BioPhorum

INDUSTRY POSITION STATEMENT

Developing a harmonized approach to product carbon footprint data for the biopharma industry

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About BioPhorum

BioPhorum's mission is to create environments where the global biopharmaceutical and device industry can collaborate and accelerate its rate of progress, for the benefit of all.

Since its inception in 2004, BioPhorum has become the open and trusted environment where senior leaders of the biopharmaceutical industry come together to openly share and discuss the emerging trends and challenges facing their industry.

Growing from an end-user group in 2008, BioPhorum's membership now comprises top leaders and subject matter experts from global biopharmaceutical manufacturers and suppliers, working in both long-established and new Phorums. They articulate the industry's technology roadmap, define the supply partner practices of the future, and develop and adopt best practices in drug substance, fill finish, process development and manufacturing IT.

In each of these Phorums, BioPhorum facilitators bring leaders together to create future visions, mobilize teams of experts on the opportunities, create partnerships that enable change and provide the quickest route to implementation, so that the industry shares, learns and builds the best solutions together.

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Commitment

The key goal of the biopharma industry is to speed up development of innovative medicines and ensure availability of these medicines to a greater number of people. The longevity of the biologics industry relies on sustainable practices. In this context, driving environmental sustainability is a priority.

The BioPhorum Environmental Sustainability Roadmap[1] outlines the BioPhorum Sustainability overall vision of improving patient health by providing biopharmaceuticals while respecting the planet and responsibly using its resources.

License holders, contract development and manufacturing organizations (CDMOs) and key suppliers commit to defining a common industry approach for calculating and exchanging environmental impact data by developing a framework for self-declaration on product sustainability performance: product carbon footprint (PCF) for the biopharma industry.

Figure 1: Generic drug product lifecycle showing cradle-to-gate and cradle-to-grave approaches, with each step contributing to overall product footprint

PCF is defined as "the most established method for determining the climate impact of a product, considering the total greenhouse gas (GHG) emissions caused to produce a product, expressed as carbon dioxide equivalent. The PCF can be assessed from cradle-to-gate (partial PCF) or from cradle-to-grave (total PCF[2])".

BioPhorum Sustainability's PCF working group recognizes climate change as an urgent environmental issue where efforts to decarbonize across the industry will require collaboration and common calculation methodologies. For these reasons, the focus of this proposal is on PCF. While GHG emissions are the primary scope, the framework outlined here may be expanded to include additional impact categories in the future.

Currently, many biopharma companies have committed to Scope 3[3] (indirect) GHG emissions reduction targets and/or engaging with suppliers to improve Scope 3 accounting. Industry relies on spend-based methods for estimating Scope 3. However, these methods are generally considered to yield inaccurate insights when making decarbonization decisions. By adopting a more granular calculation method, uncertainty is reduced and direct actions to reduce impact can be identified.

The emphasis on transparency enables a deeper understanding of the GHG emission hotspots in the supply chain. Equipped with this knowledge, license holders, CDMOs and suppliers can take a collaborative approach to identifying opportunities for emissions reductions.

Adopting this proposed framework demonstrates a company's commitment to environmental responsibility and helps build credibility and trust with other stakeholders. As part of this commitment, member companies agree to pilot this framework to understand its effectiveness, identify challenges and limitations, and define and refine the calculation methodology based on practical feedback. This will ensure that the framework is robust, reliable and fit for purpose before wider adoption. These pilots also serve as tangible demonstrations of the value the PCF framework can provide. By showcasing real-world examples, companies can demonstrate the benefits of adopting the framework, building confidence among potential adopters and encouraging wider implementation.

1.0

Context

The need for action on environmental sustainability is increasing and evident in recent announcements. In January 2022, the UK National Health Service (NHS) proposed an environmental impact rating (EIR) system for pharmaceutical manufacturers: "The EIR would consider the entire pharmaceutical lifecycle. This covers manufacture, sterilization, packaging, and waste products. Stages that take place outside of the UK must be accounted for"[4].

By April 2028, the UK NHS will require product-level carbon footprints for any products supplied to the NHS, not just medicines[5].

In November 2022, the Sustainable Markets Initiative (SMI) Health Systems Task Force, a public-private partnership launched at COP26, announced plans to align on a standardized framework to calculate GHG emissions "[…] across the care pathway and will publish product-level lifecycle assessments (LCA) data to increase transparency on treatment emissions.[6]"

As of mid-2023, 85 biopharma companies* have committed to GHG emissions reductions via the Science-Based Target Initiative and most of these companies have included a quantitative Scope 3 reduction target in that commitment. To meet their Scope 3 reduction target, biopharma companies will require GHG accounting on a sufficiently granular level to capture GHG savings. PCFs can be the foundation of this accounting.

While these are just a few examples of public and private entities calling for action on sustainability transparency in healthcare, anticipation of future sustainability regulations has many healthcare companies and supply chain partners proactively addressing their environmental footprint.

The Pharmaceutical Life Cycle Assessment Consortium (Pharma LCA), with support from the SMI, is developing industry-wide product category rules (PCRs) to allow pharmaceutical companies to evaluate the environmental sustainability of drug products. The development of these LCAs will require product lifecycle inventory (LCI) data for consumables and original equipment manufacturer (OEM) components. Starting with PCF in this framework and expanding in the future to include additional impact categories, the scope may align well with these PCRs, by improving inventory data and allowing more accurate LCAs for pharmaceutical products.

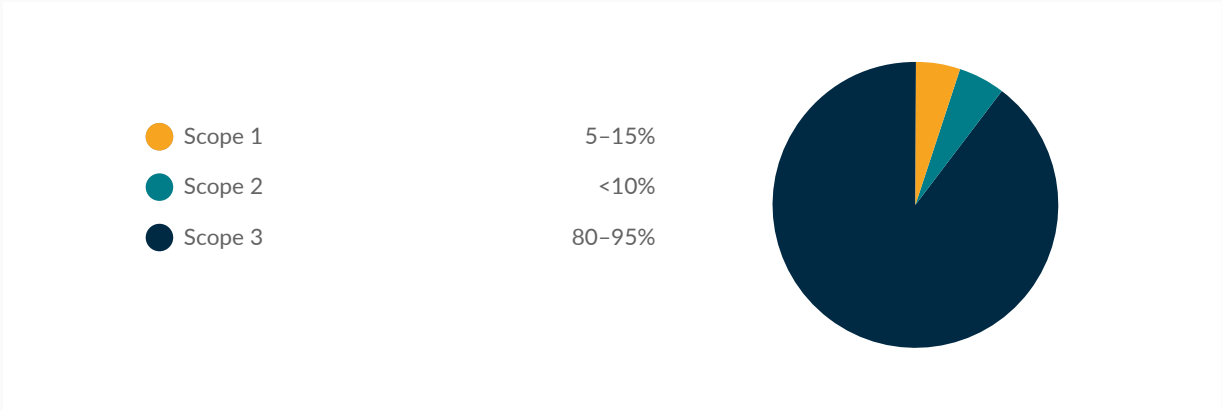
*https://sciencebasedtargets.org/companies-taking-action#dashboard

2.0

Use cases for product carbon footprints

Currently, the biopharma industry, like many other industries, is facing the complex challenge of GHG transparency along the entire value chain. For downstream value chain players, such as license holders and brand owners, this challenge increasingly affects their Scope 3 emissions, which often represent around 80–95% of their overall climate change impact, with purchased goods and services making up ~65% of the Scope 3 emissions (Figure 2).

Figure 2: Average greenhouse gas (GHG) emissions for biopharma companies, by scope



Note: data taken from recent environmental, social and governance reports from 16 biopharma companies

Limited value chain GHG transparency is often the result of many factors:

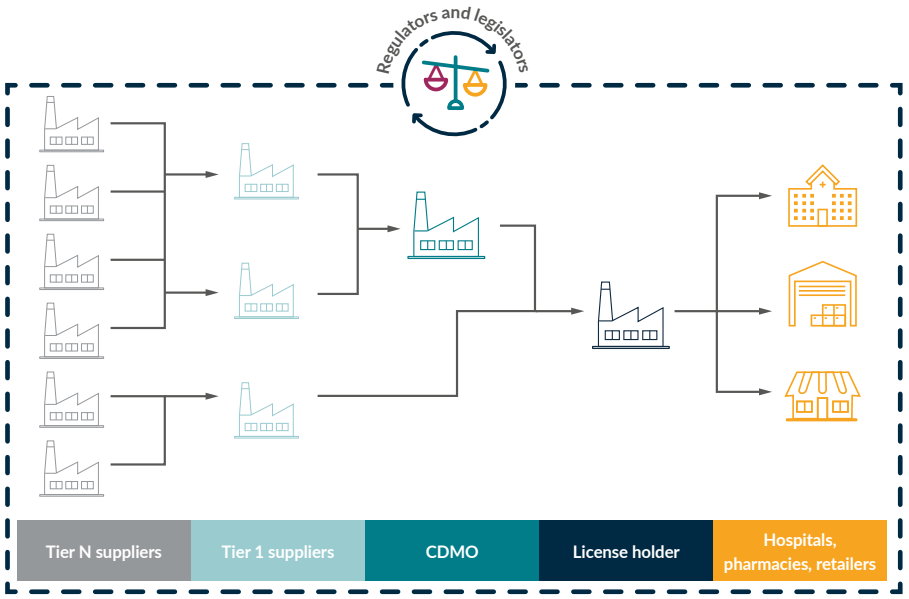
- A lack of accurate primary data
- Continuously evolving (and sometimes conflicting) calculation methodologies that are open to interpretation
- A wide range of sustainability maturity levels among organizations
- Inadequate resourcing of lifecycle assessment expertise
- Commercial sensitivities restricting broad data sharing
- Challenges in coordinating complex, multi-tiered supply chains.

Without increased value chain GHG emissions transparency, many companies are forced to adopt spend-based models for estimating Scope 3 emissions, which ultimately provide limited accuracy and limited insights for future GHG emission reduction opportunities.

PCFs are a key metric to unlock value chain GHG emission transparency and to enable organizations to develop GHG emission reduction roadmaps to meet their targets. With increased calculation and sharing of PCFs in the biopharma value chain, industry can gain clarity on climate change impact hotspots to drive decision-making and a rapid net zero transformation.

PCFs can also provide other benefits to different parts of the biopharma value chain, as shown in simplified form in Figure 3. For example, PCFs, along with other impact categories, can serve as a key quantitative metric in the eco-design of new drug products. Eco-design, also often called 'sustainability by design', involves assessing potential environmental impacts of a product early in the development process, including considering the manufacturing processes, green chemistry principles, raw material choices, cold chain requirements, etc. and balancing these impacts with other product requirements such as cost, technical specifications, safety and shelf life. For example, the European Commission estimates that over 80% of all product-related environmental impacts are determined during the design phase of a product[7].

Figure 3: Simplified value chain graphic



Value chain benefits of calculating PCFs

Benefits of calculating product carbon footprints (PCF)					
Support eco-design of products across the value chain	Tier N suppliers	Tier 1 suppliers	CDMO	License holder	
Improved Scope 3 accounting		Tier 1 suppliers	CDMO	License holder	Hospitals, pharmacies, retailers
Inform procurement decisions		Tier 1 suppliers	CDMO	License holder	Hospitals, pharmacies, retailers
Identification of hotspots	Tier N suppliers	Tier 1 suppliers	CDMO	License holder	Hospitals, pharmacies, retailers
Facilitate collaboration on emission reduction	Tier N suppliers	Tier 1 suppliers	CDMO	License holder	
Support investment decisions	Tier N suppliers	Tier 1 suppliers	CDMO	License holder	
Meet regulatory requirements				License holder	Hospitals, pharmacies, retailers

3.0

Next steps

Members of BioPhorum Sustainability are committed to embedding sustainable approaches into biopharma industry products and services.

They have established a PCF working group of subject matter experts, overseen by a leadership team of senior industry representatives from multiple functions providing governance, guidance and strategic direction.

Through the development of this framework for self-declaration on product sustainability performance for the biopharma industry, the group aims to deliver:

- A harmonized industry approach to calculating PCFs of supplies into the drug manufacturing process, that aligns to and complements existing standards and methodologies (e.g. the Together for Sustainability PCF Guideline)
- Additional guidance specific to the biopharma industry where this is required
- A framework that ensures the industry is well positioned and equipped to meet upcoming industry and regulatory requirements
- A clear industry commitment to tackling environmental impact in a holistic way and aligns to future industry guidance where applicable.

We hope this serves as a signal of industry commitment and we ask the wider industry to support this concept.

How can you get involved?

- Actively engage in our working group by contacting info@biophorum.com. Your participation and expertise can contribute to the development of a robust framework for our industry
- **Share this position statement:** share the benefits of a common framework and advocate for the framework within your industry and network
- Begin to consider future resourcing requirements related to GHG accounting and lifecycle assessment
- Engage your own supply chain to encourage data sharing
- Identify key people across your organization and begin to prepare for data sharing.

References

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