic and the war in Ukraine [14].

By improving specific aspects of manufacturing, the ripple effect will enhance the overall sustainability of the supply chain.

Distribution:

Delivering a Greener Future

Distribution:

Delivering a Greener Future

Cold-chain shipping is necessary for the transport and distribution of many medicines, such as vaccines, and uses a large amount of energy for running refrigerated vehicles, as well as the emissions produced by the vehicles themselves.

Shipping can be made more sustainable by increasing the amount of green fuels used [23]. By using biofuels made from hydrotreated vegetable oil in diesel vehicles, emissions can be reduced by 90% compared to regular diesel-fuelled vehicles [23].

As the pharmaceutical industry moves forward into a new technological age, adopting Industry 4.0 practices throughout the chain, this will have a large impact on the

In a recent **podcast** with Sanjay Sharma, Global Head of Manufacturing at Dr Reddy's, Sharma explains that through the digitalisation of processes operations can become more predictable and more consistent, meaning companies don't have to rely on 'rush' orders of product to the customer and at **Dr Reddy's** this led to an almost 20% reduction in carbon emissions by changing from air freight to sea freight [24].

Nearshoring will be key to reducing the emissions from transporting pharmaceutical products. It can also help to mitigate the risks associated with long distance transport of goods due to climate change, such as adverse weather events or the spread of disease incapacitating the workforce as we saw with the COVID-19 pandemic [25]. With manufacturing plants being built *in situ* in countries, getting the medicines to the consumer will involve much shorter journeys, less air travel, and less time. Although a large investment to begin with, which does seem less accessible for smaller pharmaceutical companies, the long-term financial advantages are undeniable.

Different countries and regions have different pharmaceutical needs, so prioritising the most in-demand drugs for the area is logical and advantageous in providing those populations with faster and more consistent care. Different regions also have to follow different environmental regulations; by having production *in situ* there will be a greater alignment of regulations and this will increase compliance to legislature [11].

Conscious Water and Waste Management

Conscious Water and Waste Management

Water is an integral part of the pharmaceutical supply chain with extensive use in the manufacturing stages for drug production, cleaning, and cooling. Currently, the pharmaceutical industry is responsible for 23% of the world's water usage [25].

This usage is also relatively wasteful; not only does this increase water consumption, contributing to water shortages, but there are risks in regard to water quality and it leaves the industry vulnerable if there are water shortages due to other consequences of climate change.

Responsible waste and water management, including water-saving policies and water/waste recycling, are

becoming a priority in the industry. However many companies are still hesitant due to the economic cost to the business of implementing such strategies.

Cashin from CordenPharma encourages looking at these issues from a different perspective to overcome them:

"Ideally, decouple waste elimination and water use from business growth so the economic imperative to grow your business does not hand-in-hand lead to more waste net to net. At a CDMO, this requires customers to openly approach capital investment with a different perspective than yield."

Waste management throughout the supply chain is not only imperative to reducing the environmental impact at various stages, but it also can help to increase efficiency and reduce costs for companies in the long term.

Pharmaceutical use has increased in the last 20 years and is predicted to only increase further from 42% to 68% in the next few years in the consumption of pharmaceutical products. This means, as demand increases, so will supply, which in turn would mean an increase in waste. Waste can take the form of leakage of pharmaceutical materials into the environment, most commonly through water systems, then at the end of the supply chain when medicines are not used, or not disposed of properly [7].

Waste in water systems can contribute to wider concerns such as a decrease in biodiversity and antibiotic resistance; leakage of APIs can have unplanned effects on animals and organisms in the freshwater system, even at low doses [25]. Wastewater plants are currently not equipped to filter out pharmaceutical waste leaving this as a yet unimpeded risk [7].

The WWF in conjunction with AstraZeneca outlines 6 opportunities for water stewardship that pharmaceutical companies would be encouraged to adopt. The areas they suggest focusing on include reframing water management to water stewardship, with the hope of encouraging collaborative approaches to find water-safe solutions; taking greater control of water quality and confronting this throughout the supply chain; increasing companies'

understanding of the risks associated with raw materials; adopting a more shared responsibility role in regard to shared water basins when it comes to considering future flooding risks or water shortages; and finally in incentivising governments to build a stronger network of regulation whilst increasing education and awareness [26].

Infamously, the use of chemicals and chemical waste can have a significant impact on the environment; although safety surrounding chemical use in pharma has been vastly improved over the years, further reductions in the use of chemicals to produce pharmaceutical products, as well as better management of chemical waste, would only be beneficial [27].

Downstream in the supply chain, processes can be substituted to reduce waste such as with the use of green chemistry. The use of biocatalysts – either naturally occurring or engineered enzymes – instead of synthetic chemicals can also help to reduce waste [20]. An example of this can be seen with **Merck,** where they were granted approval to use a biocatalyst in the making of an API for

a diabetes drug, leading to a reduction in waste from the whole process by 19% [20].

At the product's end-of-life, many medicines aren't even used by consumers – up to 50% of prescribed drugs are disposed of incorrectly [7]. More education, better dimensioning of products, and more efficient disposal processes are needed to reduce waste at this stage in the supply chain and the subsequent scope 3 emissions.

Again, the implementation of digitalisation through pharma 4.0 can help to decrease waste and energy consumption by creating a system that is more stable, ensuring operations are running in a sustainable manner and increasing efficiency [24].

The Future of the Pharma Industry:

Working Towards a Healthier Planet

The Future of the Pharma Industry: Working Towards a Healthier Planet

The path forward is well mapped out, with a myriad of targets and goal-setting initiatives, all with a view to guiding stakeholders in the pharma supply chain and the wider industry on their way to being more sustainable; measurable checkpoints along the way will help to keep them accountable and to ensure they are making the greatest impact.

Many experts have already agreed that the target set out in the Paris Agreement (2015, to come into play in 2016) should realistically be amended, as even the slightest increase in temperature could have further devasting effects. Currently the agreement limits "the increase in the global average temperature to well below 2 °C above pre-industrial levels" with an ideal situation "to limit the temperature increase to 1.5 °C above pre-industrial levels." [10]

World leaders have since agreed that this 1.5 °C limit must be achieved and not surpassed within this century; their timeline shows that for this goal to be attainable greenhouse gas emissions must peak by 2025 and be in a continuous state of decline, hitting a figure of 43% decline, by 2030 [10]. It is these figures that have encouraged the race to Net Zero, and what many companies are basing their net zero emissions targets on.

Arias added:

> **"In the top 100 companies by revenue in 2022, 41 reported time-bound commitments. Similarly, 13 companies pledged net zero or carbon neutral commitments across their direct and indirect emissions."**

Although this is an encouraging commitment from some of the most influential pharmaceutical companies in the world and will certainly go a long way to reducing carbon emissions in the sector, such a commitment needs to be coming from 100% of pharma companies. It needs to be a commitment shared across the board, and it needs to be addressed now if there is any hope of limiting the peak in emissions to 2025.

Some aspects that companies are basing their goals around include:

"Decarbonising the supply chain is the big goal for our industry over the next 10–20 years. It's a huge, complex challenge, but one that is driven by the rise of the ESG agenda for investors, government regulation, and customer expectations, not to mention the environmental need in the face of climate change risks.

Companies themselves have committed to reducing their own scope 1 and 2 emissions for a number of years, but the majority of their emissions are found in the external supply chain. Therefore, engaging with the external supply chain on how they can also measure and reduce their own emissions is central to achieving decarbonisation," stated Vande Velde from the PSCI.

Coles also notes decarbonisation as a crucial aspect to work on:

> **"BioPhorum is addressing three areas in its roadmap: data integrity and transparency, decarbonisation and circularity.Our work around decarbonisation aims to remove the carbon load from the biopharmaceutical value chain – examining raw material extraction, biomanufacturing, logistics, and product use and end-of-life."**

Decarbonisation of the supply chain, as Coles states, is an essential part of achieving Net Zero, and this must happen throughout the value chain, from sourcing to distribution of medicines [4].

Coles from BioPhorum continues to highlight the importance of circularity:

"Regarding circularity, the industry and society is less mature on this topic. The intent is there, all sustainability professionals recognise that just through decarbonisation initiatives to shift to green energy and reduce embedded carbon we are not going to meet the targets. However, we need to understand what circularity means in an industry context and then track our own performance. This is a significant and somewhat daunting agenda that challenges our industry consumption habits and existing business models. It also demands a level of engagement with other sectors we have not previously considered – the recycling infrastructure for example."

In a recent webinar on creating a circular economy for the pharmaceutical packaging industry, Félice Pachot, Health Market Manager at Adelphe, expanded upon the concept of the circular economy and supporting BioPhorum's view, stating that cross-industry partnerships are essential; manufacturers and marketers should be responsible for their product and packaging's end-of-life impact, which would incentivise more environmentally friendly practices and product design further up the chain [28].

Legislation and regulations could be put in place to make eco-design of packaging obligatory in the future, but Pachot doesn't see this as happening any time soon so encourages companies to think ahead and use this to their advantage to become industry leaders in more sustainable drug manufacturing and packaging solutions [28].

The final area that Coles comments on is the availability of data.

"The third area is like the beating heart that underpins everything we do: the transparency of data. As an industry, we have started to improve data at an organisational level, but we need to collect and share better data at the product level to allow effective decision-making to drive improvements across the value chain."

There is a definite lack of data on the emissions from the pharmaceutical industry. There are a few groups that are starting to categorise countries' emissions per sector [29], including the pharmaceutical industry, but a further breakdown of the energy usage and carbon emissions from the different factions of the supply chain are minimal. Data that is publicly available is that which are volunteered by pharmaceutical companies themselves, who see the need for transparency to be able to reduce emissions in line with the targets set out in the **Paris Agreement** [10].

Cashin outlines just how joining initiatives can help to increase this transparency and reporting on targets:

"In December 2022, CordenPharma publicly committed to joining the **Science-Based Targets initiative** (SBTi) process. This is a best practice approach to share our targets externally with SBTi, and when validated, publish them in an annual report so all stakeholders (customers, employees, communities, and other stakeholders) gain transparency into our efforts to reduce carbon emissions."

New regulations are being set out to increase ESG compliance in the pharmaceutical industry, such as the corporate sustainability due diligence directive from the EU Commission, which aims to nurture sustainable and responsible practices, securing human and environmental concerns at the heart of companies' decision-making [30].

Arias from IQVIA commented:

> **"There is an external component where the pace of innovation outside a pharma company's control has to speed up to provide viable green alternatives in energy supply, green vehicles and other technology. Areas that a pharma company can influence, include building supplier networks to align standards across the many stakeholders, and reform procurement to incentivise greener innovation."**

Although many pharmaceutical companies are acknowledging that this must be done, there are challenges to making this work. Nicola Coles from BioPhorum sets out some of the most pressing difficulties:

"I see three key challenges:

1. Leadership – moving to a sustainable level of performance requires a fundamental shift in thinking – it demands us to let go of old models of consumption, of growth, of success – it demands a reframe of our core purpose. This requires leadership from the top. With strong leadership and a commitment to integrate sustainability into the heart of the organisation we can truly unleash our talent to tackle the most pressing issues of our time. Given the relationship between climate change and global health – our leaders need to fully own the sustainability strategy of their organisation for there to be congruence with the broader aims of advancing global health. Leaders can model their intent by bringing sustainability to the core of decision-making from the way they incentivise teams to the way business cases are approved and funded.

2. Data – The absence of good data across the industry in critical areas can make it difficult to make good decisions

– in fact, it can paralyse action. That's why working together to harmonise data collection standards and create industry benchmarks is so important.

3. Capability and capacity – We need to move beyond the idea that sustainability can be an annex to a person's day job. We are getting there, and I strongly believe we will get to the point where sustainability is fully embedded in everyone's role and it will become central to how we think about operational excellence – it will simply be the way we do good business. But until that time, there requires a level of investment to increase the capability and capacity, at every level within an organisation so that we create the freedom and confidence to innovate as we adapt to our new operating environment."

Vande Velde weighed in on how achievable some of these goals really are in practical terms:

"We believe that decarbonisation is achievable, but only through collaboration across the whole value chain. These are shared problems that can only be solved through shared solutions. Companies need to understand the scale of their scope 3 emissions and engage with their suppliers as a partner on the road to decarbonisation. Suppliers themselves will also need to play their part and cascade their emissions reduction plans down to their own suppliers too.

Education is the first step and tools like the **PSCI Decarbonisation Pathway** can help suppliers understand both where to start and where to go. Furthermore, initiatives like Energize and the Sustainable Markets Initiative's Health Systems Task Force are enabling companies and suppliers to join forces through an industry-wide approach."

BioPhorum also see the goals as achievable, despite the challenges, as Coles puts it:

"I would argue that our goals are fully achievable. The pharmaceutical industry has the resources to become fully sustainable at its disposal, we have the brain power, the guiding purpose to improve health and the finances to match our ambition. We only need to look at the COVID response to give us confidence that we can turn things around when the pressure is on. With the right leadership, the industry can surpass the goals it has set and become

an exemplar for other industries."

In a study by Chen *et al,* they found that by using certain optimised models for pharmaceutical development processes, energy consumption could be reduced and confirming that these targets, if achieved, will make a difference:

"Using the nominal batch operations as a basis, the optimised batch operation results in a 71.7% reduction of energy consumption, whereas the optimised continuous case results in an energy saving of 83.3%." [31]

Conclusions from COP27 implied that although many contributors to the field were indeed setting out private goals and commitments themselves, there was little to be done to keep them accountable and on closer scrutiny, the paths to these goals could lack a certain robustness. Therefore, the United Nations Secretary-General engaged The High-Level Expert Group on the Net Zero Emissions Commitments of Non-State Entities to create a

transparent framework to model plans to achieve Net Zero, that a range of players should be able to follow [32].

Having a credible framework for pharmaceutical companies to follow, would help to increase the amount of data available on the progress of such plans, reducing greenwashing, and working towards the implementation of regulations across the industry. The report lays out ten recommendations, covering how to set out a path to Net Zero, addressing how to replace the use of fossil fuels with renewable energy sources, how companies can use lobbying and advocacy, the relationship between nature and people in the context of such a transition and how to invest in establishing a greener future [32].

Arias stated that to avoid greenwashing and see discernible change, the industry needs to be more forthcoming:

"Public disclosures, external validation and working with rating agencies to ensure credible targets are being set and progress is captured accurately is an important way of tracking real impact."

Harking back to the aim of reducing emissions by approximately 45% by 2030, the reality shows that emissions are in fact more likely to increase by around 11% [32]. These figures are hidden behind a smokescreen of pledges made by the industry. However, scrutiny from the public and experts in the field has led to the debunking of several pledges that have no discernible effect on reducing emissions. The High-Level Expert Group gives several recommendations, based on concrete and, thus far, successful plans such as the **Race to Zero** and **The Science Based Targets initiative,** on how to ideate pledges that do not contribute to greenwashing [32].

CordenPharma are spirited in their commitments and believe that other companies should adopt similar goals with as much ardour.

Cashin commented: "Commit to SBTi. In our view, Science-Based Targets go beyond marketing jargon into robust objectives which are tangible and measurable. As scientists and engineers, this approach most resonated internally with our strategic objective."

Conclusion

The pharmaceutical industry has an undeniable impact on the planet in contributing to climate change, but the industry is also in a good position to make positive and effective changes to reduce this impact. Through continued collaboration, comprehensive reporting, and genuine efforts to cut down on emissions, the future of sustainability in the pharmaceutical supply chain is looking bright.

Cashin shares CordenPharma's very tangible enthusiasm:

"Successful companies have harmony between their production sites, employees, the communities in which their production plants are based, and with the wider macro-economic factors including their suppliers and customers. As our customers respond more quickly now to the demands of their shareholders and employees – we start to see responsible sourcing becoming much more important than in the past. We are ready to play our part."

The pharmaceutical industry has a real chance to exemplify how to act in regard to the environment, paving the way for other industries to follow suit. Coles paints a picture of what BioPhorum hopes to see from the industry in the coming years:

"It will be powered by renewable energy. We will have more efficient manufacturing processes, so we may have shift, for example, to continuous manufacturing, inline monitoring, and real-time release to reduce waste. To reduce the carbon load of transport burden, we may see a shift to local production, this could be local production of supplies into the biomanufacturing industry or the drug manufacturing itself. There will be less reliance on virgin material – for plastics, water, and packaging – as we shift to more circular industry model. Ultimately, as healthcare providers shine a light on their own scope 3 emissions, there will be a move towards care pathways and therapies that require fewer patient journeys. To be successful and achieve this level of change in the industry we must start to think about sustainability how we do in life – it can no longer be a side-line activity managed by "the green team"."

Sentimenti sums up the general feeling from the industry quite nicely: "We should be able to save life or to preserve life, but it is mandatory to preserve also the environment where those people are living."

Contributors

With thanks to our contributors for their time and expertise

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Coles joined BioPhorum in 2019. Initially focusing on raw materials, she has worked to connect technical, supply chain, and regulatory experts to develop a strategy to future proof raw materials for the biologics industry. She now leads BioPhorum Sustainability.

Her passion is creating the link between executive strategy, technical capability, and front-line delivery. A qualified coach, Coles works with behaviours, mindsets, and capabilities to develop impactful change programs.

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Cashin is responsible for global quality, global safety/ health/environment, and legal compliance functions.

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Sentimenti has been a member of the senior leadership team for 3 years and runs the marketing innovation department globally. The main function of the department is investigating and understanding the needs of the customers and transforming those needs into ideas and then into the form of final solutions or products. Bormioli Pharma has always been a pioneering company and a company that is always working towards changing the status of the pharmaceutical packaging industry.

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