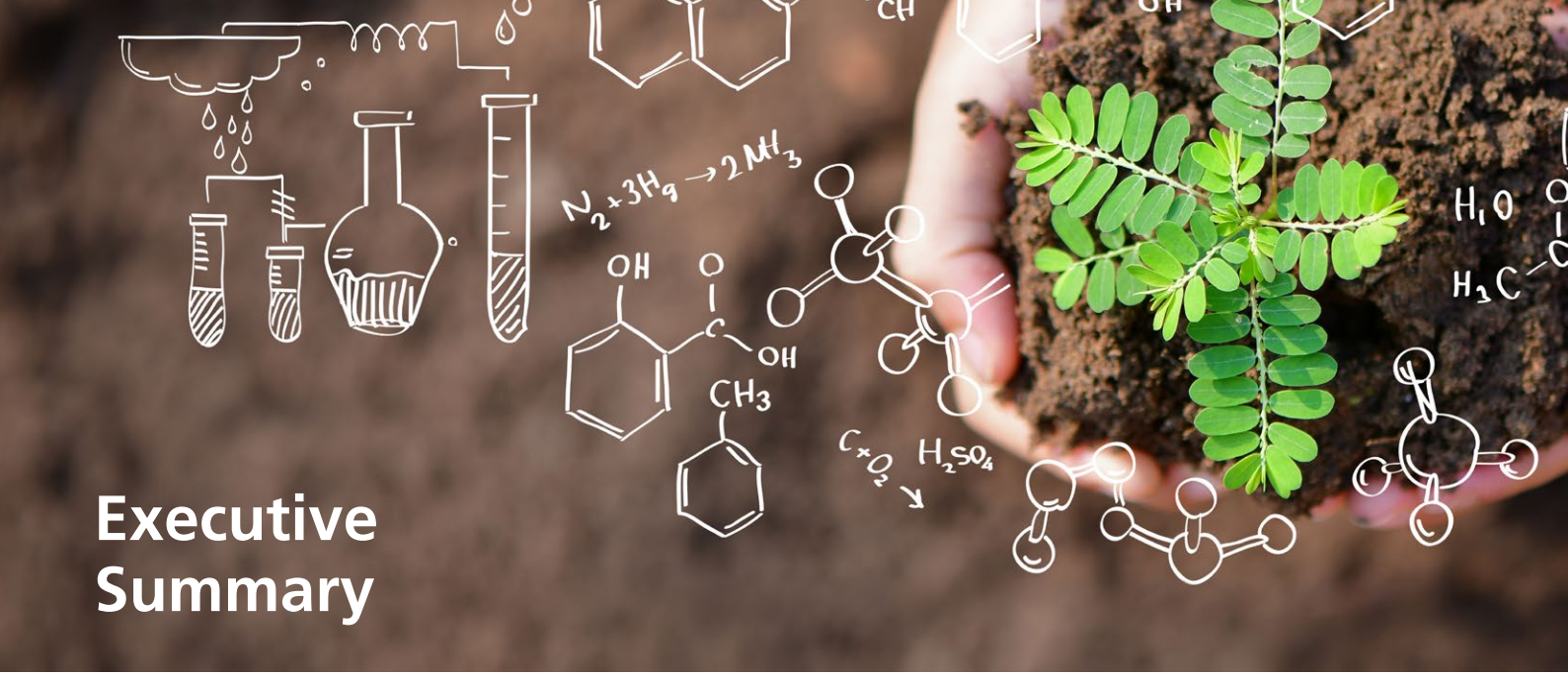
efpia

European Federation of Pharmaceutical Industries and Associations

Advancing Environmental Sustainability Assessment of Pharmaceuticals through Standardisation and Harmonisation of Product Carbon Footprint Assessment







Executive Summary

The innovative pharmaceutical industry as represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA) is committed to climate action and further environmental sustainability aspects.[1] Increasingly, policymakers, healthcare systems, buyers, and the wider society are calling for transparent, product-level environmental information, primarily Product Carbon Footprints (PCF), as the expectation for granular data grows across all industries.

To date, there's been an absence of harmonised PCF or Life Cycle Assessment (LCA)[2] standards tailored specifically to pharmaceuticals, leading to significant methodological discrepancies between companies, and resulting in inconsistent and potentially misleading results.

A widely accepted cross-national standard has yet to be established, despite the pressing need for standardisation and harmonisation. This gap has been recognised, and in response "PAS 2090:2025, Pharmaceutical products – Product category rules for environmental life cycle assessments"[3] – has been developed by key stakeholders across industry (e. g. Sustainable Markets Initiative, Pharma Environment Group), academia, and healthcare, together with the British Standards Institution (BSI) and with the co-sponsorship of NHS England and the Office for Life Sciences (UK). PAS 2090 is the first publicly available specification to establish harmonised Product Category Rules (PCR) for conducting LCAs and PCFs of pharmaceutical products. The standard was published on the 30th November 2025'. PAS 2090 sets minimum requirements for data quality, methodological consistency, and reporting, and is designed to be internationally applicable.

Without standardisation of environmental footprint methodologies across the healthcare and pharmaceutical sectors, several risks emerge, including:

- Reduced credibility of environmental claims and perceptions of greenwashing;
- Procurement decisions being shaped by methodological discrepancies rather than by the actual sustainability performance of products and operations;
- Regulatory inefficiencies from duplicated efforts and inconsistent data;
- Missing the opportunity to make progress towards sustainable products, innovation and collaboration.

[1] https://www.efpia.eu/media/554662/white-paper-climate-change.pdf

[2] LCA is a globally recognised method for evaluating environmental impacts, including the carbon footprint, across a product's life cycle [ISO 14044:2006].

[3] https://knowledge.bsigroup.com/products/pharmaceutical-products-product-category-rules-for-life-cycle-assessments-specification

EFPIA Ask

EFPIA, representing the innovative biopharmaceutical industry in Europe, calls on policymakers, regulators, and healthcare stakeholders:

Recognise
the importance of standardised transparency through the disclosure of PCFs,

Endorse
one internationally accepted standard in support of a harmonised approach addressing the risks of methodological variability;

Support
international cross-stakeholder awareness and collaboration.

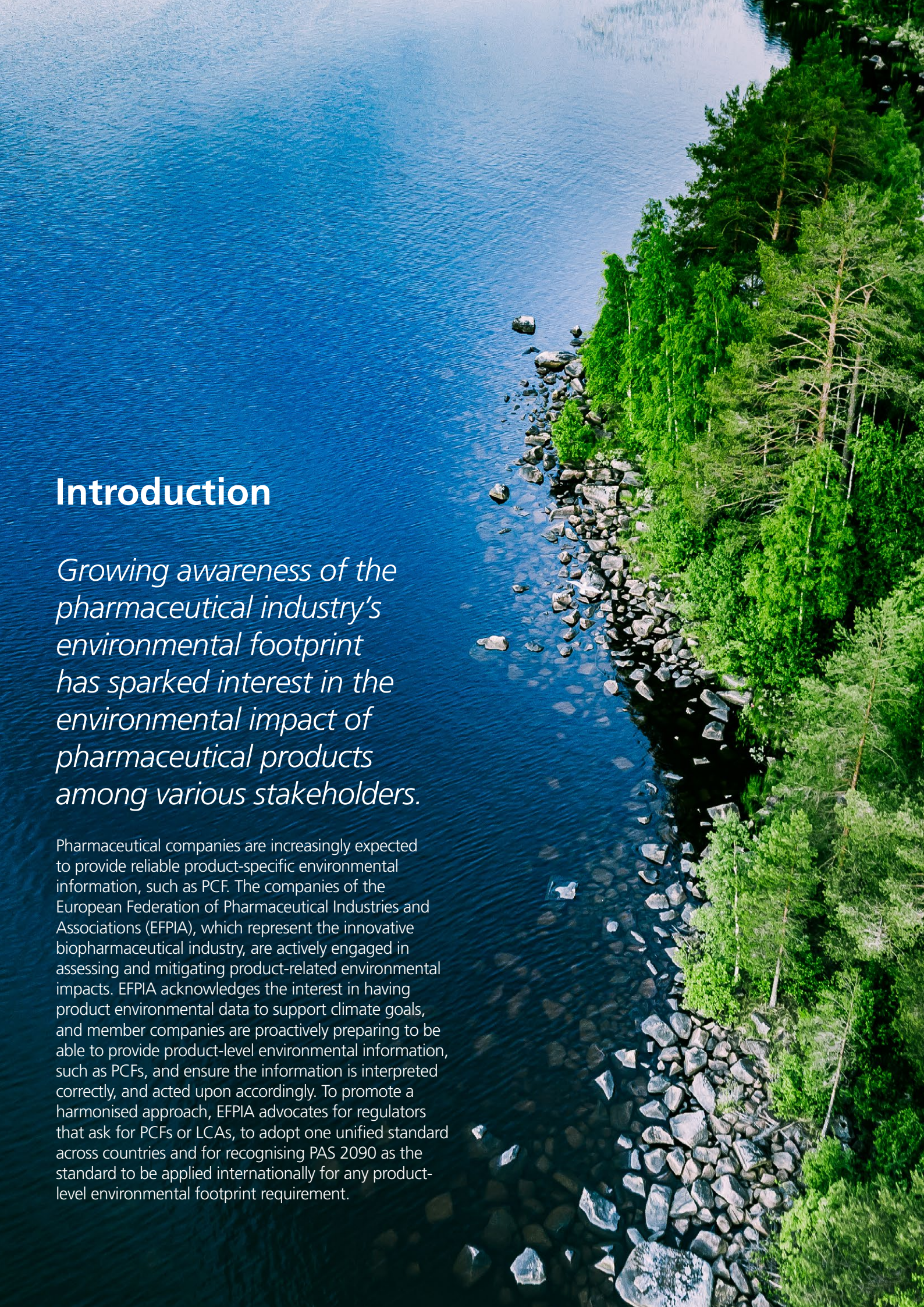
Increase
transparency and trust, support regulatory alignment, and accelerate the transition to more sustainable healthcare systems through a harmonised PCF methodology;

Recognise
that PAS 2090 is the most robust approach for pharmaceuticals, as it was developed independently and designed for international use with the support of stakeholders from academia, health authorities, NGOs, and the pharmaceutical industry (incl. suppliers);

Product Comparison:

EFPIA companies recognise that despite this standardisation, differences in data quality, data availability, and complex supply chains limit the direct comparison of PCF results of pharmaceuticals across companies.

EFPIA companies reinforce the need to contextualise product comparisons within the patient care pathway. The environmental and clinical impacts of pharmaceutical products are deeply intertwined with how, when, and where they are used across the continuum of care, and cannot be compared as a sole product.



Introduction

Growing awareness of the pharmaceutical industry's environmental footprint has sparked interest in the environmental impact of pharmaceutical products among various stakeholders.

Pharmaceutical companies are increasingly expected to provide reliable product-specific environmental information, such as PCF. The companies of the European Federation of Pharmaceutical Industries and Associations (EFPIA), which represent the innovative biopharmaceutical industry, are actively engaged in assessing and mitigating product-related environmental impacts. EFPIA acknowledges the interest in having product environmental data to support climate goals, and member companies are proactively preparing to be able to provide product-level environmental information, such as PCFs, and ensure the information is interpreted correctly, and acted upon accordingly. To promote a harmonised approach, EFPIA advocates for regulators that ask for PCFs or LCAs, to adopt one unified standard across countries and for recognising PAS 2090 as the standard to be applied internationally for any product-level environmental footprint requirement.

Background and Challenges

The methodology for assessing and reporting Greenhouse Gas (GHG) emissions at the corporate level is well-established, standardised and widely adopted[4]. In contrast, product-level environmental reporting in the pharmaceutical sector, particularly for life cycle-based metrics such as product carbon footprint, is still evolving:

- PCFs are a subsection of LCAs focusing on the carbon footprint only, whereas LCA assesses the environmental impact across multiple dimensions[5].
- PCF and LCA are defined in ISO14067 and ISO 14040-44, respectively for assessing the carbon footprint and environmental footprint of products across their entire life cycle[6]. These methods are the basis for, among others, the GHG protocol Product Life Cycle Accounting and Reporting Standard[7]. Given their wide recognition and use in similar sectors such as the fine chemical sector, PCFs and LCAs are the most robust methodologies for responding to stakeholders' requests for product-level footprints;
- While ISO and GHG protocol standards offer comprehensive, industry-agnostic guidance for conducting a PCF or an LCA, they do not specify the methodological choices or data requirements needed for specific sectoral product groups. Such specific rules exist for some sectors, but not yet for pharmaceutical products. As a result, methodological discretion across approaches is substantial, making it highly probable that PCFs would differ for the same product depending on the methodological choices made. Given the complexity and number of variables involved, it is also likely that methodological approaches will vary between companies, further contributing to inconsistency in reported environmental footprints.

A growing number of stakeholders and governments have acknowledged the need for standardisation of pharmaceutical product PCFs and LCA. The absence of such standardisation presents significant risks and imminent challenges for pharmaceutical companies, regulators, and customers alike, including:

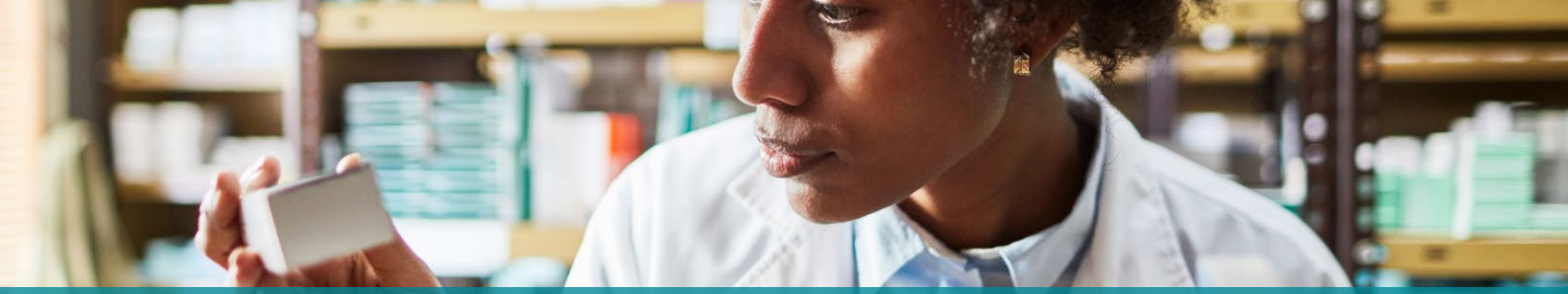
- Undermined credibility & engagement: Inconsistent modelling and reporting methodologies erode stakeholders' trust in environmental claims;
- Fragmentation & duplication creating regulatory uncertainties: The absence of a universal standard leads to siloed efforts, duplicated work, and missed opportunities for collaboration and innovation among stakeholders in the pharmaceutical sector and the wider healthcare industry. This also applies to policymakers when trying to develop effective sustainability regulations. The lack of harmonisation delays the development of coherent policies, creating compliance challenges across the EU and beyond;
- Increased workload and inefficiencies for regulators and companies: Inconsistent methods lead to multiple PCFs for a single product, requiring greater resources for modelling, regulatory verification and validation and an increased bureaucratic burden on the industry. This hinders the ability to identify industry-wide inefficiencies and environmental hotspots, limiting systemic improvements;
- Environmental performance: Methodological discrepancies can distort environmental performance metrics, which do not accurately reflect the company's true sustainability performance;
- Inconsistent Scope 3 reporting: Varying approaches to assessing the carbon footprint of products prevent downstream organisations from accurately incorporating them into their own Scope 3 emissions reporting.

[4] Standards & Guidance | GHG Protocol

[5] ISO 14067:2018 Greenhouse gases — Carbon footprint of products — Requirements and guidelines for quantification

[6] ISO 14040:2006 - Environmental management — Life cycle assessment — Principles and framework and ISO 14044:2006 - Environmental management — Life cycle assessment — Requirements and guidelines

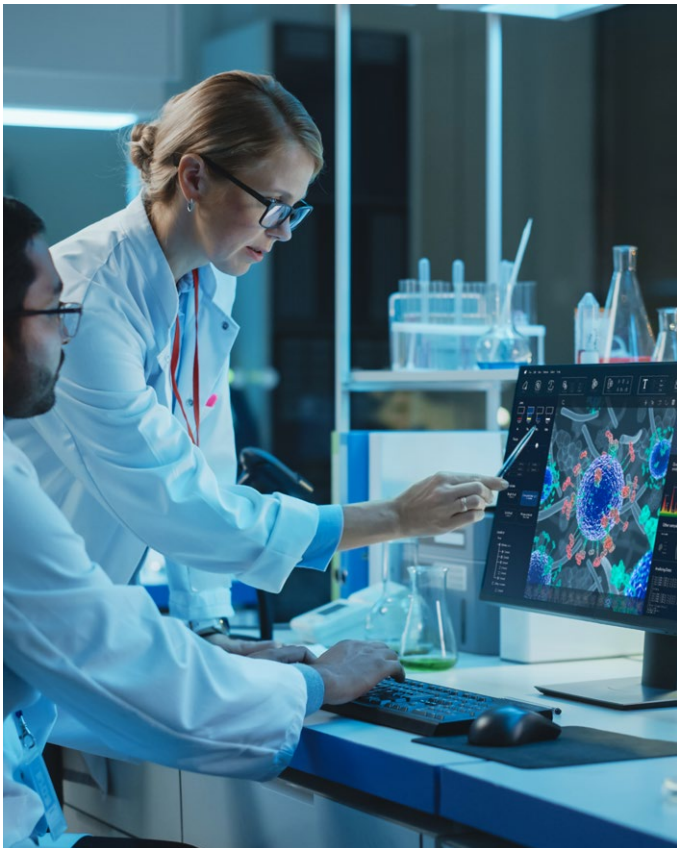
[7] Product Standard | GHG Protocol



Opportunities within Product Category Rules and the Standardisation of PCFs and LCA

Product Category Rules (PCRs) are supplementary documents to the main LCA standards[8]. They provide industry- or product-specific guidance and clarify methodological choices to ensure LCA are conducted in a consistent and harmonised manner across specific industries or product categories. This standardisation enables:

- Enhance transparency and accountability: Standardising methodologies for PCF and LCA improves transparency, credibility and accountability. It supports informed decision-making along the value chain not only for companies, but also for regulators, healthcare professionals and patients;
- Harmonising policy development and compliance: An internationally adopted standard offers legislators looking to integrate PCF requirements a robust methodological framework and allows companies to meet requirements and requests across markets adhering to a single standard;
- Streamlining and resource efficiency: The availability of ready-to-adopt, internationally recognised standards reduces the need for individual governments or institutions to develop their own methodologies, saving time and resources;
- Encouraging innovation: Standardisation of PCF and LCA methodology highlights product-specific environmental hotspots. These insights foster the development of new technologies and practices aimed at reducing emissions, often resulting in both environmental and economic benefits.



…internationally recognised standards reduce the need for individual governments or institutions to develop their own methodologies.

[8] JRC Publications Repository - Guidance for Product Category Rule Development

PAS 2090:
2025 is the leading methodology with a standardization vision in mind

PAS 2090, "Pharmaceutical products – Product category rules for environmental life cycle assessments" has been developed to standardize the methodology for measuring the environmental impacts of pharmaceutical products. The standard provides a set of rules, i.e. in terms of minimum levels of data inclusion and quality, methodological choices, and reporting designed to balance the need for comprehensiveness and simplicity without compromising the robustness of the results.

It has been developed for international applicability by BSI with the co-sponsorship of NHS England and Office Life Science UK, in collaboration with international scientific and expert community, representatives of health authorities, and the PEG and SMI Pharmaceutical LCA Consortium[9], which represents eleven global pharmaceutical companies. PAS 2090 is the result of a cross-stakeholder collaboration, reuniting experts in LCA as well as the pharmaceutical industry, and subject to a rigorous process for standard development[10]. It was published in late 2025.

Implementation Considerations

EFPIA acknowledges that while PAS 2090 represents the most robust and internationally applicable framework for assessing the environmental impact of pharmaceutical products, further collaborative efforts are needed to enable effective implementation.

Interpretation of PAS results

EFPIA recognises that even with standardised methodologies, comparability of PCF across pharmaceutical products and companies remains limited and this is due to several interrelated challenges:

- Variability in data quality and availability: Despite applying a harmonised methodology, companies may rely on different data sources and levels of data quality, especially for upstream and downstream processes.
- Complex and opaque supply chains: Pharmaceuticals often involve global, multi-tiered supply chains with limited visibility. Differences in supplier practices, energy mixes, and transportation routes can significantly affect PCF results but are not always transparently disclosed or harmonised.
- Contextual relevance in healthcare: EFPIA emphasises that pharmaceutical products cannot be meaningfully compared in isolation. Their environmental impact is deeply intertwined with how, when, and where they are used within the patient care pathway. For example, a product with a higher PCF might reduce hospitalisation time or prevent the need for more resource-intensive treatments, resulting in a lower overall environmental burden when viewed from a system perspective.[11]

Therefore, **EFPIA advocates for contextualised interpretation of PCF results**—considering both the clinical and environmental outcomes across the continuum of care—rather than simplistic product-to-product comparisons.

[9] Pharmaceutical Environment Group and SMI: Sustainable Markets Initiative

[10] BS 0:2021 Principles of Standardization |BSI

[11] smi-hstf-pcp-whitepaper.pdf

EFPIA Recommendations

EFPIA acknowledges the critical role of product-level environmental and carbon footprints to advance climate action and foster sustainability across the industry. Transparent and harmonised provision of product-specific environmental data is essential to enable informed decisions and credible sustainability claims. EFPIA stresses the need for an internationally accepted approach to ensure consistent and credible results, given the subjectivity and methodological discretion of LCA without a uniform standard:

Unified Framework

EFPIA companies recommend that the European Commission and other international policy bodies support the adoption of a single, harmonised standard. A unified, scientifically sound framework will enable a more consistent, impactful, and globally aligned transition towards sustainable pharmaceutical products, for the benefit of patients, public health, and the planet.

Supporting the use of PCFs

EFPIA companies strongly support the use of PCFs to identify the product categories, platforms, and lifecycle areas with the greatest potential environmental impact and to prioritize footprint reduction projects.

Adoption of PAS 2090

EFPIA companies recognise PAS 2090 as the most robust PCR for pharmaceutical products to date, as it was developed by an independent standards body in collaboration with LCA and industry experts. EFPIA encourages stakeholders interested in PCFs to work with the industry to identify how to pragmatically implement it and support its wider adoption as the basis for harmonised pharmaceutical product-level carbon footprint assessments.

Conclusion

Product-specific environmental information is increasingly of interest for various stakeholders of the healthcare industry, due to its insightful contribution to the industry's decarbonization and progress towards environmental sustainability.

EFPIA member companies are committed to proactively collaborate with stakeholders and global authorities to lay the foundation for a harmonised PCF framework for pharmaceuticals and recognize PAS 2090 as the most robust approach available.

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